

HPTN 037

A phase III randomized study to evaluate the efficacy of a network-oriented peer education intervention for the prevention of HIV transmission among injection drug users and their network members

Study-Specific Procedures Manual

Sponsored by:

**US National Institute of Allergy and Infectious Diseases and
U.S. National Institute of Child Health and Human Development
U.S. National Institute on Drug Abuse
U.S. National Institute of Mental Health
U.S. National Institutes of Health**

**Version 2.0
February 26, 2004**

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List of Abbreviations and Acronyms

CAB	Community Advisory Board
CFR	Code of Federal Regulations
CL	Central Lab
CORE	HPTN Coordinating and Operations Center
DAIDS	Division of AIDS
DHHS	Department of Health and Human Services
FHI	Family Health International
FSR	Financial Status Report
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HPTN	HIV Prevention Trials Network
HPTU	HIV Prevention Trials Unit
ICH	International Conference on Harmonization
IRB	Institutional Review Board
LL	Local Lab
NDTC	Northern Drug Dependence Treatment Center
PTID	SCHARP Participant Identification Number
QC	Quality Control
RCC	Regulatory Compliance Center
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SOP	Standard Operating Procedure
SRO	Site Registration Office
SSP	Study-Specific Procedures (manual)

Section 1. Introduction

This section specifies the sources of HPTN 037 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 037 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 protocol is included as Section 2 of this manual.

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. HPTU staff should contact the HPTN Central Lab (CL) Manager with questions related to the collection, processing, and storage of local and central lab specimens.

CORE Protocol Specialist:

Deborah Hilgenberg
dhilgenberg@fhi.org
tel: 919-544-7040 x 594

SCHARP Protocol Operations Coordinator:

Tom Perdue or Eileen Hess
tperdue@scharp.org eileen@scharp.org
tel: 206-667-6216 206-667-2841

CL Manager:

Hua Shuan or Estelle Piwowar
hshan@jhmi.edu epiwowa@jhmi.edu
tel: 410-614-4246 410-614-6736

1.2 Investigator Responsibilities

As with all DAIDS-sponsored studies, HPTN 037 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 Practice (GCP) are included in Appendix A. The *DAIDS Standard Operating Procedures for Essential Documents* and *Source Documentation* for interpreting and operationalizing the regulations and GCP guidelines are included in Appendices B and C.

HPTN 037 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 037 is required to sign an HPTN Investigator's Agreement (sample in Section 11) 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 permission of the study sponsor and the HPTN CORE, except when necessary to protect the safety, rights, or welfare of study participants.
- 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 sponsor, HPTN CORE, and IRB approval, except where necessary to eliminate apparent immediate hazards to study participants.
- 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 Compliance Center (RCC) and Study Activation procedures with the HPTN CORE. This section outlines the steps required to complete these procedures. HPTN 037 study procedures may not be initiated prior to notification by the HPTN CORE (via a Site Activation Notice) that each of these steps has successfully been completed.

1.3.1 Development and CORE Review of Site-Specific Informed Consent Forms

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

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 (defined as someone who has not seen the original English samples) 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.

1.3.2 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. The HPTU will also submit will be any participant information sheets, promotional materials, advertisements, flyers, etc, and any other study-related materials for approval required by the IRBs.

It is essential that the cover letter to the IRB reference the protocol number, full title, version number and date of the submitted protocol. The DAIDS ROCC requires these details in the approval letter from the IRB requires these details. The cover letter to the IRB should also list attached/enclosed documents.

For sites in which both a US and in-country IRB oversee the research, 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.

1.3.3 Protocol Registration

Note: Additional details on the protocol registration process can be found in the DAIDS Protocol Registration Policy and Procedure Manual (April 12, 2001 Revised February 2003).

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

- A completed HPTN Investigator's Agreement

- Current Curriculum Vitae(s) (CV) of the Investigator(s) of Record in English
- 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 documentation of IRB approval is in a language other than English, the document must be translated into English, and both the local language version and the translation 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 translator(s) must be documented on the back translation.

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.

Upon receipt of the documents listed above, the CORE Protocol Specialist will forward them for review to the DAIDS Regulatory Compliance Center (RCC) Site Registration Office (SRO). SRO 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.

1.3.4 Study Activation

In addition to the above, the HPTN has specified certain requirements that must be met to activate HPTN study operations. The activation requirements follow:

- Protocol signature page
- US State Department approval to conduct HPTN studies (Chiang Mai only international sites only)
- Certificate of Confidentiality (Philadelphia only)
- US Federal Wide Assurance (FWA) number on file with OHRP for the study site institution(s)
- Local regulatory authority approval of the study protocol, e.g., Ministry of Health, drug controller/regulatory agency (if applicable)

- Completion of human subjects training for all “key” study staff (as defined by US National Institutes of Health policy)
- Completion of good clinical practices training by at least one study staff member with responsibility for oversight of study implementation (e.g., Investigator, Study Coordinator, Lead Clinician, Data Manager)
- PPD Study-Specific Initiation Visit and DAIDS approved site response
- Completion of study-specific training and resolution of any related action items
- Protocol Registration approval from the DAIDS Regulatory Operations Compliance Center, based on the following:
 - US and in-country IRB/EC approvals and approved informed consent forms (local language and back translation, where applicable)
 - IRB approval of all written materials used to recruit volunteers and any other materials given to volunteers including, posters, flyers, radio announcements, and recruitment cards
 - DAIDS Investigator of Record Agreement
 - CV of the Investigator of Record
- Study staff signature sheet, roster, and delegation of duties
- Resolution of action items identified in study-specific training and/or other site preparation/initiation activities (e.g., PPD site initiation visits) including documentation that all staff have reviewed the final study-specific procedures manual
- SCHARP approval of site readiness for data management:
 - Installation of required data transfer equipment
 - SOP for data management, including data QC/QA procedures
 - Availability of SCHARP-provided materials (e.g., DataFax forms) on site
- HPTN Central Lab approval of local lab readiness, including approval of:
 - Proficiency in performing protocol-required tests
 - QC/QA procedures
 - SOP for establishing/maintaining normal ranges or other appropriate validation for protocol-specified tests
 - Documentation of normal ranges or other appropriate validation
 - SOP for local specimen handling and “chain of custody” related to testing for primary study endpoints
 - SOP for local laboratory back-up arrangements
 - LDMS set up and connected to CL
 - IATA specimen shipping certification (for at least one study staff member)
- SOP for communication with responsible Institutional Review Boards/Ethics Committees
- SOP for source documentation (see Table 1 in Section 3.2.2.2)
- SOP for obtaining informed consent from potential study participants

- SOP for participant eligibility determination
- Documentation of site specific standard HIV counseling procedures
- Participant accrual plan
- Participant retention plan
- Quality Management Plan
- Others as needed (site-and study-specific)

This list of activities may be updated according to revised DAIDS requirements.

Upon review of these documents, the Protocol Specialist will notify the HPTU of any deficiencies and required re-submissions. After study-specific training has taken place, the protocol study activation process described in Section 1.3.4 has been satisfactorily completed; the Protocol Specialist will provide written approval to the HPTU to begin study implementation.

Section 2. Protocol

This section contains a complete reference copy of the current version of the HPTN 037 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

This section contains a listing of required administrative and regulatory documentation that each 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 the HPTU must maintain for DAIDS-sponsored studies. 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.

In lieu of the FDA Form 1572 listed in the *DAIDS SOP for Essential Documents*, the DAIDS Investigator of Record Agreement must be filed (Sample in section 11). In addition, since HPTN 037 is not a drug study, the following categories of documents listed in the *DAIDS SOP for Essential Documents* need not be filed for HPTN 037:

- Investigator's Brochures
- Pharmacy Accountability Records
- Serious Adverse Events and Safety Reports
- Unblinding

Based on the DAIDS SOP, the documentation listed below must be maintained for HPTN 037:

- Protocol (version 1.0, 2.0, and any subsequent amendments, clarifications, etc)
- Informed Consent Forms
- Investigator of Record Agreement
- Protocol Registration documents (see Section 1.3.3) and documentation of approved registration from the ROC RCC SRO
- Documentation of study activation from the CORE Protocol Specialist
- Current project assurance number (MPA, CPA, or FWA) and expiration date on file with OHRP for the study site institutions(s)
- IRB membership roster (or documentation from the IRB stating the roster is not available)
- All correspondence to and from all responsible IRBs, including documentation of all reviews and approvals
- SSP manual

- Study specific procedures (SSP) manual, original versions and all updates, bulletins, clarifications, and communiqués
- Participant information/education materials (if not filed with IRB correspondence)
- Study staff roster, signature sheet, and delegation of duties; job description and CV for each study staff member *Note: All CVs must be dated.*
- Screening, enrollment, and randomization logs
- Original case report forms (CRFs)
- Documentation of delegation of investigator's responsibilities
- Documentation of staff members' humans subjects training
- Documentation of staff members' study-specific training
- Signed and dated CV for each study staff member, current within the last year
- 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
- 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 1)
- 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 (See Table 1)

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 (see Appendix C) 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, and attempted 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
- A record of the participant's randomization assignment
- Study-related information on the participant's condition before, during, and after the study, including:
 - Data obtained directly from the participant (e.g., interview responses) 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).
 - Data ascertained by study staff (e.g., exam and lab findings)
 - 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. HPTU staff 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, laboratory reports, non-DataFax forms, and DataFax forms. 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 and DataFax forms as source documents is provided below.

3.2.2.1 Chart Notes

Study staff must document every 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: be used to document the informed consent process (see also Section 4.1.1); 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 in other source documents.

- The informed consent process (see also SSP Section 4.1)
- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- All protocol deviations, or violations that are not otherwise captured on other source documents.

3.2.2.2 DataFax Forms

The case report forms for this study are designed for use with the DataFax data management system described in Section 6. The forms also have been designed, to the extent possible, to serve as source documents. HPTU staff must complete Table 1 below to document the DataFax forms that they routinely will use as source documents. As noted above, once completed, this table 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 1 consistently for all study participants throughout the study. A site-specific table will be maintained on site.

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 037 Required Case History Elements and Source Document Guide

Required Case History Element	Document	DataFax Acronym	Source	Comments
1) Basic Pt. Identifiers	• Demographics	DM	Yes	Form is interviewer-administered.
	• Locator Form		Yes	
	• Signed and dated chart notes		Yes	
2) Documentation that Pt. provided consent to participate in screening (index only) and in the study (index and network members) ^ψ	• Signed and dated consent(s)		Yes	
	• Signed and dated chart notes stating that consent was obtained prior to initiating study procedures.		Yes	
3) Documentation that Pt. met the study selection criteria	• Demographics	DM	Yes	Form is interviewer-administered.
	• Index Screening Assessment	IS	Yes	Form is interviewer-administered.
	• Member Screening Assessment	MS	Yes	Form is interviewer-administered.
	• HIV test results from local lab [§]		Yes	Source documentation for Screening HIV Status form.
	• Screening HIV Status	SS	No	All items on this form require local documentation as source.
	• Network Survey and Grid		Yes	Grid is interviewer-administered; items on grid determine if pt. has <u>sufficient</u> network members to participate and <u>which</u> members should be recruited for study.
	• Network Summary	NS	No	The network survey and grid will be the source for the information on this form.
	• Post-test Visit	PV	Mixed	Chart notes may be source.
	• Index Eligibility Checklist	IC	No	All items on this form require source documentation.
	• Member Eligibility Checklist	MC	No	All items on this form require source documentation.
4) Randomization Assignment	• Randomization/ Enrollment	RE	No	All items on this form require source documentation
	• Randomization List	RL	Yes	
	• Randomization envelopes		Yes	
5) A record of all contacts with the participant ^{†*}	• Signed and dated chart notes		Yes	
	• Intervention Session Participation Log	IL	Mixed	Site attendance list may be the source for the information on this form.
	• Booster Session Participation Log	BL	Mixed	Site attendance list may be the source for the information on this form.
	• Intervention Cohort Participant Transfer	IPT	No	

6) A record of all procedures performed by study staff [†]	• Signed and dated chart notes		Yes	Note should detail (a) procedures performed in addition to those documented on CRFs or other source document and/or (b) the reason why scheduled procedures were not performed.
	• Intervention Session 1 – 6	IN (A-F)	Mixed	Site records may be the source for the information on this form.
	• Missed Visit	MV	Mixed	The chart note may be source.
	• Termination Form	TM	Mixed	The chart note may be source.
7) Information on the participant's condition before, during, and after the study	• Risk Assessment	RA	Yes	Form is interviewer administered.
	• Network Norms	NN	Yes	Form is interviewer administered.
	• Social Impact Assessment	SIA	Mixed	Chart note may be source.
	• Social Impact Log	SIL	Mixed	Chart note may be source.
	• Exposure/ Contamination	EX	Yes	Form is interviewer administered.
	• HIV test results from local lab or rapid test documentation [§]		Yes	Source documentation for Follow-up Local Lab Result form.
	• Follow-up Local Lab Result	LL	No	All items on this form require local lab or rapid test documentation as source.
	• Comments	COM	Mixed	The chart note may be source.
	• End of Study Inventory	ESI	No	All items on this form require source documentation.
	• All items listed above in section 3			
• Signed and dated chart notes				

See next page for instructions for completing this table.

Name of Investigator of Record

Signature of Investigator of Record

Date

Ψ The *DAIDS SOP for Source Documentation (Appendix C)* provides detailed requirements and suggestions for documenting the informed consent process.

§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.

†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 1

1. Table 1 lists each DataFax and non-DataFax form used in this study. The 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.
2. Table 1 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 1.3.4). 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 1 forms the basis for monitoring study data, and its specifications must be followed consistently for all study participants. Retain a copy in regulatory/administrative files for reference by the monitor.
 - ☞ 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 making appropriate changes directly onto the table and then signing and dating the table in the space provided.

3.3 Visit Checklists

The checklists provided in Section 7 of this SSP manual provide a convenient tool for study staff to use in order to ensure that all staff are following the same procedures consistently for all participants. In addition, the site is encouraged to use the checklists as a training device for all new staff until competency is reached.

3.4 Document Organization

All case history records must be stored securely at the HPTU. Each site should establish a single place where they will keep DataFax forms waiting to be faxed and DataFax forms waiting to be refilled after faxing. After being faxed to SCHARP, DataFax forms should always be kept in the appropriate section within the participant file.

All DataFax forms, laboratory specimens, reports, process, and administrative forms must be identified by the participant ID provided by SCHARP to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from study records identified by the participant ID number whenever possible. 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.

3.5 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. Informed Consent

This section provides an overview of requirements and procedures for obtaining informed consent from study participants for screening and enrolling in the study. Given the ongoing nature of informed consent, key elements of informed consent also should be reviewed at study follow-up visits.

As a condition for study activation, each study site must establish an SOP for obtaining informed consent from potential study participants. This SOP should reflect all of the information provided in this section and the DAIDS SOP for Source Documentation (Appendix C).

4.1 Informed Consent Procedures

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.

45 CFR 46 (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 HTPN 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:

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

Each study site is responsible for developing study informed consent forms for local use, (based on the templates in Appendices III through V in the Protocol), which describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations. The study site also is responsible for translating the template forms into local languages and verifying the accuracy of the translation by performing an independent back-translation.

As a starting point, at the Screening/Enrollment Visit, if the participant is literate, give him/her a copy of the informed consent form to read. 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/her verbatim. After the participant has read the written material (or had it read to him/her), verbally review the information provided. A checklist or 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.

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/her medical care and any other services obtained from the recruitment site and/or research institution will not be affected by his/her decision whether or not to take part in the study. Encourage the participant to take as much time as he/she needs — and to talk about his/her potential participation with others, if he/she chooses — before making a decision.

Confirm that the participant comprehends the information.

The participant must not be asked to agree to take part in the screening procedures or study, or sign the informed consent form, until he/she 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.

There are three separate consent form documents for this study as follows:

- 1) **Screening consent form for initial HIV testing and screening of index participants**
- 2) **Study enrollment consent form for study participation of index participants**
- 3) **Network member study consent form for study participation of network members**

[Note: If an index participant is found to not be eligible as an index but is later identified as a network member he/she must sign the network study consent form prior to undergoing any study assessments for enrollment as a network member. If a network member is found not to be eligible as a network member, i.e. the network is ineligible, but is later screened for participation as an index participant he/she must sign the screening consent and study consent for index participants.]

Prior to signing the study consent form both index and network participants will be administered a “quiz” to assess comprehension. Another approach in addition to the quiz 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 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/her to sign the informed consent form or screen/enroll in the study. Similarly, if the participant has concerns about possible adverse impacts on him if he/she were to take part in the study, or indicates that he/she may have difficulty adhering to the study requirements, do not ask him/her to sign the informed consent form or screen for/enroll in the study.

4.1.1 Documentation

Note: See the DAIDS SOP for Source Documentation (Appendix C) 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, complete all signature and date blocks on the informed consent form per IRB requirements. It is essential that the date documented on the forms either precedes or coincides 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. If a participant opts not to receive a copy, document this in a chart note.

The signed informed consent forms will be considered a permanent part of the participants record but must be filed in a separate location. While the informed consents will be audited in the same manner as other records, copies will not be transferred to any agency outside of the clinic.

Staff must ensure that they use the correct version of the informed consent, to ensure that participants enter the date themselves (if able) and that all participants are offered a signed copy of the consent to keep.

4.1.2 Consent of Illiterate Participants

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, or meet and discuss participant requirements at the end of the visit. Preferably this third party will not be a staff member of HPTN 037 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.

If a participant cannot sign his/her name

Study staff cannot sign participant names onto informed consent forms. If a person cannot write his/her name, the study staff member who completed the informed consent process with the participant should enter the participant's name below the "participant's printed name" block, together with a signed and dated note documenting the name of the person who made the entry and the date of the entry. The participant will imprint their thumbprint or make their mark on the signature line. **The participant date block should be left blank.** The third person should then write, sign and date as the witness. Document in the research record that the participant cannot sign his/her name.

4.2 Ongoing Consent of Participants

Given the ongoing nature of informed consent, key elements of informed consent also should be reviewed at study follow-up visits. At these visits, study staff should review key elements of informed consent with the participant, focusing on the remainder of their study participation. For example, at study month 6, the discussion might focus on the fact that the participant has completed the first follow-up visit, and therefore has another two follow-up visits (or more, depending on the time of enrollment into the study) of scheduled follow-up remaining.

Section 5. Study Visits Procedures

This section contains the procedures and flow for scheduled and unscheduled (interim) study visits. The study visit procedures are designed to guide the study staff in proper study implementation and sequence. The visit checklists included in Section 7 also outline the procedures and are used to ensure that the study staff complete all required procedures at each participant visit.

5.1 Target Enrollment

Approximately 600 networks will be enrolled in Chiang Mai and Chiang Rai, Thailand, and approximately 300 networks will be enrolled in Philadelphia, Pennsylvania, USA. Together, the HPTU sites will recruit 900 networks consisting of 900 index participants and approximately 1710 network members (an average of 1.9 network members per index participant), for a total of approximately 2,610 participants. Recruitment will be done over the course of a 30-month accrual period at each site. A slower recruitment rate in the first 60 days of the study at each site is anticipated. The recruitment/enrollment is expected to be on target after the first couple of months with approximately 10 networks enrolled per month in Philadelphia and approximately 20 networks enrolled per month in Thailand. Overall, during the enrollment phase, in Thailand approximately 59 participants (20 index and 39 network members) per month will be entered into the study and in Philadelphia approximately 28 participants (10 index participants and 18 network members) per month will be entered into the study.

5.2 Recruitment and Screening

HPTU staff is responsible for establishing an outreach and recruitment plan for this study, and for updating the plan and recruitment efforts undertaken, if needed, to meet the study accrual goals as specified in Section 5.1. The recruitment plan -- including specification of minimum age of independent consent, when and how compensation is provided, clarification of what activities will be undertaken before informed consent for screening is obtained (as pre-screening), and what will be done only after screening consent is obtained – and all of the written materials (ads, flyers, posters, telephone transcripts) used for general recruitment as well as written materials given to individuals – must be approved by the relevant IRBs. The plans and materials should be stored with the “local study-specific SOPs” noted above in Section 3.1. IRB approvals of these plans and materials should be stored with the site regulatory documentation.

The study screening and enrollment procedures are described in detail in the checklists in Section 7 of this Study Specific Procedures Manual. Screening and enrollment procedures will be completed over the course of multiple visits. **Regardless of the number of visits required, randomization must be completed within 60 days of collecting a sample for HIV testing from the participant at screening. If all required procedures are not completed within 60 days, the screening procedures must be repeated for those participants in the network that exceed the 60-day window in order for them to be eligible for enrollment/randomization.**

Participants will undergo eligibility screening during an in-person study visit. Written informed consent will be obtained prior to the conduct of any screening and study procedures. Demographic and behavioral eligibility will be determined based on participant responses to a standard interview instrument. All participants will receive HIV testing and pre and post HIV test counseling as described in Section 5.13 of this Study Specific Procedures Manual and according to “Local Study-Specific SOPs” (noted in Section 3.1 of this Study Specific Procedures Manual). Eligibility related to HIV serostatus will be ascertained via local HIV testing. Randomization and enrollment cannot occur

until the eligibility of the entire network (index + 1 or more network participants) has been determined and at least 12 networks are accrued for randomization.

5.2.1 Index Participant Recruitment and Screening

Prospective index participants will be recruited as described below and according to "Local Study-Specific SOPs" (noted in Section 3.1 of this Study Specific Procedures Manual). Street outreach workers will be the primary recruiters, supplying basic information about the study in geographic areas and settings frequented by drug users and encouraging these individuals to seek screening at a local study site.

Study outreach workers will be trained against pre-selecting individuals who fit their description of "drug users;" rather, they will provide information to a range of individuals from a wide range of settings and encourage those individuals to pass information about the study to others in the community. The outreach workers will be selected from the community and must be knowledgeable about the community's dynamics and trained on basic rapid assessment procedures in order to target areas of high drug use. They will also be trained in methods of approaching and communicating with potential participants, personal safety, and confidentiality.

Index Screening – Pre-test Visit

NOTE: If rapid HIV testing is used at screening, index pre- and post-test screening visits may be conducted on the same day. All visit procedures must be completed as described below.

At the initial screening visit, prospective index participants will undergo the informed consent process for screening and be assigned a participant identification (PTID) number (for more information on assignment of PTID numbers see Section 6.11 in this manual). After providing consent for screening, prospective index participants will be administered a screening form to assess demographic and behavioral eligibility based on the eligibility criteria specified in the protocol, Sections 3.1 and 3.2 and below:

Index initial inclusion criteria determined during the pre-test visit:

- Of legal age to independently provide written informed consent for research
- Provide written informed consent for screening
- Report having injected drugs at least 12 times in the last three months
- Been out of methadone maintenance treatment for at least 3 months and have relapsed
- Willing to identify and attempt to recruit at least two HIV risk network participants who are eligible for study participation according to the criteria in the protocol Sections 3.1.2 and 3.2.2

Index initial exclusion criteria:

- Prior or concurrent enrollment in the last 6 months in another HIV behavioral or biomedical prevention study
- Appearance of psychological disturbance or cognitive impairment that would limit the ability to understand study procedures, as determined by clinic staff
- Any other condition that, in the opinion of the investigator, would make participation in the study unsafe, or otherwise interfere with the study objectives
- Enrollment as a network participant or index participant in another network of HPTN

If the prospective index participant meets the initial eligibility criteria, then he/she will be administered demographic and risk assessment questionnaires and undergo further screening assessments including HIV counseling and a blood draw for HIV testing. It should be clearly explained and emphasized to the participant that although they themselves may screen eligible for the study, the final decision regarding enrollment will depend on the other network participants' willingness to participate and eligibility. This will be determined after all the network members have been screened. Study staff will schedule the next screening visit and post-test counseling to occur after HIV test results are available (approximately 7 days for non-rapid testing or same day for rapid testing). Staff will also 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 post test counseling visit, document the visit in a signed and dated chart note and in the screening log or database, and provide compensation according to site specific procedures. All data collection forms should be reviewed for completeness and accuracy.

Note: DataFax forms will only be submitted to SCHARP after the index and their network members have been deemed eligible and randomized.

If the prospective index participant does not meet initial eligibility criteria, document the reason for ineligibility in a signed and dated note in the participant's chart and in the screening log or database. Thank the volunteer for his or her willingness to participate and inform him/her that he/she does not qualify for the study and provide compensation according to site-specific procedures. Offer him or her HIV testing and counseling if desired.

Index Screening – Post-test Visit

At the post-test screening visit, study staff will first confirm the participant identity and PTID number according to local study specific SOPs (if the post-test visit occurs on a different day than the pre-test visit). Prospective index members will receive HIV post-test and risk reduction counseling. If possible, the same counselor that administered the pre-test counseling will administer post-test counseling. Document the counseling session in a signed and dated chart note; complete the post-test visit form.

- **If the HIV test is positive**, HIV infection is suspected and the participant is ineligible, unless a negative test is later obtained. The screening and enrollment process should be discontinued and the reason for ineligibility documented in a signed and dated chart note and in the screening log or database. Participants should be provided with referrals for confirmatory testing and counseling.
- **If the test results are indeterminate**, HIV infection is suspected. If possible, the participant should have a second sample drawn for confirmatory testing. If the second sample is HIV negative, then the participant is eligible and can continue the screening and enrollment process. If the second sample is indeterminate or positive, then the screening and enrollment process should be discontinued and the reason for ineligibility documented in a signed and dated chart note and in the screening log or database.

- **If the HIV test is negative**, HIV infection is ruled out and the participant is eligible for further screening. Participant's willingness to participate should be re-confirmed and if willing, he/she will be asked to undergo the informed consent discussion and process for study enrollment as described in Section 4 of this manual. After undergoing the informed consent process and providing informed consent for study enrollment, prospective index participants will be administered a network norms assessment and network inventory survey.

Network Inventory Survey

Participants who have consented will be administered a Network Inventory Survey. Instructions for completing the survey and a sample Network Interview Survey are included in Section 11 of this manual. The Network Inventory Survey is interviewer- administered. The interviewers should emphasize that the more individuals identified, the greater the chances for success in recruiting the minimal number of network members, and the more likely that the index participant will be eligible to participate. Participants should be reminded that not all the individuals they identify will be able to participate and that they cannot add individuals after leaving the study clinic. Participants should provide nicknames or initials or any other information that can be used by study staff to identify the member when they present to the clinic.

The interview may take up to 60 minutes to complete. Interviewers should insure that participants have sufficient time to complete the interview. After completing the survey, the interviewer will choose the network participants that qualify for recruitment by the prospective index participant based on the criteria specified below. Individuals listed on the Network Inventory Survey must meet all of the criteria outlined below in order to be eligible for recruitment by the prospective index member as a prospective network participant.

- Listed in Question 6 as an individual the index participant has had sex with in the last 6 months and/or in Question 8 as a person with whom they do drugs
- Be ≥ 18 years old (Q 10-11)
- Be seen or spoken to by the index participant at least about once a month or more frequently [The answer to Question 19 must be 1 (everyday), 2 (a few times a week), 3 (about once a week), 4 (2 or 3 times a month), or 5 (about once a month)]

Prospective index participants who meet all eligibility requirements and each prospective network participant will be assigned a network and unique member identification number. For additional information on assignment of network and member identification numbers, see Sections 5.2.4 of this manual.

5.2.2 Recruitment of Network Participants by Index Participants

As described above, the interviewer will choose the network participants that are eligible for enrollment based on the information provided by the index member during the administration of the network survey and the criteria specified above.

In order to facilitate recruitment of the eligible network participants, the index participants will be provided with a recruitment card. The recruitment card will include the network and member identification numbers to link the prospective network participant with their index member, the initials of the prospective network participant (to ensure that the correct card is given to the prospective network participant by their index), and the address and phone

number of the study site. Study staff will link the prospective network participant to their index when they present for screening by using the network and member identification numbers and/or the description of the network participant provided by the prospective index participant during administration of the network survey.

Following each prospective index participant's post-test counseling screening visit, their prospective network participants will be able to present at the local study site to participate in study screening, as described below and in the checklists in Section 7 of this Study Specific Procedures Manual. All procedures must be completed within 60 days of the index's initial blood draw.

5.2.3 Network Participant Screening

NOTE: If rapid HIV testing is used at screening, network participant pre and post-test screening visits may be conducted on the same day. All visit procedures must be completed as described below.

Network Participant Screening – Pre-test Visit

For prospective network participants to participate in the screening process, they must either present at a local study site with a card bearing the prospective member's network member ID and initials or match the description provided by the index during his or her screening survey in terms of age, gender, frequency of contact with the index, and duration of relationship with the index.

Study staff will introduce the study and explain the informed consent and screening process to prospective participants. If willing to participate, participants will be asked to undergo the informed consent discussion and process for study enrollment as described in Section 4 of this manual. After undergoing the informed consent process and providing informed consent for study enrollment, prospective network participants will be assigned a PTID number (for more information on assignment of PTID numbers see Section 5.2.4 below) and entered into screening log and database. Participants will be administered a screening form to assess demographic and behavioral eligibility based on the eligibility criteria specified in the protocol, Sections 3.1 and 3.2 and below:

Network Participant Inclusion Criteria:

- Of legal age to independently provide written informed consent for research
- Recruited for the study by an eligible index participant
- Have injected drugs with and/or had sex with the relevant index participant within the three months prior to screening
- Provide written informed consent for study participation

Network Participant Exclusion Criteria:

- Appearance of psychological disturbance or cognitive impairment that would limit the ability to understand study procedures, as determined by clinic staff
- Any other condition that, in the opinion of the investigator, would make participation in the study unsafe, or otherwise interfere with the study objectives
- Enrollment as a network participant or index participant in another network of HPTN 037

If the prospective network participant meets the initial eligibility criteria, then he/she will be administered demographic and risk assessment questionnaires and undergo HIV counseling and a blood draw for HIV testing. It should be clearly explained and emphasized to the participant that although they themselves may screen eligible for the study, the final decision regarding enrollment will depend on the index and the other network participants' willingness to participate and eligibility. This will be determined after all the network participants have been screened.

Study staff will schedule the next screening visit and post-test counseling to occur when the HIV test results are ready (either the same day for rapid testing, or approximately 7 days if using standard testing). Staff will also 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 post test counseling visit, document the visit in a signed and dated chart note and in the screening log or database and provide compensation according to site specific procedures. Network participants will be able to enroll only once in the study. All data collection forms should be reviewed for completeness and accuracy.

Note: DataFax forms will only be submitted to SCHARP after the index and their network participants have been deemed eligible and randomized.

If the prospective network participant does not meet initial eligibility criteria, document the reason for ineligibility in a signed and dated note in the participant's chart and in the screening log or database. Thank the volunteer for his or her willingness to participate and inform him/her that he/she does not qualify for the study and provide compensation according to site-specific procedures. Offer him or her HIV testing if desired.

Network Participant Screening – Post-test Visit

Network participants must return for their post-test counseling to be eligible for enrollment and randomization. At the post-test screening visit, first confirm the participant's identity and PTID number according to local study specific SOPs (if the post-test visit occurs on a different day than the pre-test visit). Prospective network participants will receive HIV post-test counseling. If possible, the same counselor that administered pre-test counseling will administer post-test counseling. The counseling session should be documented in the counseling notes and on the post-test visit form.

Note: Network participants are eligible to participate regardless of HIV infection status.

If the HIV test is HIV positive or indeterminate, HIV infection is suspected. Participants should be provided with referrals for confirmatory testing and counseling. Participants are still eligible to enroll, and if enrolled and randomized will undergo all study procedures except HIV testing. Participants should be offered risk-reduction counseling at each follow-up visit.

Study staff will review the screening process and study procedures with the prospective participant and confirm the prospective network participant's willingness to continue with the screening process.

If the prospective network participant is unwilling or unable to continue with the screening process, then document the reason for not continuing in a signed and dated chart note and in the screening log or database.

If the prospective network participant is willing to continue with the screening process, then participant will be administered a network norms assessment. Staff will schedule a 3-month locator visit, inform the participant that the study staff will contact them when final eligibility has been determined, provide study site contact information, document the visit in a signed and dated chart note and in the screening log and database and provide compensation according to site specific procedures. Data collection forms should be reviewed for completeness and accuracy.

Note: DataFax forms will only be submitted to SCHARP after the index and their network participants have been randomized.

5.2.4 Assignment of Study Identification Numbers

Assignment of Index and Network Participant HPTN Study Identification Numbers (PTID)

HPTN Participant identification (PTIDs) numbers will be assigned at study screening (not pre-screening) for both prospective indexes and network participants. Prospective indexes will be assigned a PTID after they sign the screening consent form and agree to screening. Prospective network participants will be assigned a PTID after they agree to screening and sign the study consent form. The same PTID stays with each prospective index and network participants regardless of how many times they present for screening.

Assignment of Network and Member Identification Numbers

Prospective index participants at their post-test screening visit will complete the network survey and undergo other study procedures described in Section 5.2.1. If still eligible for further screening, they will be assigned a four-digit network ID number and a two-digit member number. At this time, each prospective network participant identified by the index participant will also be assigned the same four-digit network ID number as the relevant index member and a unique two-digit member number.

For example:

- A prospective index participant was assigned PTID 222-00110-5 at the first screening visit.
- At the post-test screening visit, this prospective index participant receives HIV test results, completes the network survey, and is determined still eligible. He is then assigned the next available sequential network identification number (0004) and because he is the index member of the network, his network participant number will be '00'. He named 4 network participants that met the eligibility requirements for recruitment as a network participant; each prospective network participant is assigned the same network number as the prospective index participant (0004) and a unique sequentially assigned member number as shown:

Prospective Index Participant:
0004-00

Prospective Network participants for this Index Participant:
0004-01
0004-02
0004-03
0004-04

- A recruitment card for each prospective network participant bearing the prospective network ID, member ID, and initials will be given to the index member to aid in recruitment. This network and member ID number will be linked to whatever identifying information the index participant provided for the network participant as described in Section 5.2.2 of this manual.
- As any or all of these prospective network participants present for screening, the staff should use the recruitment cards given to the network participant by the index participant and the identifying information provided by the index participant to match them with their index and confirm that they are the person named by the index. If the prospective network participant presents to the clinic without the recruitment card, then the study staff must use only the identifying information to match them to their index participant. Network participants that match to the index member's description and consent for enrollment are assigned a PTID.

Note: DataFax forms will only be submitted to SCHARP after the index and their network participants have been deemed eligible and randomized.

5.2.5 Tracking the Status of Prospective Networks During Screening

Study sites will develop and maintain a database to track individual participants as they screen for the study, and to determine when a network has become eligible for randomization and enrollment. At a minimum, this database will include the following variables: Participant name, HPTN PTID, network ID number, member number, date of all screening visits, and HIV test results. The database must be programmed to track the time elapsed since the first screening visit, because randomization and enrollment must occur within 60 days of the first screening visit blood draw. The database must also be able to identify when prospective networks have qualified for enrollment (when an eligible index and at least 1 eligible network participant named by that index have completed the screening process). The database will also be set up to disqualify prospective networks that become ineligible for enrollment, either because none of the network participants named by an eligible index complete the screening process within 60 days, or when an index or network participant are in consideration in a different network which qualifies for enrollment first.

Information will be added to the database as prospective indexes and network participants screen for the study. The database should be updated on a daily basis, and sites will develop a system for identifying networks that have qualified for enrollment. Once a sufficient number of networks (approximately 12-20) have qualified for enrollment, the site will schedule randomization (see section 5.3).

Prior to enrollment, individuals who screen for the study may be considered as indexes and network participants (named by other indexes) simultaneously. Individuals may also be considered as prospective network participants for more than one index at the same time. The screening database must allow for multiple network IDs and multiple member numbers for individuals screened and considered in different networks. The HPTN PTID, however, will be unique for each individual screened, and will stay with that individual if he/she is considered within another network. Common elements of the screening process (HIV testing, risk assessment) do not need to be repeated as individuals are considered in different networks as long as enrollment occurs within 60 days of the first screening visit.

Note: Individuals who initially screen (and provide consent) as an index member may subsequently be screened as a network participant for another network, but must first complete the network participant informed consent process and member screening assessment. As above, if the time between the participant's initial HIV blood draw and enrollment/randomization of the network exceeds 60 days, all screening procedures and assessments must be repeated.

Note: Individuals who initially screen as a network participant may subsequently be screened as a network participant for another network, but must first complete the member screening assessment for each network they are screening for. As above, if the time between the participant's initial HIV blood draw and enrollment/randomization of the network for which they qualify exceeds 60 days, all screening procedures and assessments must be repeated.

Note: Individuals who initially screen as a network participant may not screen as an index participant for 3 months (90 days) after their initial blood draw for HIV testing. After this three-month (90 day) period, the individual may screen as an index participant after completing the index screening informed consent process.

As prospective network participants named by eligible indexes complete their screening visits, the database will track the status of each prospective network. As soon as at least one eligible network participant completes his/her post-test visit, that network is deemed qualified to enroll. Additional prospective network participants named by that index must complete all screening procedures (and meet eligibility criteria) before randomization to be included in the network. Efforts should be made to complete screening visits for prospective network participants to maximize the size of the network to be randomized and enrolled.

As members of a particular network (index and network participants) become qualified to enroll, they must be removed from consideration as indexes or network participants in other networks. The database must be able to identify and disqualify all other cases where a PTID is under consideration once that PTID qualifies for enrollment in a network. Qualification of networks depends on the time it takes for at least one eligible network participant to complete his or her screening visits; the first one that has at least one eligible network participant qualifies, and those individuals (index and network member[s]) are removed from consideration in other networks. If a prospective index qualifies first as a network participant in another network, then the entire network he/she named as an index would not qualify for enrollment (because there is no longer an index for that network). If an individual under consideration as a member in two different networks completes the screening visits and is determined to be eligible, the network that qualifies is the one that had the first qualifying index participant, and that network participant must then be removed from consideration in all other networks.

If a prospective index participant is not randomized and enrolled within 60 days of his/her initial screening visit HIV test blood draw, that index and all prospective network participants for that network are disqualified for enrollment, unless that index is re-screened to keep the network active (see section 5.2.6. “Re-screening indexes and network participants to keep the same eligible network qualified for randomization”).

Individuals in networks that fail to qualify will be notified that they did not qualify for the study, but may be re-screened in the future, if approached by study staff or named by another prospective index as a prospective network participant. Networks that qualify for randomization and enrollment (eligible index and at least one eligible network participant) will be randomized and enrolled according to procedures in section 5.3. Members of enrolled networks will be notified that they have been enrolled in the study and scheduled for their next study contact as follows: index participants randomized to the treatment arm will be notified and scheduled for the next intervention session, while index participants randomized to the control arm will be notified and scheduled for their 3-month locator contact and 6-month follow-up visit. All network participants, regardless of treatment arm, will be notified of their enrolled status and scheduled for 3-month locator contacts and 6-month follow-up visits.

In accordance with HPTN policies, HPTU staff will report the number of participants screened for and enrolled in the study (Prospective Index and Network participants) to the CORE Protocol Specialist on a weekly basis. **The definition of a ‘screened’ index participant is any participant that has completed the index screening consent process. The definition of a ‘screened’ network participant is any participant that has completed the network participant screening and enrollment consent process.** The Protocol Specialist will distribute this information to the Protocol Team as needed to monitor the accrual process. In addition, SCHARP will report monthly the number of participants enrolled and randomized at each site based on data submitted to the DataFax system.

5.2.6 Re-screening indexes and network participants to keep the same eligible network qualified for randomization

Indexes and network participants that are approaching or have passed the 60-day limit from initial blood draw to randomization may be re-screened to keep the network qualified for randomization, using the following procedures:

Participant IDs, network IDs, and member numbers all remain the same. Re-screening should follow the same procedures as initial screening, with the exception of the network inventory and the network summary form. If the network membership has not changed, these procedures are not repeated. If new members are *added* to the network, the network inventory and network summary form must be repeated with the index.

Re-screening procedures should follow the screening visit checklists in section 7 of the SSP for pre- and post-test visits. The same eligibility criteria apply and must be followed. For example, if the index tests positive at re-screening, he or she would not be eligible, and that network would not qualify for randomization.

When re-screening, repeat all steps outlined in the visit checklist, including obtaining screening and/or study consent, collection of demographics, index/member screening assessments, risk assessment, HIV counseling, phlebotomy, and HIV testing (including

network participants who tested HIV positive at the first screening). Use a new copy of each DataFax form. Do not repeat the network inventory and network summary form, *unless* a new member is being added to the network, in which case, a new inventory and summary are completed.

For new DataFax forms at re-screening, use the same participant ID and network ID/member numbers. The date of re-screening is the form completion date for these new forms. All forms (e.g., risk assessment) must be re-administered. Information must not be copied from the first set of screening forms. The original network summary form (NS-1) should be removed from the first (or previous) set of screening forms to be included with the current (active) set. The original form completion date on this form is NOT changed. The remaining forms from the first screening visits must be deactivated so they are not accidentally mixed up with the current (active) screening forms and sent to SCHARP following randomization. Use the following steps to deactivate these forms: 1) draw a line diagonally across each page; 2) stamp the front of each page with an “EXPIRED” stamp, and 3) staple the pages together. These forms should be retained in the participant chart, but may be isolated from the “active” forms to further reduce the possibility of mix-up.

If the network qualifies and is randomized, the current (active) set of forms should be completed and reviewed per the study SSP, and submitted to SCHARP.

Specimen tracking for participants who are re-screened: Samples collected at re-screening should be processed following the same procedures for screening (see section 10.3). Use a new specimen tracking sheet. Use a new label for the same PTID on the blood tube and the specimen tracking sheet. The date label on both will be the new specimen collection date. The visit code and visit type on the specimen tracking sheet will still be “screening (1.0).” When this sheet is scanned into LDMS, an error message will appear because there will have already been an entry for a screening visit for this PTID. LDMS will allow multiple entries for a visit with different specimen collection dates. Press ‘ok’ at the error message and the record will be saved. If that participant enrolls, the specimen associated with the screening visit will be the **most recent** sample (determined by the specimen collection date) with the visit code of 1.0. This is the specimen that would be sent to the central lab if they requested QA testing on that PTID for the screening visit.

5.3 Randomization and Network Enrollment Procedures

At enrollment/randomization, each eligible network is randomized to either the treatment or control arm. At this point, the network (which includes an index member and a minimum of one network member) is officially enrolled in the study.

5.3.1 Pre-Randomization/Enrollment Procedures

A period of up to 60 days is allowed for enrollment of each network. During this period of time, the following occurs:

- Index participants attend approximately two screening visits to determine eligibility.
- **A minimum of one eligible and consenting network member is required for each index participant.**

Note: Prospective index participants may be asked to return to the study clinic approximately one week after recruitment of network members begins. The purpose of this visit is twofold:

1. To see if network members have presented for screening, and
2. To get assistance from staff members on recruitment procedures, if needed.

Once recruited, network members attend one or more screening visits (depending on use of HIV rapid test) to determine eligibility.

Once a minimum of 12 networks is determined to be eligible, randomization/enrollment occurs. However, **staff should aim to randomize more eligible networks, up to a maximum of 20, at each randomization.**

Note: A minimum of 12 eligible networks is required for randomization so that an adequate number of index participants are available to participate in the intervention sessions.

Note: All screening and enrollment procedures for each study participant (index and network members) must be completed within 60 days of collecting an initial HIV testing sample from him/her. If the 60-day limit has been exceeded, all screening procedures for the study participant must be repeated. See Section 6 for additional instructions regarding DataFax form completion when multiple visits are required.

It is the responsibility of the HPTU Investigator and other designated staff to ensure that only those participants who meet the study eligibility criteria (see Protocol Section 3) are enrolled and randomized into 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).

5.3.2 Randomization/Enrollment

Once a minimum of 12 eligible networks qualifies for enrollment, staff members conduct the in-office randomization/enrollment process using the randomization packet system provided by SCHARP. Staff should aim for more eligible networks, up to a maximum of 20, for each randomization. All members of networks to be randomized must have a blood draw for HIV testing performed within 60 days prior to randomization.

Note: The effective date of enrollment is the randomization date. Participants (index and network members) are considered “enrolled” once they have been randomized.

Note: Once an individual is enrolled in the study, he/she will be unable to enroll in any other study network. If the network is found not to be eligible, the following applies:

- *Prospective network member(s) can screen as a network member for another network immediately, or return in three months from the date of the first blood draw to screen as an index.*
- *The prospective index member can screen as a network member for another network immediately. See section 5.2.5 of this manual for further instructions.*

Note: Once a network is randomized, any and all members will continue to be followed unless he/she withdraws consent or is terminated (see Section 5.10). Index participants and their respective network members will be followed regardless of whether or not they complete

any intervention sessions.

Randomization Packets:

SCHARP provides each site with randomization lists prior to the first randomization/enrollment session. Each randomization list comes in a sealed packet. Packets are labeled by cluster size (cluster size indicates the number of index participants to be randomized).

How does the site choose which packet to use for each randomization?

- If an **even** number of index participants is to be randomized, the site should choose a packet whose cluster size exactly matches that number. For example, if 16 index participants are eligible, the packet labeled “Cluster Size: 16” should be used.
- If an **odd** number of index participants are to be randomized, the site should choose a packet whose cluster size is one greater than that number. For example, if 17 index participants are eligible, the packet labeled “Cluster Size: 18” should be used.

In addition to cluster size, packets will be labeled with a packet number. This is because SCHARP provides each site with multiple packets of each cluster size. For example, if four packets of cluster size 12 are sent to a site, the packets are labeled “Cluster Size: 12, Packet #1,” “Cluster Size: 12, Packet #2,” “Cluster Size: 12, Packet #3,” and “Cluster Size: 12, Packet #4,” respectively. This allows the site to conduct multiple randomizations of size 12, 14, 16, etc. SCHARP will provide the site with additional packets if necessary.

Packets should be used in packet number order for each cluster size. For example, the first time the site randomizes a group of size 18, the packet labeled “Cluster Size: 18, Packet #1” should be used. The second time the site randomizes a group of size 18, they should use the packet labeled “Cluster Size: 18, Packet #2.”

Each packet contains a randomization list. The randomization list consists of three columns: sequence number, assignment (treatment of control), and participant identification number (PTID). The sequence number is six digits, consisting of a two-digit cluster number, a two-digit packet number, and a two-digit sequential number from 01 to 20. For example a sequence number of “12-01-01” is the first number in the first packet of cluster size 12. “18-04-17” is the 17th number in the 4th packet of cluster size 18.

Randomization procedures: (to be conducted by site staff)

The site should conduct the following procedures for each randomization:

- Send e-mail to SCHARP, at least 24 hours prior to randomization, indicating the scheduled date of the randomization and the number of networks to be randomized.
- Compile a list of PTIDS of eligible index participants. The list must be arranged in numeric order, from lowest to highest PTID.
- Select a randomization packet based on the number of PTIDS to be randomized.

- From the packet, remove the randomization list (DataFax form RL-1). Record each PTID, in ascending order in the space provided on the randomization list. The second column of each line contains the assignment for that PTID (treatment or control).
- Submit the completed Randomization List (RL-1) form to SCHARP using DataFax.
- Record the date of randomization and the sequence number on the Randomization/Enrollment form (RE-1) for each PTID. Submit the RE-1 form and all other enrollment visit forms to SCHARP.
- Store the randomization lists and packets, which are source documents, in a locked file according to local site procedures. Return by traceable courier (i.e., FedEx) any unused randomization packets to SCHARP at the end of the study enrollment period.
- This randomization procedure must be conducted by one site staff member and witnessed by a second. A note must be filed in the site administrative binder documenting the date and time of each randomization, the name of the person conducting the randomization, and the name of the person witnessing the randomization.

Source documents: Randomization lists are the local site source documentation for randomization, and must be maintained separately from other study records to prevent unblinding.

After submitting the RL-1 form to SCHARP, the site should retain the randomization list in order to complete the Randomization/Enrollment form for each enrolled index participant (see Section 6 of this manual).

5.3.3 Post-Randomization/Enrollment Procedures

Scheduling/Rescheduling of the first intervention session: The first intervention session should be scheduled within seven days of randomization. A minimum of five index participants must be present to conduct the first session. If fewer than five are present, the session is rescheduled. The first session may be rescheduled a maximum of two times due to fewer than five index participants presenting. At the third attempt, the session is conducted, regardless of the number of participants attending.

Missed sessions: Index participants who miss the first session of the intervention series are encouraged to join the group at the second session. After the second session, no new index participants may join the group.

Participants who miss the first two sessions: Index participants who miss both the first and second sessions are then scheduled to join the next available group intervention cohort. For an index participant who has not successfully attended an intervention session, the site may continue to attempt rescheduling the participant to join new group cohorts until that participant reaches the target date of his or her 6-month follow-up visit. After the 6-month visit target date, the index participant is no longer eligible to join any intervention group. The site will maintain a record of those index participants who have been randomized, those who have attended or failed to attend the group intervention, and those who are eligible to attend a future intervention session cohort.

Procedures for transferring an index participant to alternative intervention sessions:

Index participants who are randomized to the intervention but fail to attend either of the first two sessions with their intended randomization group are then scheduled to attend the next available intervention group sessions. Staff will continue to attempt to reschedule such a participant until their 6-month follow-up visit target date. After the 6-month visit target date, the participant is no longer eligible to join any intervention sessions. The site will maintain a record of which index participants have been randomized and failed to attend their intended group intervention, making them eligible to attend the next scheduled intervention sessions.

Note: DO NOT count a re-scheduled index participant in the number of index participants to be randomized.

Note: A re-scheduled index participant DOES count toward the minimum number of participants needed for a first intervention session to proceed.

Procedures:

1. When an index participant who is randomized to the intervention fails to attend either of the first two sessions they were originally scheduled to attend, leave their PTID on the original Intervention Session Participation Logs (IL-1) and mark “No” under “Did participant attend?” on all six logs.
2. When the next intervention sessions are scheduled, contact the index participant who failed to attend the previous sessions to invite him or her to the next sessions (attendance should be strongly encouraged).
3. When the re-scheduled index participant presents at either the first or second session of the new intervention group, add their PTID to the Intervention Session Participation Log for the current sessions, and complete an Intervention Cohort Participant Transfer form (IPT-1).
4. If the re-scheduled index participant does NOT present at the first or second session, do not add their PTID to the new Intervention Session Participation Log, and do not complete the Intervention Cohort Participant Transfer form.
5. Continue to attempt to reschedule the participant to the next intervention sessions, using the procedures above, up until their 6-month follow-up date.

Visit scheduling:

- **Index participants:** Study staff should schedule all six intervention sessions, the 3-month locator contact, and 6-month pre-test follow-up visit for all index participants in the treatment arm. For control participants, staff should schedule the 3-month locator visit and 6-month pre-test follow-up visit.
- **Network participants:** Study staff should contact network members to inform them of their eligibility/enrollment status and confirm the date of the first locator contact and pre-test follow-up visit to occur at the month-6 visit. Staff should 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 3-month contact.

5.4 Study Blinding

Behavioral risk survey interviewers must remain blinded to the study arm of the participants. HPTU staff are responsible for establishing procedures to ensure that the interviewer maintains blinding throughout the study. These procedures should include the following:

- Ensure that interviewers are not involved in the scheduling of the intervention sessions
- Ensure that interviewers are not involved in the conduct of the intervention sessions
- Ensure that interviewers do not have access to study records that indicate the randomization arm by participant

5.5 Behavioral Intervention Sessions

Index participants randomized to the intervention arm will attend the intervention sessions. The six sessions must be completed within a four-week time frame. The first four sessions will occur, if possible, in the first two weeks, and the final two sessions will occur, if possible, in weeks three and four. The intervention will be delivered in six two-hour sessions by two facilitators to groups with a maximum of 12 index participants. Please refer to Section 5.3.3 for details on scheduling the first intervention session.

The HPTN 037 Intervention Manual, maintained on site, provides additional detail about the specific topic and activities conducted at each of the sessions. A basic description of each of the sessions is provided in the protocol in Section 4.0. Facilitators will audiotape all sessions that are conducted and complete session monitoring forms to document the topics covered at each session.

Visit Procedures:

- Confirm participant identity and PTID according to local study specific SOP's.
- Conduct the session according to the 037 Intervention Manual; all sessions will be audiotaped.
- Distribute reminder cards to participants for the next session.
- Document PTID, attendance, session date, session number, facilitator, length of session, and any comments on the conduct of the session on the Intervention Participation Log; submit to SCHARP.
- Document the content of the intervention session and any comments on the conduct of the session on the Site Session Content Checklists; store in a secure location at the site.
- Package and send all six session tapes to the RTI monitor for review within five dates following the completion of the last session for each intervention cohort.

5.6 Booster Sessions

Within no more than two months following the six and 12-month follow-up assessments, index participants in the intervention arm will meet for a one to two hour booster session. Booster session groups will have a maximum of 12 participants. Participants do not have to attend a booster session with the same group of people as they attended the first six intervention sessions.

Visit Procedures:

- Confirm participant identity and PTID according to local study specific SOP's.
- Conduct the session; all sessions will be audiotaped.
- After the 6-month booster session, distribute reminder cards to participants for the 12-month session.
- Document PTID, month six or month 12 session, session date, facilitator, length of session, and any comments on the conduct of the session on the Booster Session Participation Log; submit to SCHARP.
- Booster Session tape review will be conducted by Site Supervisors.

5.7 Locator Contacts (every 3 months)

The Locator Contacts procedure is described in detail in the checklists in Section 7 of this Study Specific Procedures Manual. Locator Contacts are scheduled to take place every three months on a quarterly basis for all participants. However, the locator contact visit may take place any time between the three-month time point before and after a follow-up visit. The contact also may take place via any modality that the study site deems appropriate for its local study population.

Visit Procedures:

- 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 semiannual follow-up visit.
- Document the contact in a signed and dated chart note.

5.8 Follow-up Visits for Index and Network participants

The follow-up visit procedures are described in detail in the checklists in Section 7 of this Study Specific Procedures Manual. Follow-up visits will be scheduled every six months until the study end, for a minimum of 18 months and a maximum of 30 months. Follow-up pre-test visits are scheduled to take place every six months; 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. Follow-up post-test visits will take place when the test results are available, which may be the same day in the case of rapid testing. Day 0 will be assigned to the participant's randomization day and scheduling of follow-up visits will be done from Day 0. The 6-month target date is 182 days from the day of randomization; the 12-month target date is 365 days after randomization, and so on until the participant reaches the last follow-up visit. These target dates are set at randomization and stay the same throughout the participant's enrollment regardless of when the last visit actually took place. In addition, indexes that are randomized to the intervention arm will be scheduled to return within 60 days following their first 6-month and 12-month follow-up assessments for a booster session.

Note: Network members who are HIV infected at enrollment and any participants who seroconvert during the study will continue in follow-up and undergo all study procedures outlined below except HIV testing and post-test visits.

Note: If a study participant becomes incarcerated during follow-up, study staff should not contact the participant. No study procedures can be undertaken while the participant is incarcerated; submit a missed visit form if necessary. Follow-up should be resumed when the participant has been released. The dates of incarceration should be documented in a chart note.

Note: If an HIV un-infected study participant is unwilling or unable to complete all the follow-up visits, he/she should be asked whether or not he/she will undergo HIV counseling and testing at the point at which their last follow-up visit would have been scheduled or 18 month, whichever is soonest. If the participant does not agree, then he/she should be terminated from the study.

Note: Once a network has been randomized, all members will continue to be followed unless he/she withdraws consent or is terminated from the study (see Section 5.10). Index participants will be followed regardless of whether or not they complete one or more intervention sessions.

Note: The visit procedures can be completed over multiple visits; however, the Risk Assessment must be administered prior to receiving HIV counseling. Interviewers must be blinded to participants study arm.

5.8.1 Visit Windows

Pre-test follow-up 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 take place outside this interval are treated as "interim visits" (see Section 5.9). Missed visits should be recorded on the Missed Visit Form after the 30-day window has passed.

Although the six-week visit windows allow considerable flexibility, every effort should be made to conduct visit as close to the visit target date as possible. Deviation from 6-month intervals must be avoided. SCHARP will provide the Protocol Team with routine visit completion reports for purposes of monitoring adherence to the visit schedule (see Section 9).

5.9 Interim Visits

Interim visits are unscheduled visits between scheduled study visits, initiated by the participant. Interim visits that involve study procedures such as HIV testing or social impact reporting are recorded on DataFax forms using an interim visit code. Visits not involving study procedures, such as clinical referrals or locator updates, are only documented in a signed and dated chart note.

Interim visit procedures are described in detail in the checklists in Section 7 of this Study Specific Procedures Manual. All interim contacts and visits, and the results of all interim HIV tests, must be documented in participant's study records and on applicable case report forms. Participants who come to the study site for interim visits will not be compensated for their visit.

5.9.1 Making up missed study visits

Scheduled study visits not completed within the visit window (SSP section 5.8.1), may be completed outside the visit window **up until 30 days prior to the target date for the next scheduled visit**, with the following conditions:

- A Missed Visit form (section 6.14.13) must be completed for the scheduled study visit, regardless of whether or not the visit is later “made up” with an interim study visit.
- All procedures required for the scheduled study visit should be conducted at the “make-up” visit.
- The case report forms completed at the “make-up” visit should be coded using an interim visit code.

Example: Study staff are unable to locate a participant before his or her 6-month visit window closes. At the close of the visit window staff should complete a Missed Visit form using visit code 3.0. A month later the participant is located. The participant should be invited to the study site to complete the missed 6-month visit. All visit procedures should be completed according to the study visit checklists (Section 7). The case report forms for this visit (i.e., risk assessment, network summary, follow-up local lab results, post-test visit, exposure/contamination assessment.) are assigned an interim visit code (e.g., 3.1) and sent to SCHARP. The participant then returns to his or her regular visit schedule.

5.10 Termination

Once a network has been randomized, all members will continue to be followed unless he/she withdraws consent or is terminated for one of the conditions listed below. Index participants will be followed regardless of whether or not they complete one or more intervention sessions. All randomized participants will be followed according to the protocol.

- Participant refused further participation; if known, document the reason for refusal
- Death
- Participant unable to adhere to visit schedule
- Participant relocated, no remote follow-up planned
- Investigator decision; specify the reason

5.11 Compensation

Study participants will be compensated for their time and effort in this study. Each site is responsible for developing a compensation plan. The compensation plan must be reviewed and approved by the relevant IRB's as specified in Section 3.1. An overview of each site's plan follows.

In Philadelphia, compensation will be paid as follows:

- Indexes will receive compensation plus travel vouchers for initial screening visits
- Indexes and network members will receive compensation and travel vouchers for all scheduled visits
- Indexes will receive compensation and travel vouchers for intervention and booster sessions
- Indexes will receive compensation for each network member (up to 5) that presents for screening. Compensation will be provided after all network members are enrolled

In Thailand, compensation will be paid as follows:

- Indexes and network members will receive compensation for all screening and regularly scheduled visits. The amount is equivalent to lost wages and travel for a day of work missed
- Indexes will receive compensation for intervention and booster sessions

5.12 Social Impact Monitoring

5.12.1 Definition of a Social Impact

- ◆ Events leading to **significant psychological, social, or physical effects** on a participant;
- ◆ that **result from his/her participation in the study**, including disclosure of participant's drug or sex-related behaviors or of their HIV serostatus, being exposed to intervention activity or implementing a personal goal or practicing a skill as part of participating in the study treatment or control group;
- ◆ and that are **reported to or observed by a study staff**.

5.12.2 Social Impact Monitoring

Social impacts will be monitored closely throughout the study. At each scheduled follow-up visit, participants will be asked if they have had any negative experiences as a result of participation in the study. Participants who report a negative experience will be asked a series of structured questions to probe for interpersonal, legal, housing, and healthcare

problems that have occurred as part of study participation. All subjects will also be reminded of the importance of reporting problems to study staff between regularly scheduled visits and instructed on how to contact study staff between regularly scheduled visits.

Social impacts should be distinguished from the mild, transient, and normal discomfort or awkwardness that some participants may experience during study participation.

Examples of Social Impacts (this list does not include all possible examples)

Harassment or violence. Examples include violence directed at a participant as a result of taking part in some study activity; physical or verbal abuse from a partner as a result of participating in a study activity or requesting a safe sex practice such as using condoms; family abuse or conflict following a young person's becoming publicly identified as HIV – infected or a drug user by virtue of participation in the study or intervention.

Negative reactions from the community. An example is a participant losing housing or other services because of participation in the study.

These experiences are considered a social impact if the person is observed to have or reports having serious psychological, social, or physical impact.

5.12.3 Responding to Social Impact Events

Social impacts are recorded on the **Social Impact Assessment Form**.

Each reported **social impact** must be reported on a **Social Impact Log Form** and reviewed by the Investigator or designated sub-Investigators at each site. (The investigator or sub-investigator must sign and date the form to indicate that they have reviewed the event and appropriate follow-up has occurred.)

Completed forms should be faxed to SCHARP as soon as possible, ideally within 7 days of site awareness.

Reports will **be reviewed and monitored by the 037 Study Team** as they occur.

Sites, in collaboration with the study team, will be responsible for:

- (A) **carrying out measures to address** social impacts as they occur,
- (B) **carrying out measures to prevent** similar events in the future,
- (C) **following up with the affected participants**, if needed, after the report has been made,
- (D) reporting to the relevant IRB – **as per IRB requirements**.

5.13 HIV Counseling

HIV test counseling for both index and network participants will be standard across both study arms. Participants will be offered pre- and post- HIV test counseling sessions every time they have blood drawn for HIV testing during screening and in follow-up. A pre-test counseling session will be conducted directly prior to the phlebotomy for HIV antibody testing. A post-test counseling session will be administered when the participant receives their HIV test results. Every effort will be made to have participants see the same counselor for both their pre- and post-HIV test sessions. HPTU staff

are responsible for establishing HIV testing and counseling standard procedures and a quality assurance plan to evaluate the procedures throughout the study. The procedures should be stored on site with the “local study-specific SOPs” (noted in Section 3.1 of this study manual).

- All counseling sessions and disclosure of HIV test results will be offered in private rooms with only the counselor and the participant present, to ensure the maintenance of participant confidentiality.

The following guidelines will be followed:

- No one but the participant will be notified of his/her HIV status in the post-test counseling session.
- It is solely the right and choice of the participant to disclose his/her HIV status.
- Counselors will discuss prospective consequences of participant disclosure of serostatus during the post-test counseling session.

Neither counselors nor any other member of the study staff will provide information about a participant to anyone without a written and signed request from the participant. Even with such a request, the desired information will only be directly released to the participant.

Section 6. Data Collection

This section provides guidelines for completing the study data forms and describes DataFax, which is the data and forms management system used in HPTN studies.

6.1 DataFax Introduction

DataFax automates much of the clerical work involved in managing and tracking participant forms. It increases efficiency and reduces the overall cost of data management for sites and SCHARP. In addition, DataFax can increase the timeliness of form collection, review, and quality control.

DataFax's success depends on the people who use it both at the sites and at SCHARP. It is important that participating sites fax completed forms to DataFax as soon as possible after completion (NOTE: Refer to Section 6.8 regarding when to send screening and enrollment forms to SCHARP). It is also important that sites attend to requests from SCHARP for form clarifications and corrections in a timely manner. This will allow SCHARP to keep up with the review of incoming faxed forms and send quality control (QC) reports to the sites on a timely basis.

6.2 DataFax Questions and Answers

What is DataFax?

DataFax is a data management system that integrates fax and computer technologies. It provides a statistical and data management center with tools that facilitate the collection, review, correction and tracking of study forms.

Do Study Centers Need Any Special Equipment?

Completed forms are faxed from the participating HPTN sites to DataFax at SCHARP over ordinary phone lines using a fax machine. Forms are "faxed" to SCHARP DataFax by scanning forms to the Internet fax-relay system connected to SCHARP. All of these faxes are stored as electronic images at SCHARP.

How Does DataFax Work?

When a fax arrives at SCHARP, DataFax breaks it into pages and processes each page. It corrects any misalignment problems, flips pages faxed upside down, identifies which study each page belongs to, reads the data from each page, enters the data into the study database, and stores images of all pages from the fax on disk. Data management staff then use the DataFax split-screen validation tool to review all pages received, complete data entry and flag any problems they identify (e.g., missing or potentially incorrect data) with Quality Control (QC) notes.

At least two people view every form received at SCHARP to ensure accuracy and data quality. On a regular basis DataFax generates and faxes or e-mails a QC report back to each site. The QC reports show the follow-up status of all screened and enrolled participants at the site and identify any problems flagged during the SCHARP data review. Sites are asked to correct any problems identified on the QC reports and refax the corrected form pages to SCHARP DataFax. When received, these pages are identified as re-faxes by DataFax and data management staff review them again and resolve the QC note.

The original paper forms remain on file at each participating site. At SCHARP, the faxed forms and corresponding data records can be reviewed simultaneously, on-screen, any time during the study, thus eliminating the need to print, file and track paper forms. It is important that sites re-fax any form that they correct. If SCHARP requests a QC correction, DataFax will keep track of whether or not it has been made and re-faxed to SCHARP DataFax. **SCHARP has no way of knowing if a site has corrected a form unless they re-fax it to SCHARP DataFax.**

If your site experiences any technical difficulties with the fax relay equipment, please notify SCHARP as soon as possible.

6.3 Form Completion Tips

- **Always** use a black or blue medium ballpoint pen to complete forms. Do not use any other type of writing implement.
- Legibly print written responses or comments.
- Press firmly when recording data or writing comments.
- Keep all responses within the margins of the individual data boxes.
- Do not type data onto forms. Handwrite all data on all DataFax forms.
- Record data on the front of forms only. DataFax cannot read the back of forms.
- Do not use the .5-inch margins at the top, bottom, or sides of the forms for recording data.
- Record “specify” responses in the space provided. If the line provided is not long enough, continue in another blank area of the form (within the margins), or use a comments form if more space is needed.
- Never mark over or punch holes through the barcodes at the top of each form. DataFax requires the barcode each time the form is faxed in.
- Never use correction fluid on DataFax forms.
- Do not attach stick-on notes to DataFax forms.

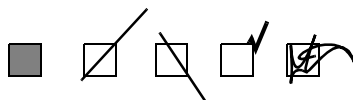
Marking Item Boxes

Many items have a box or series of boxes for recording a response. Mark the box clearly with an X. Do not shade in the box or mark it with a slash or other character.

Correct



Incorrect

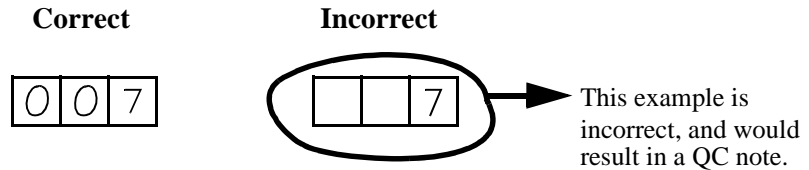


Do not mark more than one box in response to an item *unless instructed to do so*. Many items provide boxes marked with a *yes*, a *no* or other distinct answer, and should only have one box marked.

Entering Numeric Data

The data management staff viewing your faxes are able to interpret many different handwriting styles for numerical data as long as they are clearly written and not ambiguous or confusing.

- Right justify all numerical data and fill in any blank leading boxes with zeroes. For example, to record a “7” into a three-digit box, enter a “0” in the first two boxes, and a “7” in the third box:



- Write the number completely within the box as shown in the example below; try not to touch the edges or stray outside the margins



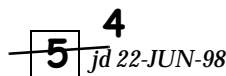
In the following example, the “4” on the right could be misinterpreted as a “7” or a “1”.



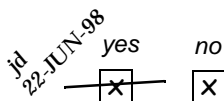
Correcting Mistakes

- If a numeric box is completed incorrectly, draw a single line through the incorrect entry, place the correct answer near the box, and initial and date the correction as shown below. Remember that your responses are being read by the data management staff at SCHARP. As long as your corrections are clear, they will be interpreted correctly.

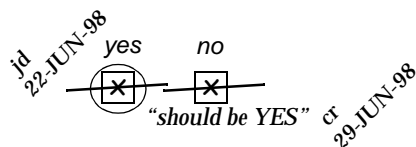
Make all corrections to the original form. Never transfer information on a completed DataFax form to a new form.



If an X is marked in the wrong box, draw a single line through the incorrectly marked box, initial and date it, then mark the correct box as shown below.

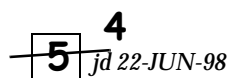


If the correct answer has previously been crossed out, circle the correct item, write an explanation in a blank area near the item, and initial and date all corrections.



When changing an entry, draw a single line through the incorrect entry so that it still can be read. Do not obliterate by excessive cross-outs.

Correct



Incorrect



Handling Missing and Unknown Data

Blank items on data forms are considered missing data and will therefore result in a QC note *unless* they are blank due to skip pattern requirements. To avoid a QC note on items where the answer to an item is not known or is unavailable, or where the participant refuses to answer an item, draw a line through the blank boxes corresponding to the item.

For example, when complete information for a date is unavailable, draw a single line through the boxes:



Items on Interviewer administered forms, such as a Risk Assessment must be completed during the appropriate visit. Ask the items in order, following instructions below and on the form. Follow skip pattern instructions carefully. Skip items as indicated. Use probes and clarifications as needed to get participants to provide a response to each item. If a response is indicated, but the participant refuses to answer, line through the item and write “REF” beside the item and add interviewer initials and the date. If the participant can’t answer the item because the answer is not known, line through the item and write “DK” beside the item and add interviewer initials and the date. Before the participant leaves the room for the next part of the visit, be sure that all parts of each interviewer-administered form have been completed, and that no items are left blank unless the instructions and/or skip patterns indicate to leave those item blank. Items that are left blank which should have been completed CANNOT be corrected after that visit, so it is important to be sure that all interviewer-administered forms are completed during the appropriate visit.

6.4 Question Completion, Order, and Skip Patterns

For every question, there should be only one answer, unless the direction “Mark All That Apply” is printed right after the question. If a participant is unable to provide one answer, use non-leading probes to try to get a more precise answer from him or her.

In filling out the DataFax forms, always follow the questions in the order they are printed. Use the arrows and written directions to guide you to answer questions in the appropriate order. If there is no arrow or direction attached to the answer box, always go to the next sequential item.

Read all items to the participant **word-for-word**, including parenthetical text.

Provide explanation or interpretation if necessary only after reading the item word-for-word. As much as possible, avoid tangential — though related — counseling and educational discussions during data collection. Acknowledge the question/concern raised by the participant, state that you will come back to it, and continue the interview.

For “mark all that apply” items, read each possible response category to the participant and mark all responses that apply, based on active participant report.

For items with multiple sub-items for which a yes/no or a response from a card is requested, read all sub-items to the participant and mark the appropriate response to each, based on active participant report.

Items that are skipped due to instructions should be left blank, NOT filled in with zeros. For example, if the response to Risk Assessment item 30 (“In the last week, how many times did you had vaginal or anal sex with your primary partner?”) is 0, then item 30a (“How many of these times did you or your partner use a condom?”) should be left blank, not filled in with “000”.

6.5 Study Site Review of Data Collection Forms

It is recommended that sites review each completed form for completeness, accuracy, and legibility before faxing to SCHARP DataFax. The following list can be used as a review checklist.

- Never record any information on a DataFax form that identifies the participant, other than the Participant ID Number. This includes the participant’s initials, name, phone number, address, or any other personal identifiers.
- Make sure all items are answered, unless skipped according to the instructions on the form.
- Make sure only one response box per item is marked, unless instructed otherwise.
- Make sure all written entries are clear enough to be legible after faxing.
- Make sure staff initials and the date are entered in the spaces provided on the bottom right corner of every page.
- Take extra care to ensure that nothing is written on or above the DataFax barcode as this can result in misread forms.
- Check for common errors. The largest percentage of avoidable QC notes are associated with:
 - missing dates
 - transposed or incorrectly transcribed Participant ID numbers
 - missing entry for the lead item that begins a skip pattern
 - missing visit codes

6.6 When to fax the forms

Forms should be faxed to DataFax as soon as possible after each visit, after careful review of each form for missing data or other errors. NOTE: In HPTN 037, screening forms are NOT to be faxed until after the participant has enrolled (see section 6.8).

Pages of forms that are NOT required because they do not apply to the site should NOT be faxed to DataFax. Also, if entire pages are skipped because of the gender or behavior of the participant, those pages should NOT be faxed to DataFax.

6.7 Schedule of Forms

Table 1 lists scheduled study visits and interventions sessions and forms completed at those visits and sessions. The table indicates the visit codes for each visit, and both required and optional forms.

Table 1: HPTN037 Schedule of DataFax Forms for Study Visits

Visit name:	Screening visits	Randomization/Enrollment	6 month follow-up visit	12 month follow-up visit	18 month follow-up visit	24 month follow-up visit	30 month follow-up visit
Visit Code	1.0	2.0	3.0	4.0	5.0	6.0	7.0
Demographics (DM1 to DM2)	X						
Index Screening Assessment (IS-1) ^I	X						
Member Screening Assessment (MS-1) ^M	X						
Risk Assessment (RA-1 to RA-7)	X		X	X	X	X	X
Screening HIV Status (SS-1)	X						
Network Summary (NS-1) ^I	X		X	X	X	X	X
Network Norms (NN-1)	X			X		X	
Index Eligibility Checklist (EC-1–EC-2) ^I		X					
Member Eligibility Checklist (MC-1) ^M		X					
Randomization List (RL-1) ^N		X					
Randomization/Enrollment (EN-1–EN-2)		X					
Follow-Up Local Lab Results (LL-1)			X	X	X	X	X

Table 1: (Continued) HPTN037 Schedule of DataFAX Forms for Study Visits

Post-Test Visit (PV-1)	X						
Exposure/Contamination Assessment (EX-1)			X	X	X	X	X
Social Impact Assessment (SIA-1)			X	X	X	X	X
Social Impact Log (SIL-1)			[X]	[X]	[X]	[X]	[X]
Comments (COM-1)*	[X]	[X]	[X]	[X]	[X]	[X]	[X]
Missed Visit (MV-1)			[X]	[X]	[X]	[X]	[X]
Termination (TM-1)**							X
End of Study Inventory (ESI-1)							X

X – Required at indicated visit

[X] – Allowed but not required of all participants at indicated visit

Notes:

^I Required of Index participant

^M Required of Network Member participant

^N One RL-1 form is completed for at each randomization, and transmitted to SCHARP immediately.

* Complete and fax the Comments form to provide pertinent information that is not otherwise captured on another form.

** Required of all enrolled participants when they exit the study. For most participants this will be at 24-month follow-up visit (visit code 6.0). For all other participants, complete and fax Termination form when participant is withdrawn from the study or completes all study visits per protocol.

6.8 When to send forms completed at Screening visits.

In HPTN 037, some DataFAX forms will be completed at screening visits (these are listed in table 2), but NO forms are sent to SCHARP until after enrollment. ONLY forms from ENROLLED Index participants and their Network members are sent to SCHARP, after the randomization/enrollment session. DataFAX forms that are completed at screening visits for potential Index and Network participants who are NOT randomized and enrolled are NOT sent to SCHARP. These forms are maintained in client records at the site, but not recorded in the central database at SCHARP.

Forms completed at screening visits for participants who do not enroll should be clearly marked or stamped so that they are not accidentally sent to DataFAX. However, because individual participants may be considered in more than one network during the screening process, and some of the forms would be the same, it is important that the forms are marked only after it clear that ALL networks for which the participant may have qualified will not qualify.

During the accrual period, potential participants may screen for the study multiple times, so there may be multiple sets of completed screening forms in an individual participant's chart. It is important that the site mark or stamp or isolate older sets of screening forms so that they do not get mixed up with screening forms that are "active" or in consideration for enrollment.

Following each Randomization/Enrollment session, Randomization/Enrollment forms are completed for each index participant and each one of their eligible network member participants. All screening forms for enrolled Indexes and their eligible network members are gathered, checked for accuracy and completeness, and all screening and enrollment forms are sent to DataFax together.

Table 2: DataFax forms completed at screening visits

Visit	Index	Member
Screening 1 (pre-test)	Demographics (DM) Index Screening Assessment (IS) Risk Assessment (RA)	Demographics (DM) Member Screening Assessment (MS) Risk Assessment (RA)
Screening 2 (post-test)	Screening HIV Status Network Summary Network Norms Post-Test Visit	Screening HIV Status Network Norms Post-Test Visit
(completed prior to randomization/enrollment session)	Index Eligibility Checklist (IC)	Member Eligibility Checklist (MC)
(completed and transmitted immediately following randomization)	Randomization List (RL-1) NOTE: one RL form is completed for each randomization.	

6.9 Visit Codes

The Visit Code tells Datafax which visit the forms were completed at. Visit codes are needed on each page of forms that are used repeatedly at different visits during the course of the study. Forms that do not have spaces for the visit code do not require a visit code. The following forms in HPTN 037 require visit codes:

- Risk Assessment (RA-1 to RA-7)
- Network Summary (NS-1)
- Network Norms (NN-1)
- Follow-up Local Lab Results (LL-1)
- Post Test Visit (PV-1)
- Exposure/Contamination Assessment (EX-1)
- Social Impact Assessment (SIA-1)
- Missed Visit (MV-1)
- Comments (COM-1)

Table 3: Visit Codes for HPTN 037 study visits

Visit	Visit Code
Screening (1 & 2)	1.0
Randomization/Enrollment	2.0
6 Month Follow-Up	3.0
12 Month Follow-Up	4.0
18 Month Follow-Up	5.0
24 Month Follow-Up	6.0
30 Month Follow-Up	7.0

6.10 Interim Visit Codes

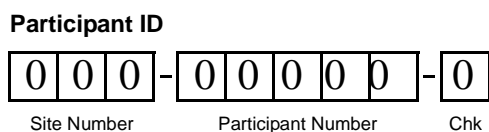
Interim visit codes are used to indicate that forms were completed at **unscheduled visits**. Visit codes for interim visits are the whole number from the previous scheduled visit plus one increment in the decimal. Increase the decimal by one for each additional visit between scheduled visits.

Examples:

- A participant returns for additional HIV testing at 8 months. **Visit code = 3.1**
- Same participant returns at 10 months for additional HIV testing. **Visit code = 3.2**

6.11 HPTN 037 Participant IDs (PTIDs)

The ID numbers that SCHARP uses to identify each study participant are called Participant IDs (PTIDs). The PTIDs used for this study are made up of three parts: the first three digits are the site and protocol number; the next five digits are the participant number; the final digit is a numerical check digit, which helps to ensure that the PTID recorded on the form is the correct one (see example below).



A list of PTIDs to be used for this study will be provided to the site prior to the beginning of the study. That list should be kept at the study site, and each time a number is assigned to a participant, the number should be checked off the list so that it is not assigned to more than one participant.

6.12 Recording of Dates

The date format on the HPTN 033 forms is “dd MMM yy,” representing a 2-digit day, followed by a 3-character month, followed by a 2-digit year (the last 2 digits of the year). When recording the month, use the codes below. These codes correspond to the first 3 characters of the month’s English name.

Month	Numeric Code	Code to Use When Completing Datafax Forms
January	01	JAN
February	02	FEB
March	03	MAR
April	04	APR
May	05	MAY
June	06	JUN
July	07	JUL
August	08	AUG
September	09	SEP
October	10	OCT
November	11	NOV
December	12	DEC

6.13 Common Elements of HPTN 037 Forms

Form Completion Date

The first page of each form (except for log forms, intervention session forms, and the Follow-up Local Lab Form) contains a space for form completion date. This date is the day on which the form is COMPLETED, or the day on which the last original entry is made. If a form is started on 10 JUL 03, but completed on 14 JUL 03, the form completion date should read: "14 JUL 03."

Questions With a Fill In Date

In some questions, the interviewer must complete the question by filling in the appropriate date while asking the question. For example, item 2a on the Index Screening Assessment (IS-1): "In the last 3 months (that is, since _____), how many times total have you injected drugs?" The interviewer should complete the question with the appropriate month and day. Interviewers should either write the appropriate month in all these items before the interview starts, or have a monthly calendar available so the proper month can be quickly determined. A wall calendar showing all 12 months may be useful. Looking at the same calendar may also help participants to more accurately recall behaviors during the time period asked about in the question.

Questions with Response Categories

Many items are followed by a list of possible responses for the interviewer to mark based upon the participant's response. Unless the instructions indicate otherwise, DO NOT read the list of possible responses to the participant. Let the participant respond after the question is read and mark the most appropriate category. Use non-leading probes if necessary to confirm the participant's response. Mark only one response unless the question says "Mark all that apply."

Questions with Response Cards

A number of items require the interviewer to show a response card to the participant. These cards are provided in small ring binders that are opened while the interviewer is asking the question, so that the participant can read the possible responses from the appropriate card. The participant must select a response from the card, and the interviewer then records which response was selected on the form. The possible responses are read out loud in order, and the interviewer should point to each response as they are reading it. The cards should be oriented so that the participant can easily read the responses as they are being read and pointed out. There are a total of five different response cards for HPTN 037. The interviewer should have the binder with the appropriate cards available to use during each interview with every participant.


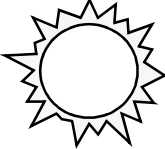
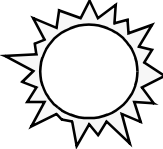

Comments Fields

Many of the forms have an area for written comments at the bottom. This is a place to add any information about the participant or the form that the interviewer feels is important. At a minimum, any missing or inconsistent information should be explained in this area. All of the comments areas are divided into two sections: one for the interviewer to write comments in the local language (if not English), and an area for those comments to be translated into English. All comments are to be translated into English BEFORE the form is faxed to DataFax.

Use of 24-hour Clock

HPTN forms require times to be entered using a 24-hour clock. See “24 hour clock Conversion Table” below for assistance in converting to the 24-hour clock.

24-hour clock Conversion Table:

	24:00 Midnight → 24 00	12:00 Noon → 12 00	
	1:00 a.m. → 01 00	1:00 p.m. → 13 00	
	2:00 a.m. → 02 00	2:00 p.m. → 14 00	
	3:00 a.m. → 03 00	3:00 p.m. → 15 00	
	4:00 a.m. → 04 00	4:00 p.m. → 16 00	
	5:00 a.m. → 05 00	5:00 p.m. → 17 00	
	6:00 a.m. → 06 00	6:00 p.m. → 18 00	
	7:00 a.m. → 07 00	7:00 p.m. → 19 00	
	8:00 a.m. → 08 00	8:00 p.m. → 20 00	
	9:00 a.m. → 09 00	9:00 p.m. → 21 00	
	10:00 a.m. → 10 00	10:00 p.m. → 22 00	
	11:00 a.m. → 11 00	11:00 p.m. → 23 00	

6.14 PTN 037 Forms Descriptions and Instructions

6.14.1 Demographics (DM-1–DM-2)

Description and Purpose

This form collects demographic information from participants including race/ethnicity, marital status, education, and employment status. This form is administered to every participant who consents to be screened for the study.

Form-specific Instructions

All sites complete items 1, 2 and 6-9. Items 3 and 4 are completed by Philadelphia sites only; item 5 is completed by Thailand sites only.

Item 1: Record the participant's complete date of birth OR their age. If date of birth is recorded, age is left blank; conversely, if age is recorded, date of birth is left blank. Full date of birth is preferable; only ask for age if participant is unable to give complete date of birth.

Item 9: "Full time" means a regular job with 30 or more hours per week. "Part-time" means a regular job with less than 30 hours of work per week. "Occasional or time-to-time" means the participant does not have a regular job but finds work with no regular or predictable hours or schedule. "Unemployed" means they are not currently working, or have no regular or occasional job. Response choices are read out loud by the interviewer, not shown to the respondent. If unsure about which category to choose, respondent should be instructed to choose the category that "best" describes his or her current employment status.

Figure 6-1
Demographics (DM-1–DM-2)



Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Demographics (DM-1)	
			
HPTN 037 IDU Networks (095) DM-1 (001)		Page 1 of 2	
Participant ID		Demographics	
Form Completion Date			
Site Number Participant Number Chk Network ID Member		dd MMM yy	
1. What is your date of birth?		OR Age:	
dd MMM yy		years (estimate OK)	
2. What is your sex?		male female	
		<input type="checkbox"/> <input type="checkbox"/>	
Items 3 and 4 for Philadelphia site only. Thailand site go to item 5.			
3. Do you consider yourself to be Latino/a or of Hispanic origin?		yes no	
		<input type="checkbox"/> <input type="checkbox"/>	
4. What is your race? <i>Mark all that apply.</i>			
<input type="checkbox"/> White			
<input type="checkbox"/> Black/African American			
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander			
<input type="checkbox"/> Asian			
<input type="checkbox"/> American Indian or Alaska Native			
<input type="checkbox"/> other, specify: _____			
Item 5 for Thailand site only. Philadelphia site go to item 6.			
5. What is your ethnicity? <i>Mark all that apply.</i>			
<input type="checkbox"/> Thai		<input type="checkbox"/> Yao	
<input type="checkbox"/> Karen		<input type="checkbox"/> Lisu	
<input type="checkbox"/> Tai Yai		<input type="checkbox"/> Lahu	
<input type="checkbox"/> Akha		<input type="checkbox"/> Lua	
<input type="checkbox"/> Hmong		<input type="checkbox"/> other, specify: _____	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02		SAMPLE—English	
/hivnet/forms/PTN_037/forms/demographics.fm		01 Language Staff Initials / Date	

Figure 6-2
Demographics (DM-1–DM-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Demographics (DM-2)	
 HPTN 037 IDU Networks (095) DM-2 (002)		Page 2 of 2	
Participant ID		Demographics	
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>		
Site Number	Participant Number	Chk	Member
6. What is your current marital status?		7. What is your highest level of education?	
<input type="checkbox"/> single <input type="checkbox"/> married <input type="checkbox"/> living with partner/not married <input type="checkbox"/> separated/married but living separately <input type="checkbox"/> divorced <input type="checkbox"/> widowed		<input type="checkbox"/> no schooling <input type="checkbox"/> primary schooling <input type="checkbox"/> some secondary schooling (middle school or high school) <input type="checkbox"/> completed secondary schooling (high school) <input type="checkbox"/> vocational or trade schooling <input type="checkbox"/> some university or community college <input type="checkbox"/> completed university <input type="checkbox"/> graduate/professional schooling	
8. Are you currently a student?		yes <input type="checkbox"/>	no <input type="checkbox"/>
9. Are you employed... <i>Read categories.</i>			
<input type="checkbox"/> full time (≥ 30 hours per week) <input type="checkbox"/> part-time <input type="checkbox"/> occasional or time-to-time <input type="checkbox"/> unemployed			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02 /hivnet/forms/PTN_037/forms/demographics.fm		SAMPLE—English	
		<input type="text"/> <input type="text"/>	Staff Initials / Date

6.14.2 Index Screening Assessment (IS-1)

Description and Purpose

This form collects information that determines initial study eligibility for potential index participants. Participant age, injection drug use details, drug and sex network size, and methadone treatment history is recorded. Dependent upon participant responses in conjunction with other screening data, the participant may invited to continue with study enrollment. The entire form should be completed for each potential Index participant screened. Bold instructions to the right of the items indicate how responses determine whether a potential Index participant is eligible to continue screening. The form should be reviewed after completion and the screening process should be discontinued for those determined to be ineligible.

Form-specific Instructions

Each item on this assessment is designed to determine participant eligibility at the Screening Visit. Per the following instructions, if the response to the item indicates that the participant is ineligible, document the reason for the ineligibility in a study note. NOTE: The entire form should be completed, even if ineligibility is established by responses to the first few items. This is because we want to “mask” the eligibility criteria as much as possible so that potential participants don’t know how to manipulate responses to “get into” the study

Fill in the date used for calculation in Item 2a (3 months ago) before administering the questionnaire.

Recruitment Location: Sites will develop and maintain codes for specific recruitment areas or venues. This code should be completed by site staff, based on where the potential index participant was recruited.

Item 1: Ask if the participant is at least 18; this may be confirmed with the date of birth if provided on the Demographics form. If the participant answers “no,” he or she is not eligible.

Item 2: Ask if the participant has ever injected drugs. If the participant answers “no,” he or she is not eligible.

Item 2a: Ask how many times the participant has injected drugs in the past 3 months. If the answer is < 12 times, he or she is ineligible.

Item 3: Record the number of people that the participant buys drugs or shoots up with.

Item 4: Record the number of people that the participant has sex with.

Item 5: Ask if the participant how many of the people mentioned in items 3 and 4 he or she is willing to recruit to join the study as part of his or her network. If the participant answers fewer than 2 people, he or she does not have an adequate network and is not eligible.

Item 6: Ask if the participant has ever been in methadone maintenance treatment. If participant answers “no,” skip to item 7. NOTE: This item is intended to assess history of Methadone Maintenance TREATMENT, not methadone detoxification or illicit or non-supervised use of methadone. Be sure that the respondent understands that we are asking about Methadone Maintenance TREATMENT.


Item 6a: If the participant has ever been in Methadone Maintenance treatment per item 6, determine how long the participant has been out of this treatment. The time out of treatment must be at least 3 months; if < 3 months, the participant is ineligible.

Item 7: Determine if the participant is currently enrolled or has been in another HIV prevention research study in the last 6 months. If yes, participant is ineligible.

Figure 6-3
Index Screening Assessment (IS-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Index Screening Assessment (IS-1)



HPTN 037 IDU Networks (095) IS-1 (011)

Page 1 of 1

Participant ID

Site Number			Participant Number				Chk	Network ID			Member

Index Screening Assessment

Form Completion Date

dd		MMM		yy	

Recruitment Location

--	--	--

	yes	no				
1. Are you at least 18 years of age?	<input type="checkbox"/>	<input type="checkbox"/>				
2. Have you ever injected drugs?.....	<input type="checkbox"/>	<input type="checkbox"/>	<i>If no to either, participant is ineligible.</i>			
2a. In the last 3 months (that is, since _____), how many times total have you injected drugs?	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td> </td><td> </td><td> </td></tr></table>					<i>If < 12, participant is ineligible.</i>
3. Thinking about the people that you know or hang out with, how many of these people do you usually buy drugs with or shoot up with?.....	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td> </td><td> </td></tr></table>					
4. Thinking about the people that you know or hang out with, how many of these people do you have sex with?.....	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td> </td><td> </td></tr></table>					
5. How many of these people that you do drugs with or have sex with are you willing to bring in to join this study?	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td> </td><td> </td></tr></table>				<i>If < 2, participant is ineligible.</i>	
6. Have you ever been in methadone maintenance treatment?	<input type="checkbox"/>	<input type="checkbox"/>	<i>If no, go to item 7.</i>			
6a. Have you been out of methadone maintenance treatment for at least 3 months?.....	<input type="checkbox"/>	<input type="checkbox"/>	<i>If no, participant is ineligible.</i>			
7. Are you currently a participant in any other HIV prevention research study or have you been in another HIV prevention study in the last 6 months?	<input type="checkbox"/>	<input type="checkbox"/>	<i>If yes, participant is ineligible.</i>			

05-DEC-02
/hivnet/forms/PTN_037/forms/screening_index.fm

SAMPLE—English

0	1
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Language Staff Initials / Date

6.14.3 Member Screening Assessment (MS-1)

Description and Purpose

Administered at the screening visit, this form collects information that determines initial study eligibility for potential network members. Participant age and injection history is recorded. Several items also assess the drug use and/or sexual relationship between the participant (potential network member) and the person who told them about the study (potential index member). The entire form should be completed for each potential Member participant screened. Bold instructions to the right of the items indicate how responses determine whether a potential Member participant is eligible to continue screening. The form should be reviewed after completion and the screening process should be discontinued for those determined to be ineligible.

Form-specific Instructions

Each item on this assessment is designed to determine participant eligibility at the Screening Visit. Per the following instructions, if the response to the item indicates that the participant is ineligible, document the reason for the ineligibility in a study note. NOTE: The entire form should be completed, even if ineligibility is established by responses to the first few items. This is because we want to “mask” the eligibility criteria as much as possible so that potential participants don’t know how to manipulate responses to “get into” the study

Fill in the date used for calculation in Item 2a and Item 3 (3 months ago) before administering the questionnaire.

Item 1: Ask if the participant is at least age 18; this may be confirmed with the date of birth if provided on the Demographics form. If the participant answers “no,” he or she is not eligible.

Item 2: Ask if the participant has ever injected drugs. If the participant answers “yes,” go to Item 2a, then follow with Items 3, 4, and 4a as indicated. If the participant answers “no,” read the instruction above Item 3 aloud to the participant to identify the name of the index. Proceed to Item 4.

Item 2a: Ask how many times the participant has injected drugs in the past 3 months.

Item 3: Ask how many times the participant has injected drugs with the named index in the past 3 months and record the total number.


Item 4: Ask if the participant has had sex with the named index. If the participant answers “no”, that is the end of this form.

Item 4a: If the participant has had sex with the named index, record how many times they have had sex in the last 3 months.

Add the responses together for Items 3 and 4a. If the total is 0 or if both are not completed, the participant does not qualify as having an injection drug or sexual relationship with the index and is ineligible. NOTE: In order for the potential network member to be eligible to continue the screening process, EITHER item 3 OR item 4a must have a response of 1 or greater. If item 3 is 0 and item 4a is left blank due to skip pattern instructions, the participant is not eligible.

Figure 6-4
Member Screening Assessment (MS-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)
Member Screening Assessment (MS-1)



HPTN 037 IDU Networks (095) MS-1 (021)

Page 1 of 1

Participant ID

Site Number	Participant Number	Chk	Network ID	Member						

Form Completion Date

<i>dd</i>	<i>MMM</i>	<i>yy</i>

Member Screening Assessment

1. Are you at least 18 years of age? yes no → **If no, participant is ineligible.**
2. Have you ever injected drugs?..... yes no → **If no, read instruction before item 3, then go to item 4.**
- 2a. In the last 3 months (that is, since _____), how many times total have you injected drugs?

Read to participant: The following question(s) is/are about your relationship with *(insert name of index)*, the person who told you about our study.

3. In the last 3 months (that is, since _____), how many times have you injected drugs with *(insert name of index)*?
4. Have you ever had sex with *(insert name of index)*? yes no → **If no, end of form.**
- 4a. In the last 3 months (that is, since _____), how many times have you had sex with *(insert name of index)*?

→ **If 0 or not completed for both, participant is ineligible.**

05-DEC-02

/hivnet/forms/PTN_037/forms/screening_member.fm

SAMPLE—English

0 1

Language Staff Initials / Date

6.14.4 Index Eligibility Checklist (IC-1–IC-2)

Description and Purpose

This form reviews the information gathered from the index participant and compares it to the study eligibility criteria. The form also documents provision and signing of screening and study informed consent.

For index participants to meet study eligibility criteria, all inclusion section boxes must be marked ‘yes’, and all exclusion section boxes marked ‘no’. This form is for staff purposes only; the items on this form are NOT read to the participant.

Form-specific Instructions

This form is completed by study staff. Complete all items for all index participants who are eligible for the study.

This form is due at the Enrollment/Randomization visit from participants who are randomized and enrolled, however most items may be completed after the Screening visits. Many items on this form are answered based on responses recorded on other study documents, as follows:

- Item 1 - Demographics form
- Item 3,4, and 7 - Index Screening Assessment form
- Item 5 - Screening HIV Status form

All other items are answered based on study staff assessment of the participant.

Item 2: Confirm that the participant has provided both screening and study informed consent. Record the date that both consent forms were signed.

Item 4: To confirm that those participants who report a history of methadone maintenance treatment have been out of treatment for at least 3 months, and have relapsed (injected 12 or more times in the last 3 months). NOTE: If the participant has never been in methadone maintenance treatment, mark “yes” for this item.

Items 6 and 7: To confirm and record that the participant has identified and attempted to recruit at least 2 eligible network members. Item 7 then indicates recruitment of at least 1 eligible network member. Note that the minimum network size is 1; larger networks are more desirable.

If all items (1-7) in the inclusion section are marked “yes”, continue and complete the exclusion section (8-11). If any items are marked “no”, the participant is ineligible. Document the reason for ineligibility in a study note. Continue and complete the exclusion section (8-11).

Item 9: If site staff determine that the participant could not provide informed consent or should not be enrolled because of a psychological disturbance or cognitive disorder, mark “yes”.

Item 10: If site staff determine that any other condition will prevent obtaining informed consent or may make participation in the study unsafe, complicate interpretation of outcome data, or interfere with study objectives, mark “yes”.

Item 11: Answer this item based on local site records.

Figure 6-6
Index Eligibility Checklist (IC-1–IC-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)	Index Eligibility Checklist (IC-2)						
HPTN 037 IDU Networks (095) IC-2 (014)							
Page 2 of 2							
Participant ID							
Index Eligibility Checklist							
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>							
Site Number Participant Number Chk Network ID Member							
Exclusion							
8. Is the participant concurrently enrolled or has he or she been previously enrolled in another HIV behavioral or biomedical prevention study in the last 6 months? <i>See item 7, IS-2.</i>	yes no <input type="checkbox"/> <input type="checkbox"/>						
9. Does the participant have any obvious psychological disturbance or cognitive impairments that would limit his or her ability to understand study procedures (as determined by clinic staff)?	<input type="checkbox"/> <input type="checkbox"/>						
10. Does the participant have, in the opinion of the investigator, any other condition that would make participation in the study unsafe or otherwise interfere with study objectives?	<input type="checkbox"/> <input type="checkbox"/>						
11. Is the participant enrolled as a network member or index participant in another HPTN 037 study network?	<input type="checkbox"/> <input type="checkbox"/>						
	→ <i>If yes to any, participant is ineligible.</i>						
<table style="width: 100%; border: none;"> <tr> <td style="width: 30%; border: none;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 26-NOV-03 <small>/hivnet/forms/PTN_037/forms/elig_checklist_index.fm</small> </td> <td style="width: 30%; border: none; text-align: center;"> SAMPLE—English </td> <td style="width: 20%; border: none; text-align: center;"> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">0</td> <td style="padding: 2px 5px;">1</td> </tr> </table> Language </td> <td style="width: 20%; border: none; text-align: center;"> _____ Staff Initials / Date </td> </tr> </table>		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 26-NOV-03 <small>/hivnet/forms/PTN_037/forms/elig_checklist_index.fm</small>	SAMPLE —English	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">0</td> <td style="padding: 2px 5px;">1</td> </tr> </table> Language	0	1	_____ Staff Initials / Date
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 26-NOV-03 <small>/hivnet/forms/PTN_037/forms/elig_checklist_index.fm</small>	SAMPLE —English	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">0</td> <td style="padding: 2px 5px;">1</td> </tr> </table> Language	0	1	_____ Staff Initials / Date		
0	1						

6.14.5 Member Eligibility Checklist (MC-1)

Description and Purpose

This form reviews the information gathered from the network member and compares it to the study eligibility criteria. The form also documents provision and signing of study informed consent.

For a network member to meet study eligibility criteria, all inclusion section boxes must be marked 'yes', and all exclusion section boxes marked 'no'. This form is for staff purposes only; the items on this form are NOT read to the participant.

Form-specific Instructions

This form is completed by study staff. Complete all items for each network member participant who is eligible for the study.

Several items on this form are answered based on responses recorded on other study documents, as follows:

- Item 1 - Demographics form
- Item 3 - Member Screening Assessment form

All other items are answered based on study staff assessment of the participant.

Item 2: Answer this question based on local screening and enrollment data.

Item 4: Confirm that the participant has provided study informed consent. Record the date that the consent form was signed.

If all items (1-4a) in the inclusion section are marked "yes", continue and complete the exclusion section (5-7). If any items are marked "no", the participant is ineligible. Document the reason for ineligibility in a study note. Continue and complete the exclusion section (5-7).

Item 5: If site staff determine that the participant could not provide informed consent or should not be enrolled because of a psychological disturbance or cognitive disorder, mark "yes".

Item 6: If site staff determine that any other condition will prevent obtaining informed consent or may make participation in the study unsafe, or interfere with study objectives, mark "yes".


Item 7: Answer this question based on local enrollment data.

If all items in the exclusion section are marked "no", the participant is eligible for the study. If any items (5-7) are marked "yes", the participant is ineligible. Document the reason for ineligibility in a study note.

Figure 6-7
Member Eligibility Checklist (MC-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Member Eligibility Checklist (MC-1)



HPTN 037 IDU Networks (095) MC-1 (022)

Page 1 of 1

Participant ID

Site Number			Participant Number						Chk	Network ID				Member					

Form Completion Date

<i>dd</i>		<i>MMM</i>		<i>yy</i>	

Inclusion

1. Is the participant of legal age to provide written informed consent for research?
See item 1, DM-1. *yes* *no*
2. Has the participant been recruited for the study by an eligible index participant? *yes* *no*
3. Does the participant report having injected drugs with and/or having had sex with the relevant index participant within 3 months prior to screening? *See items 3 and 4, MS-1.* *yes* *no*
4. Did the participant provide written informed consent for study participation? *yes* *no*

4a. Date study consent signed:

--	--

dd

--	--	--

MMM

--	--

yy

Exclusion

5. Does the participant have any obvious psychological disturbance or cognitive impairments that would limit his or her ability to understand study procedures (as determined by clinic staff)? *yes* *no*
6. Does the participant have, in the opinion of the investigator, any other condition that would make participation in the study unsafe or otherwise interfere with study objectives? *yes* *no*
7. Is the participant enrolled as a network member or index participant in another HPTN 037 study network? *yes* *no*

05-DEC-02 **SAMPLE**—English

0	1
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 Language _____ Staff Initials / Date

/hivnet/forms/PTN_037/forms/elig_checklist_member.fm

If no to any, participant is ineligible.

If yes to any, participant is ineligible.

6.14.6 Screening HIV Status (SS-1)

Description and Purpose

This form documents a potential Index or Member's HIV status at screening visits. This form is to be used only at screening visits.

Form-specific Instructions

Item 1: Record the date of initial specimen collection. This is the date that the first blood specimen was drawn at a screening visit. The date of the first specimen is recorded, even if additional specimens are required to determine HIV status.

Item 2: Record final HIV status, as determined by local lab and study staff.

Figure 6-8
 Screening HIV Status (SS-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Screening HIV Status (SS-1)					
HPTN 037 IDU Networks (095) SS-1 (051)		Page 1 of 1					
Participant ID		Screening HIV Status					
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Network ID</small>	<small>Member</small>	<small>dd</small>	<small>MMM</small>	<small>yy</small>
				<small>dd</small> <small>MMM</small> <small>yy</small>			
1. Date of initial HIV specimen collection:		<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>			
2. Participant's HIV status:		<small>negative</small> <input type="checkbox"/>	<small>positive</small> <input type="checkbox"/>				
						<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02	
				SAMPLE —English		<input type="text"/> <input type="text"/>	
				<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<small>Language</small> <small>Staff Initials / Date</small>	
						<input type="text"/> <input type="text"/>	
						<input type="text"/> <input type="text"/>	

6.14.7 Risk Assessment (RA-1–RA-7)

Description and Purpose

The Risk Assessment questionnaire collects information on housing, alcohol use, drug use, and sexual behavior. This form is administered at the screening visit to those participants found to be eligible based on the Eligibility (Index or Member) Checklist.

This form is administered to participants at all sites, though specific instructions indicate those questions not applicable for participants in Thailand.

Enrolled participants are also administered the Risk Assessment at month 6, 12, and 18 pre-test follow-up visits, and at month 24 and 30 pre-test follow-up visits when applicable.

NOTE: Items on the Risk Assessment must be completed during the pre-test visit, before HIV counseling and testing. Ask the items in order, following the instructions below and on the form. Follow skip pattern instructions carefully. Skip items as indicated. Use probes and clarifications as needed to get participants to respond to each item. If a response is indicated, but the participant refuses to answer, line through the item and write “REF” beside the item and add interviewer initials and the date. If the participant can’t answer the item because the answer is not known, line through the item and write “DK” beside the item and add interviewer initials and the date. Before the participant leaves the room for the next part of the visit, be sure that all parts of the Risk Assessment have been completed, and that no items are left blank unless the instructions and/or skip patterns indicate to leave those item blank. Items that are left blank which should have been completed CANNOT be corrected after that visit, so it is important to be sure that the Risk Assessment is completed during the appropriate visit.

Form-specific Instructions

Read out loud to the participant the section marked “Read to participant” before asking Item 1. It may also be helpful to have a calendar available to assist the participant in thinking about the time frame of the last 6 months for these questions.

Item 1 and 1a: Record if time has been spent in jail or prison. If “yes”, record the number of days imprisoned.

Item 2 and 2a: Record if time has been spent in residential or inpatient treatment. If “yes”, record the number of days imprisoned.

Item 3: Record if the participant has been homeless or lived in a non-traditional place. For Philadelphia, this may mean on the street, in a park, or in an abandoned building. For Thailand, this may mean living in a temple or at no fixed address. The intent of the question is to ascertain homelessness.

Read out loud to the participant the section marked “Read to participant” before asking Item 4.

Item 4: Use response card # 1 to help the participant identify his or her weekly drinking frequency. Non-drinkers go to Item 7.

Item 5: Record the average number of drinks per day. One drink refers to one shot of alcohol or one cocktail (mixed drink), one glass of wine, or one bottle or can of beer.

Item 6: Use response card # 2 to help the participant identify the frequency of his or her drinking to get or stay drunk.

Read out loud to the participant the section marked “Read to participant” before asking Item 7.

Item 7: Note that the time frame is ‘in the last month’. Items 7a and 7b are for Philadelphia only. For each item, mark yes or no. If “yes”, record the number of days that the drug was used in the last month. If “no”, go to the introduction on page 3.

Item 8: Note that the time frame has changed to ‘in the last 6 months’. For participants who report involvement in a treatment program, mark all applicable programs.

Item 8a: “Drug-free treatment” means treatment without pharmacological intervention (i.e., Methadone).

Read out loud to the participant the section marked “Read to participant” before asking Item 9.

Item 9: Note that the time frame is ‘in the last 6 months’ for Item 9 and ‘in the last month’ for Item 9a. Observe the skip patterns for non-injection or infrequent injection drug users.

Item 10: Note that the time frame is ‘in the last month’. Item 10b is for Philadelphia only. For each item, mark yes or no. In item 10a, “heroin by itself” means heroin NOT mixed with any other drug.

Item 11: Record the number of days.

Item 12: Record the number of times.

Item 13: For each item, record the number of times. Display response cards # 4 and 5 to assist the participant by presenting a picture of frontloading and backloading practices.

Item 14: Needle or syringes are passed to someone else. If ‘yes’, also record how many times and with how many different people in the last month.

Item 15: Needle or syringe use is after someone else. Record how many times and with how many different people in the last month.

Item 16: Needle or syringe use is after someone else known to be HIV-positive.

Item 17: Injection is done with others.

Items 18 and 19: Use response card # 2 to identify the response categories. For each item, mark the response time that best mirrors the participant’s frequency of that behavior. NOTE: In items 19a and 22a, “Needle exchange” refers to a program of exchanging used needles or syringes for new needles or syringes.

Items 20 and 21: Needle cleaning is before or after injecting. Using the categories on response card # 2 to assist the participant, indicate frequency of cleaning before injecting in Item 20a and after injecting in Item 20b. Cleaning method is recorded in Item 21. Participants who did not clean their needles go to Item 22.

Item 22: Rate the frequency per response using card #2 for needle disposal in the last month at the places listed. Use the “other” category to note any additional means of disposal.

IMPORTANT NOTE REGARDING ITEMS 21 and 22: The proper way to administer these items is to read the partial question (21 and 22) and then complete each question with items 21a-21d or items 22a-22d. After each full item is read out loud, allow the participant to choose his or her response from response card # 2, and mark the appropriate box on the form. For example:

INTERVIEWER: “In a typical week, how often do you clean your needles with bleach?” [Interviewer shows participant response card #2].

PARTICIPANT: “Less than half the time.”

[Interviewer marks the appropriate box on the form]

INTERVIEWER: “In a typical week, how often do you clean your needles with alcohol?” [Interviewer shows participant response card #2].

PARTICIPANT: “Rarely or never.”

[Interviewer marks the appropriate box on the form]

... and so on.

For item 21d (other, specify), ask “Is there any other way you clean your needle?” If the participant describes another way of cleaning, ask “In a typical week, how often do you clean your needles [complete with what the participant just said].”

For example:

INTERVIEWER: “Is there any other way you clean your needle?”

PARTICIPANT: “Yes, sometimes I use hydrogen peroxide.”

INTERVIEWER: “In a typical week, how often do you clean your needles with hydrogen peroxide?” [Interviewer shows response card #2].

PARTICIPANT: “Less than half the time.”

[Interviewer marks the appropriate box on the form]

IMPORTANT: If the participant does NOT report any other way of cleaning needles, indicate this by drawing a single line through all the response boxes to the right of “other specify” and add interviewer initials and the date.

Administer item 22 in the same way.

For item 22f (other, specify), ask “Is there any other place you have disposed of your used needles?” If the participant describes another disposal place, ask “In the last month, how often did you dispose your used needles [complete with what the participant just said].”

For example:

INTERVIEWER: “Is there any other way you dispose your used needles?”

PARTICIPANT: “Yes, sometimes I bury them in a field.”

INTERVIEWER: “In the last month, how often did you dispose of your used needles by burying them in a field?” [Interviewer shows response card #2].

PARTICIPANT: “Less than half the time.”

[Interviewer marks the appropriate box on the form]

Item 23: Addresses the disabling of used needle or syringes. Use response card #2.

Item 24: Addresses needle or syringe disposal in any way to prevent others from coming in contact with the tip. Use response card #2.

Item 25: Mark “yes” or “no” for each item describing the participant’s injection practice the last time that they injected.

Item 26: Record the number of days since the participant last injected. If he or she injected today, record zero.

Read out loud to the participant the section marked “Read to participant” before asking Item 27.

Item 27: If the participant reports no vaginal or anal sex in the last month, this is the end of the form.

Item 28 and 29: These items are asked of all participants and a response is expected for both items. Participants may report both male and female partners. ‘Zero’ is also an acceptable response.

Item 30: If the participant has more than one relationship considered to be primary, ask about the partner to whom the participant is most committed. If the participant is equally committed, ask about the partner with whom the participant has been involved with the longest. If no primary sex partner is reported, go to Item 32.

Item 31 and 32: Record the number of times that the participant had sex with his or her primary partner and then with a non-primary partner. For each, if > 0, record the number of times while using a condom.

Item 33: Record the number of unique sex partners that the participant paid or gave drugs to in exchange for sex. If the participant paid 1 partner for three different sexual encounters, count this as 1 partner.

Item 34: Record the number of unique sex partners that paid or gave drugs to the participant in exchange for sex. If the participant was paid by 1 partner for three different sexual encounters, count this as 1 partner.

Figure 6-9
Risk Assessment (RA-1–RA-7)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

HPTN 037 IDU Networks (095) RA-1 (121)

Risk Assessment (RA-1)

Visit Code . 1

Page 1 of 7

Participant ID

- -

Site Number Participant Number Chk

Risk Assessment

-

Network ID Member

Do not use at follow-up visits

Form Completion Date

dd MMM yy

HOUSING

Read to participant: The next few questions are about where you live or stay. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.

1. In the last 6 months, did you spend time in jail or prison? *yes* *no* → **If no, go to item 2.**
 - 1a. How many days total did you spend in these places? # of days
2. In the last 6 months, did you spend time in residential or inpatient treatment? *yes* *no* → **If no, go to item 3.**
 - 2a. How many days total did you spend in these places? # of days
3. In the last 6 months, did you live on the street, in a car, in a park, or in an abandoned building? *yes* *no*

ALCOHOL USE

Read to participant: The next few questions are about alcohol use. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.

4. Using this card, tell me, on average, how often do you have a drink? *Show Card #1.*

<i>never</i>	<i>less than once per week</i>	<i>1–2 days per week</i>	<i>3–4 days per week</i>	<i>5–6 days per week</i>	<i>every day</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

→ **If never, go to item 7 on page 2.**
5. On days that you drink, how many drinks do you usually have? # of drinks
6. When you drink alcohol, how often do you drink enough to get drunk or stay drunk? *Show Card #2.*

<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

05-DEC-02

/hivnet/forms/PTN_037/forms/risk_assessment.fm

SAMPLE—English

01

Language Staff Initials / Date

Figure 6-10
Risk Assessment (RA-1–RA-7)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Risk Assessment (RA-2)	
		Visit Code <input type="text"/> . <input type="text"/>	1
HPTN 037 IDU Networks (095) RA-2 (122)		Page 2 of 7	

<p>Participant ID</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> <td style="border: 1px solid black; width: 15%; text-align: center;"> </td> </tr> <tr> <td style="text-align: center; font-size: small;">Site Number</td> <td style="text-align: center; font-size: small;">Participant Number</td> <td style="text-align: center; font-size: small;">Chk</td> <td colspan="2" style="text-align: center; font-size: small;">Network ID</td> <td colspan="2" style="text-align: center; font-size: small;">Member</td> <td colspan="5"></td> </tr> </table>													Site Number	Participant Number	Chk	Network ID		Member							<p style="text-align: center;">Risk Assessment</p> <p style="text-align: center; font-size: small;">Do not use at follow-up visits</p>
Site Number	Participant Number	Chk	Network ID		Member																				

NON-INJECTION DRUG USE

Read to participant: The next few questions are about non-injection drug use. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.

7. In the last month did you...

	yes	no	
7a. smoke crack or rock cocaine?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>
7b. snort or sniff cocaine?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>
7c. snort or take amphetamines such as speed or crystal?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>
7d. smoke amphetamines?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>
7e. smoke, snort, or take heroin, opium, or other opiates?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>
7f. take (eat or pop) benzodiazepenes, downers, or sedatives (such as Valium, Dalmane, Xanax, or Rohypnol)?	<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>

If yes, how many days in the last month?

8. In the last 6 months, did you participate in any type of drug treatment program, drug counseling, or drug detoxification?

	yes	no	
	<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If no, go to introduction before item 9 on page 3.</i>

8a. What types of treatment did you receive? *Mark all that apply.*

- inpatient or residential treatment/therapeutic community
- outpatient or drug-free treatment
- methadone maintenance → 8a1. How many weeks on methadone?
- recovery house
- detoxification
- Narcotics Anonymous, Cocaine Anonymous, or Alcoholics Anonymous
- religious program, specify: _____
- herbal program, specify: _____
- other, specify: _____

of weeks

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02 <small>/hivnet/forms/PTN_037/forms/risk_assessment.fm</small>	SAMPLE —English	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; text-align: center;">0</td> <td style="width: 20px; text-align: center;">1</td> </tr> </table> <small>Language</small>	0	1	<small>Staff Initials / Date</small>
0	1				

Figure 6-11
Risk Assessment (RA-1–RA-7)


Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Risk Assessment (RA-3)
		Visit Code <input type="text"/> . <input type="text"/>
HPTN 037 IDU Networks (095) RA-3 (123)		1
Page 3 of 7		
Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>		Risk Assessment <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <small>Network ID Member</small> <small>Do not use at follow-up visits</small>
<p>INJECTION DRUG USE</p> <p><i>Read to participant:</i> The next few questions are about injection drug use. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.</p>		
9. In the last 6 months, did you use a needle to inject any drugs under your skin or into a vein?	yes <input type="checkbox"/>	no <input type="checkbox"/> If no, go to item 27 on page 7.
9a. Did you do this in the last month?	<input type="checkbox"/>	<input type="checkbox"/> If no, go to item 25 on page 6.
10. In the last month, did you inject...	yes	no
10a. heroin by itself?	<input type="checkbox"/>	<input type="checkbox"/>
10b. cocaine by itself?	<input type="checkbox"/>	<input type="checkbox"/>
10c. heroin mixed with cocaine (speedball)?	<input type="checkbox"/>	<input type="checkbox"/>
10d. heroin mixed with amphetamines?	<input type="checkbox"/>	<input type="checkbox"/>
10e. amphetamines?	<input type="checkbox"/>	<input type="checkbox"/>
10f. other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
11. In the last month, on how many days did you inject?	<input type="text"/> <input type="text"/>	# of days
12. On days that you inject, how many times a day do you usually inject?	<input type="text"/> <input type="text"/>	# of times
13. In the last month, how many times did you...	# of times	
13a. use rinse water that others had used?	<input type="text"/> <input type="text"/> <input type="text"/>	
13b. use a cooker that others had used?	<input type="text"/> <input type="text"/> <input type="text"/>	
13c. use cotton that others had used?	<input type="text"/> <input type="text"/> <input type="text"/>	
13d. inject drugs that were frontloaded or backloaded into the syringe or needle that you used? <i>Show Cards #3 and #4.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	
13e. use a needle that others had discarded?	<input type="text"/> <input type="text"/> <input type="text"/>	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02	SAMPLE—English	01 Language Staff Initials / Date
<small>/hivnet/forms/PTN_037/forms/risk_assessment.fm</small>		

Figure 6-12
Risk Assessment (RA-1–RA-7)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Risk Assessment (RA-4)

HPTN 037 IDU Networks (095) RA-4 (124)

Visit Code .

1

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Participant ID

Site Number Participant Number Chk

Network ID Member

Do not use at follow-up visits

Risk Assessment

14. In the last month, did you ever even once pass on a needle or syringe to someone else after you used it? yes no → **If no, go to item 15.**

14a. How many times did you do this in the last month? # of times

14b. With how many different people did you do this in the last month? # of people

15. In the last month, did you ever even once use a needle or syringe after someone else used it? yes no → **If no, go to item 17.**

15a. How many times did you do this during the last month? # of times

15b. With how many different people did you do this in the last month? # of people

16. In the last month, did you ever use a needle or syringe after someone that you know is HIV-positive used it? yes no don't know

17. In the last month, did you ever inject drugs **with others** in a shooting gallery, in an abandoned building, in a car, or in a public park or public restroom? yes no

18. In the last month, how often did you inject drugs... *Show Card #2.*

	<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
18a. by yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18b. with people you know well?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18c. with people you don't know well?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. In the last month, how often did you get your needles new from a... *Show Card #2.*

	<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
19a. needle exchange?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19b. drugstore/pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19c. needle seller?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19d. diabetic?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Language Staff Initials / Date


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HPTN 037 SSP Version 2.0

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02 JUN 2004

Figure 6-13
Risk Assessment (RA-1–RA-7)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Risk Assessment (RA-5)				
										Visit Code <input type="text"/> . <input type="text"/>				
HPTN 037 IDU Networks (095) RA-5 (125)										<div style="border: 1px solid black; padding: 2px; display: inline-block;">1</div>				
										Page 5 of 7				
Risk Assessment														
Participant ID														
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<div style="border: 1px dashed black; padding: 2px; display: inline-block;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> </div>													
Site Number Participant Number Chk			Network ID Member											
										Do not use at follow-up visits				
20. In the last month, did you ever clean your needle either before or after injecting?										yes	no			
										<input type="checkbox"/>	<input type="checkbox"/> → If no, go to item 22.			
										<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
20a. In a typical week, how often do you clean your needle before injecting? Show Card #2.										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20b. In a typical week, how often do you clean your needle after injecting? Show Card #2.										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. In a typical week, how often do you clean your needle... Show Card #2.										<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
21a. with bleach?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21b. with alcohol?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21c. with water?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21d. other, specify:										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

22. I'm going to read you a list of places where you may have disposed of your used needles. In the last month, how often did you dispose of your used needles... Show card #2.										<i>always/ almost always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>rarely or never</i>
22a. at a needle exchange?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22b. in the trash?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22c. in a toilet?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22d. on the street or in a park or building or other public place?										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
										<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02	SAMPLE—English		<div style="border: 1px solid black; padding: 2px; display: inline-block;">01</div>	_____
										/hivnet/forms/PTN_037/forms/risk_assessment.fm		Language Staff Initials / Date		

Figure 6-14
Risk Assessment (RA-1–RA-7)



Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Risk Assessment (RA-6)																			
										Visit Code <input type="text"/> . <input type="text"/>																			
HPTN 037 IDU Networks (095) RA-6 (126)										1																			
										Page 6 of 7																			
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Site Number	Participant Number						Chk	Network ID			Member																		
Do not use at follow-up visits																													
<p>22. Needle disposal, continued</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 10%; text-align: center;">always/ almost always</th> <th style="width: 10%; text-align: center;">more than half the time</th> <th style="width: 10%; text-align: center;">about half the time</th> <th style="width: 10%; text-align: center;">less than half the time</th> <th style="width: 10%; text-align: center;">rarely or never</th> </tr> </thead> <tbody> <tr> <td>22e. by giving them to someone else for disposal?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>22f. other, specify:.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>													always/ almost always	more than half the time	about half the time	less than half the time	rarely or never	22e. by giving them to someone else for disposal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22f. other, specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	always/ almost always	more than half the time	about half the time	less than half the time	rarely or never																								
22e. by giving them to someone else for disposal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																								
22f. other, specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																								
<p>23. In the last month, when you disposed of your used needles, how often did you disable the needle or syringe so that it could not be used again (for example, you broke off the tip)? <i>Show card #2.</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 15%; text-align: center;">always/ almost always</th> <th style="width: 15%; text-align: center;">more than half the time</th> <th style="width: 15%; text-align: center;">about half the time</th> <th style="width: 15%; text-align: center;">less than half the time</th> <th style="width: 15%; text-align: center;">rarely or never</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>													always/ almost always	more than half the time	about half the time	less than half the time	rarely or never		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	always/ almost always	more than half the time	about half the time	less than half the time	rarely or never																								
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																								
<p>24. In the last month, when you disposed of your used needles, how often did you dispose of them in a way such that someone else wouldn't get stuck with the point (for example, you re-capped the needle or you put it in a sharps container or some other rigid container like a covered can or jar)? <i>Show card #2.</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 15%; text-align: center;">always/ almost always</th> <th style="width: 15%; text-align: center;">more than half the time</th> <th style="width: 15%; text-align: center;">about half the time</th> <th style="width: 15%; text-align: center;">less than half the time</th> <th style="width: 15%; text-align: center;">rarely or never</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>													always/ almost always	more than half the time	about half the time	less than half the time	rarely or never		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	always/ almost always	more than half the time	about half the time	less than half the time	rarely or never																								
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																								
<p>25. The last time you injected, did you...</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 10%; text-align: center;">yes</th> <th style="width: 10%; text-align: center;">no</th> </tr> </thead> <tbody> <tr> <td>25a. clean the needle before you injected?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>25b. use a new needle?.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>25c. clean the needle after you injected?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>25d. share the needle? By share I mean you used the needle after someone or you passed on the needle to someone else after you used it.</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>													yes	no	25a. clean the needle before you injected?	<input type="checkbox"/>	<input type="checkbox"/>	25b. use a new needle?.....	<input type="checkbox"/>	<input type="checkbox"/>	25c. clean the needle after you injected?	<input type="checkbox"/>	<input type="checkbox"/>	25d. share the needle? By share I mean you used the needle after someone or you passed on the needle to someone else after you used it.	<input type="checkbox"/>	<input type="checkbox"/>			
	yes	no																											
25a. clean the needle before you injected?	<input type="checkbox"/>	<input type="checkbox"/>																											
25b. use a new needle?.....	<input type="checkbox"/>	<input type="checkbox"/>																											
25c. clean the needle after you injected?	<input type="checkbox"/>	<input type="checkbox"/>																											
25d. share the needle? By share I mean you used the needle after someone or you passed on the needle to someone else after you used it.	<input type="checkbox"/>	<input type="checkbox"/>																											
<p>26. How many days ago did you last inject?.....</p>										<input type="text"/> <input type="text"/> <input type="text"/> # of days																			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02	SAMPLE—English					<input type="text"/> <input type="text"/>		Language		Staff Initials / Date																			
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Figure 6-15
Risk Assessment (RA-1–RA-7)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Risk Assessment (RA-7)																																												
 HPTN 037 IDU Networks (095) RA-7 (127)		Visit Code <input type="text"/> . <input type="text"/> 1																																												
Page 7 of 7																																														
Participant ID <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> </tr> <tr> <td style="text-align: center;">Site Number</td> <td colspan="4" style="text-align: center;">Participant Number</td> <td style="text-align: center;">Chk</td> <td colspan="2" style="text-align: center;">Network ID</td> <td colspan="4" style="text-align: center;">Member</td> </tr> </table>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Site Number	Participant Number				Chk	Network ID		Member				Risk Assessment <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> </tr> <tr> <td colspan="2" style="text-align: center;">Network ID</td> <td colspan="8" style="text-align: center;">Member</td> </tr> </table> Do not use at follow-up visits	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Network ID		Member							
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Site Number	Participant Number				Chk	Network ID		Member																																						
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Network ID		Member																																												
<p>SEXUAL BEHAVIOR QUESTIONS</p> <p><i>Read to participant:</i> The next few questions are about sexual behavior. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.</p>																																														
27. In the last month, did you have vaginal or anal sex?	yes <input type="checkbox"/>	no <input type="checkbox"/>	→ If no, end of form.																																											
28. In the last month, how many different female sex partners did you have?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
29. In the last month, how many different male sex partners did you have?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
30. Do you have a primary sex partner such as a husband/wife or boyfriend/girlfriend?	yes <input type="checkbox"/>	no <input type="checkbox"/>	→ If no, go to item 32.																																											
31. In the last week, how many times did you have vaginal or anal sex with your primary sex partner?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
31a. How many of these times did you (or your partner) use a condom?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
32. In the last week, how many times did you have vaginal or anal sex with someone other than a primary sex partner?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
32a. How many of these times did you (or your partner) use a condom?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
33. In the last month, how many sex partners did you give money or drugs in exchange for sex?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
34. In the last month, how many sex partners gave you money or drugs in exchange for sex?	<input type="text"/> <input type="text"/> <input type="text"/>																																													
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02		SAMPLE—English	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; text-align: center;">0</td> <td style="width: 20px; text-align: center;">1</td> </tr> </table> Language	0	1																																									
0	1																																													
/hivnet/forms/PTN_037/forms/risk_assessment.fm		Staff Initials / Date																																												

6.14.8 Randomization/Enrollment (RE-1)

Description and Purpose

The Randomization/Enrollment form documents final study eligibility, confirms the date of HIV specimen collection within 60 days prior to randomization, and details the randomization of index participants. This form is completed for all Index participants who are randomized and enrolled at each randomization/enrollment session, and for each of their eligible network members.

NOTE: This form should be completed AFTER randomization, and transmitted along with the screening forms for each participant enrolled.

Form-specific Instructions

Item 1: Refer to form IC-1 or MC-1 to determine that the participant is eligible to enroll in the study.

Item 2: Refer to SS-1. If the participant did not return for enrollment within 60 days of the specimen collection date, he or she is not eligible to enroll. The screening process and sample collection however may be repeated. Refer to the SSP for re-screening procedures.

Item3: Indicate whether or not the index participant was randomized. If yes, record the date of index randomization in Item 3a.

Item 3b: Record the randomization sequence number for index participants only. Right justify this numerical value and fill in any leading boxes with zeros.

6.14.9 Follow-up Local Lab Results (LL-1)

Description and Purpose

HIV antibody test results at all post-enrollment study visits are recorded on this form. This form is completed at all semi-annual follow-up visits, and at other visits if interim HIV testing is performed.

Form-specific Instructions

“Specimen Collection Date” refers to the date on which blood was drawn for HIV testing, not the date on which the lab provided results or the date results are given.

Mark the “Not Done/Not Collected” box only if a specimen was not obtained, or the lab test was not performed on the sample for some reason (for example, the sample was too small for HIV testing). Use the “Comments” area at the bottom of the form to explain why a sample was not collected or the test was not done.

As this form is expected a all semi-annual visits, there may be participants who enroll HIV-positive or who tested positive at a previous visit. Complete the LL-1 for these individuals as follows:

- Mark the “Not Done/Not Collected” box in front of Item 1
- In the comments section on the form, write: “Tested HIV-positive at previous visit”
- Submit this form to SCHARP along with the other forms expected at this visit

The form allows for the following confirmatory testing for HIV positive EIA samples: A Western Blot/IFA is performed on the first sample and, if positive, a Western Blot/IFA is performed on a second sample, usually collected at the post-test visit. Item 4 (sample 3) is provided to accommodate repeatedly indeterminate results. Submit the form to DataFax after the confirmatory testing is complete.

Refer to protocol appendix for the HIV seroconversion testing algorithm.

Figure 6-17
Follow-up Local Lab Results (LL-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Follow-up Local Lab Results (LL-1)					
HPTN 037 IDU Networks (095) LL-1 (151)		Visit Code <input type="text"/> . <input type="text"/>					
Page 1 of 1							
Participant ID <input type="text"/> - <input type="text"/> - <input type="text"/> <small>Site Number Participant Number Chk</small>		Follow-up Local Lab Results					
<p>SAMPLE 1</p> <p>Not Done/ Not Collected <input type="checkbox"/> Specimen Collection Date</p> <p> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small> </p> <p>1. HIV EIA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>negative positive indeterminate</small> If negative, end of form. ← </p> <p>2. Western Blot/IFA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>negative positive indeterminate</small> If negative, end of form. ← </p>							
<p>SAMPLE 2</p> <p>Not Done/ Not Collected <input type="checkbox"/> Specimen Collection Date</p> <p> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small> </p> <p>3. Western Blot/IFA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>negative positive indeterminate</small> If negative or positive, end of form. ← </p>							
<p>SAMPLE 3</p> <p>Not Done/ Not Collected <input type="checkbox"/> Specimen Collection Date</p> <p> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small> </p> <p>4. Western Blot/IFA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>negative positive indeterminate</small> If negative or positive, end of form. ← </p>							
Comments: _____ _____ _____ _____							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02 <small>/hivnet/forms/PTN_037/forms/local_lab_results.fm</small>		SAMPLE—English					
		<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">0</td> <td style="padding: 2px 5px;">1</td> </tr> <tr> <td colspan="2" style="text-align: center; font-size: 8px;">Language</td> </tr> </table> Staff Initials / Date _____		0	1	Language	
0	1						
Language							

6.14.10 Post-test Visit (PV-1)

Description and Purpose


This form documents post-test visit completion at screening for all study participants per study protocol. Complete this form **ONLY** at screening. Do **NOT** complete this form at follow up visits.

Form-specific Instructions

Item 1: Indicate whether participant received their HIV test results.

Item 2: Indicate whether participant received HIV post-test and risk reduction counseling as specified in the protocol.

Figure 6-18
Post-test Visit (PV-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Post-test Visit (PV-1)			
										Visit Code <input type="text"/> . <input type="text"/>			
HPTN 037 IDU Networks (095) PV-1 (191)										<input style="width: 20px; height: 20px; text-align: center; border: 1px solid black;" type="text"/>			
										Page 1 of 1			
Participant ID					Post-test Visit					Form Completion Date			
<input type="text"/> <input type="text"/> <input type="text"/> -		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> -			<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>			
Site Number		Participant Number			Chk	Network ID		Member		dd	MMM	yy	
<p>Instructions: This form to be completed only at Screening.</p>													
1. Did the participant receive HIV test results?										yes	no		
										<input type="checkbox"/>	<input type="checkbox"/>		
2. Did the participant receive HIV post-test and risk-reduction counseling?										yes	no		
										<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 06-MAY-04				SAMPLE—English				<input style="width: 20px; height: 20px; text-align: center; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; text-align: center; border: 1px solid black;" type="text"/>		Language		Staff Initials / Date	
/hivnet/forms/PTN_037/forms/post_test_visit.fm													

6.14.11 Intervention Cohort Participant Transfer (IPT-1)

Description and Purpose

This form documents the transfer of a participant from his/her original intervention cohort (based on randomization date) to an alternative cohort. An intervention participant is eligible for a cohort transfer in the event that he/she is unable to successfully attend the initial intervention session for his/her randomization cohort and has not reached the target date of his/her 6-month follow-up visit.

Form-specific Instructions

Confirm that the new cohort intervention (transfer in) begins prior to the target date of the participant's 6-month follow-up visit.

Complete the IPT-1 form when a transferred participant presents for intervention session 1 or 2 with the new intervention cohort.

Item 1: Record the group ID of the participant's original intervention cohort (transfer out) assigned at randomization.

Item 2: Record the group ID of the new/receiving intervention cohort (transfer in).

Item 3: Indicate the reason for the participant transfer.

Note that a participant is only eligible for one cohort transfer. Once the participant has been accepted in a new cohort, meaning that he/she has attended either intervention session 1 or 2, the participant remains in that cohort and attendance is tracked accordingly.

Figure 6-19
Intervention Cohort Participant Transfer (IPT-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Intervention Cohort Participant Transfer (IPT-1)											
	HPTN 037 IDU Networks (095)	IPT-1 (451)	Visit Code	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="2"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="0"/>							Page 1 of 1
Participant ID <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <small>Site Number Participant Number Chk</small>			Intervention Cohort Participant Transfer			Form Completion Date <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> / <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> <small>dd MMM yy</small>					
<p>Instructions: Complete this form when an intervention participant transfers to another cohort.</p> <p>1. Group ID of transferring cohort: <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> <small style="margin-left: 40px;">Site Number Group</small></p> <p>2. Group ID of receiving cohort: <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> <small style="margin-left: 40px;">Site Number Group</small> <i>(add to this group)</i></p> <p>3. Reason participant failed to attend original cohort session: <i>Mark only one.</i></p> <p><input type="checkbox"/> incarceration</p> <p><input type="checkbox"/> hospitalization/illness</p> <p><input type="checkbox"/> transportation difficulties</p> <p><input type="checkbox"/> scheduling problem, specify: _____</p> <p><input type="checkbox"/> other, specify: _____</p> <p><input type="checkbox"/> unknown</p>											
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 19-AUG-03 <small>/hivnet/forms/PTN_037/forms/int_cohort_trans.fm</small>				SAMPLE —English			<input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="0"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="1"/>		_____ <small>Staff Initials / Date</small>		

6.14.12 Network Norms (NN-1)

Description and Purpose

This form collects information about the participant's perception of the people that he or she knows or hangs out with. Interviewer administered, this form asks the participant to rank his/her response on a 5-point scale, ranging from "all" to "none," to indicate behaviors evidenced in his or her interactions with others.

Form-specific Instructions

This form is completed by both index and network members at the Screening Visit, and at the 12 and 24 month follow-up visits.

The responses for all questions are listed on response card # 5. Display this card for the participant and explain that he or she will select the response that best describes his or her perception as to friends' thoughts and attitudes for each question. Mark only one response box per item.

NOTE: A "Don't know" response is not provided on the response cards, but is allowed on the DataFax form. If the participant does not know how his or her friends feel about a specific question and thus cannot provide an answer, mark the "don't know" box. This box should be used only as a last resort, rather than as a means to skip or avoid answering questions.

Key concepts for each item are as follows:

Item 1: Shooting with a used needle after someone else.

Item 2: Using a cooker after someone else.

Item 3: Using filter cotton after someone else.

Item 4: Using a shared syringe for frontloading or backloading drugs.

Item 5: Engaging in sex with multiple partners.

Item 6: Always using condoms with primary partners.

Item 7: Approving condom use with primary partners.

Item 8: Always using condoms with non-primary partners.

Item 9: Approving condom use with non-primary partners.

Item 10: Encouraging condom use with primary partners.

Item 11: Encouraging condom use with non-primary partners.

Items 12 and 12a: Exchanging sex for drugs or money. If "yes", always using condoms with paying partners.

Items 13 and 13a: Paying for sex. If "yes", always using condoms with paid partners.

Figure 6-20
Network Norms (NN-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Network Norms (NN-1)

HPTN 037 IDU Networks (095) NN-1 (141) Visit Code .

1

Page 1 of 1

Participant ID

Site Number	Participant Number	Chk	Network ID	Member
-------------	--------------------	-----	------------	--------

Do not use at follow-up visits

Form Completion Date

<i>dd</i>		<i>MMM</i>	
		<i>yy</i>	

Read to participant: These questions ask about your perception of, or what you think about, the people that you know or hang out with. *Show Card #5.*

	<i>all</i>	<i>most</i>	<i>about half</i>	<i>some</i>	<i>none</i>	<i>don't know</i>
1. How many of your friends who shoot drugs use a needle after someone else, without bleaching or cleaning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How many of your friends who shoot drugs use a cooker that someone else has already used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. How many of your friends who shoot drugs use filter cotton that someone else has already used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How many of your friends who shoot drugs use drugs that are frontloaded or backloaded with a shared syringe?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How many of your friends have sex with more than one person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How many of your friends use condoms all the time with their primary partner (husband, wife, boyfriend, or girlfriend)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How many of your friends approve of condom use with a primary partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How many of your friends use condoms all the time with their casual or occasional partners?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How many of your friends approve of condom use with casual or occasional partners?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. How many of your friends encourage you to use condoms with a primary partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. How many of your friends encourage you to use condoms with casual or occasional partners?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. How many of your friends trade sex for money or drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12a. How many of your friends who trade sex use condoms all the time with their paying partners?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How many of your friends pay others for sex?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13a. How many of your friends who pay for sex use condoms every time with the partners that they pay?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10-MAR-03
/hivnet/forms/PTN_037/forms/norms.fm

SAMPLE—English

01

Language Staff Initials / Date

6.14.13 Network Summary (NS-1)

Description and Purpose

This form summarizes detailed information collected on the Network Inventory grid (a non-DataFax form that lists those individuals and some of their identifying characteristics with whom they inject drugs or have a sexual relationship). Items recorded on this form include descriptions of both drug and sex networks, highlighting behaviors as well as relationships. This is an administrative form completed by study staff; do NOT read this form to the participant.

Form-specific Instructions


This form is completed by study staff for potential index members at the Screening Visit and at each semi-annual visit based on the Network Inventory grid.

The Network Inventory grid, a non-DataFax form, collects detailed information about people who are important to the index participant in a number of ways. The grid compiles the names of all people mentioned by the index participant and asks questions to create a representative picture of the of his or her social and risk networks. The grid is updates at semi-annual follow-up visits. To do this, ask the participant about all individuals listed on the previous grid as well has new/additional network members.

Use the grid to work through each of the items on the summary form. Right justify this numerical value and fill in any leading boxes with zeros.

NOTE: The instructions on the form indicate how to use the numeric codes from the Network Summary. Remember that these codes are not values. When the instruction ask for “total number” of a particular code, that means the total instances of that code, not the numeric total of the code.

Figure 6-21
Network Summary (NS-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Network Summary (NS-1)			
										Visit Code <input type="text"/> <input type="text"/>		<input style="width: 20px; height: 20px;" type="text" value="1"/>	
HPTN 037 IDU Networks (095) NS-1 (131)										Page 1 of 1			
Participant ID			Network Summary						Form Completion Date				
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>						<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				
Site Number Participant Number Chk			Network ID Member						<i>dd</i> <i>MMM</i> <i>yy</i>				
Do not use at follow-up visits													
Instructions: Complete this form by totaling or summarizing items on the Network Inventory grid. Follow instructions listed in each item.													
1. Total number of names listed (total size of network enumerated):										<input type="text"/> <input type="text"/>			
2. Total number of 1s in column 6 (size of sex network):										<input type="text"/> <input type="text"/>			
3. Total number of 0s in column 7 (number who had sex with index without a condom):										<input type="text"/> <input type="text"/>			
4. Total number of 1s in column 8 (size of drug network):										<input type="text"/> <input type="text"/>			
5. Total known for 6 months or less as indicated in columns 16, 17, and 18 (number of new network members):										<input type="text"/> <input type="text"/>			
6. Total of 1s, 2s, or 3s in column 19 (number of network members seen once per week or more):										<input type="text"/> <input type="text"/>			
7. Total number of 0s in column 27 (number in drug network with whom index does not share drugs):										<input type="text"/> <input type="text"/>			
8. Total number of 0s in column 29 (number in drug network with whom index does not share needles):										<input type="text"/> <input type="text"/>			
9. Total number of 1s in column 30 (number who index talked to about drug risk):										<input type="text"/> <input type="text"/>			
10. Total number of 1s in column 31 (number who index talked to about sex risk): ..										<input type="text"/> <input type="text"/>			
11. Total number of 1s on density sheet (number of inter-relationships reported among network members enumerated):										<input type="text"/> <input type="text"/> <input type="text"/>			
Item 12 only at Screening.													
12. Number of network member cards distributed (only at Screening):										<input type="text"/> <input type="text"/>			
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 06-MAY-04				SAMPLE—English				<input style="width: 20px; height: 20px;" type="text" value="0"/> <input style="width: 20px; height: 20px;" type="text" value="1"/>		Language Staff Initials / Date			
/hivnet/forms/PTN_037/forms/network_summ.fm													

6.14.14 Exposure/Contamination Assessment (EX-1)

Description and Purpose

This form collects information that describes other ways that a participant may learn about HIV, AIDS, and protection from HIV infection outside of the study or as a result of the study intervention. This assessment documents conversations that the participant has initiated with others and also those specifically involving index participants.

Form-specific Instructions

Administer this form to every participant at each follow-up visit. Read the first paragraph aloud and ask if the participant has questions before beginning. Emphasis should be placed on “friends or people you know;” we don’t want reports of incidental conversations with strangers or mass media exposure to AIDS information. Remind participants NOT to count conversations with people who work on this study (interviewers, HIV test counselors, receptionist, etc.).

Item 1: If the participant reports no conversations in the last 6 months, skip to Item 2.

Item 1a: Record the total number of DIFFERENT people that the participant reports talking to about HIV/AIDS in the last 6 months. An estimate is acceptable if the participant cannot recall the exact number.

Item 1b: Record the TOTAL number of different conversations in the last 6 months.

Item 1c: Read the question and show card #6. Mark each item that the participant reports talking about with others. If necessary, remind the participant that we are asking which of the items on the card they TALKED about with friends or people that they know, not things that they already know about or have heard about on TV or read about in newspapers or magazines. If no subjects listed were discussed, mark only the “none” box.

Item 2: Read the question and show card #7. Mark each item that indicates “EXACT words or phrases.” If necessary, remind the participant that we want them to report only those items that they recognize, have heard, or have used as shown exactly on the card. If they are unsure, do not mark the item. If no exact words or phrases are recognized, mark only the “none” box.

Figure 6-22
Exposure/Contamination Assessment (EX-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Exposure/Contamination Assessment (EX-1)	
		Visit Code <input type="text"/> . <input type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="1"/>
HPTN 037 IDU Networks (095) EX-1 (161)		Page 1 of 1	
Participant ID <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> Site Number Participant Number Chk		Form Completion Date <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>dd MMM yy</i>	
Exposure/Contamination Assessment			
<p><i>Read to participant:</i> The next few questions are about conversations that you may have had with other people. For these questions, I'd like you to think about conversations with friends or people that you know, not including people who work on this study, or people who tested you for HIV.</p>			
1. In the last 6 months, have you talked to anyone you know, or have they talked to you, about how people can protect themselves from HIV infection?		yes no <input type="checkbox"/> <input type="checkbox"/>	→ If no, go to item 2.
1a. How many different people did you talk with?.....		<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/>	
1b. How many different conversations did you have?		<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/>	
1c. Looking at this card, which of these things did you talk about in any of the conversations that you had? <i>Show Card #6. Mark all that apply.</i>			
<input type="checkbox"/> needle exchange		<input type="checkbox"/> asking your sex partners about HIV status	
<input type="checkbox"/> using a condom		<input type="checkbox"/> asking your drug partners about HIV status	
<input type="checkbox"/> cleaning needles		<input type="checkbox"/> how to use a female condom	
<input type="checkbox"/> safer sex		<input type="checkbox"/> keeping your own works	
<input type="checkbox"/> not sharing needles		<input type="checkbox"/> none → If none, mark only this response.	
2. Looking at this card, which of these exact words or phrases have you heard before? <i>Show Card #7. Mark all that apply.</i>			
<input type="checkbox"/> peer mentor		<input type="checkbox"/> splitting drugs dry	
<input type="checkbox"/> SPEAKK		<input type="checkbox"/> PALMS	
<input type="checkbox"/> injection risk ladder		<input type="checkbox"/> harm reduction	
<input type="checkbox"/> EXPLORE		<input type="checkbox"/> Project FAST	
<input type="checkbox"/> ribbon game		<input type="checkbox"/> SCHARP	
<input type="checkbox"/> matrix method		<input type="checkbox"/> sex risk ladder	
<input type="checkbox"/> cleaning 1 x 1 x 1 (1 x water, 1 x bleach, 1 x water)		<input type="checkbox"/> freeze frame	
		<input type="checkbox"/> none → If none, mark only this response.	
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 19-AUG-03 /hivnet/forms/PTN_037/forms/exposure.fm		SAMPLE—English	
		<input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="0"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text" value="1"/>	_____ Language Staff Initials / Date

6.14.15 Social Impact Assessment (SIA-1)

Description and Purpose

This form captures information on any social impacts - positive or negative - that the participant experiences as a result of study involvement. There is a wide range of 'impacts', including relationships, education, employment, housing, and health care.

A social impact/harm is defined by the protocol as:

- Events leading to significant psychological, social, or physical harm to a participant;
- that result from his or her participation in the study, including disclosure of participant's drug or sex-related behaviors or of their HIV serostatus, being exposed to intervention activity or implementing a personal goal or practicing a skill as a part of participating in the study treatment or control group;
- and that are reported to or observed by study staff.

Form-specific Instructions

Item 1: Record if the participant has been affected negatively by his or her involvement in the the study. If "no" is marked, go to Item 3.


Item2: Read all sub-items to the participant and mark a response for each. If the participant refuses to answer any item, write "refused" and line through the response box.

Total the number of social impacts reported and enter the number in the boxes at the bottom of the column. Complete one Social Impact Log form for each impact reported.

If two separate occurrences of the same type of social impact are reported, such as two separate episodes of relationship problems, mark the "yes" box and include both episodes in the total. Complete one Social Impact Log for each episode.

Item3: A positive or beneficial impact means anything good or anything that has improved the participant's quality of life. If "yes" is marked, provide a detailed explanation in Item 2a.

Figure 6-23
Social Impact Assessment (SIA-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Social Impact Assessment (SIA-1)									
										Visit Code <input type="text"/> . <input type="text"/> 1									
HPTN 037 IDU Networks (095) SIA-1 (171)										Page 1 of 1									
Participant ID					Social Impact Assessment										Contact Date				
<input type="text"/> - <input type="text"/> - <input type="text"/>															<input type="text"/> / <input type="text"/> / <input type="text"/>				
Site Number Participant Number Chk															dd MMM yy				
<p>Instruction: Before administering this assessment, update information about any unresolved previously reported social impacts on the corresponding Social Impact Log (SIL).</p>																			
<p>1. Because of your participation in this study, did anything negative or bad happen to you in the last 6 months? <input type="checkbox"/> yes <input type="checkbox"/> no → If no, go to item 3.</p>																			
<p>2. Because of your participation in this study, have you...</p>																			
2a. been arrested or had trouble with the police or other legal problems?.....										<input type="checkbox"/> yes <input type="checkbox"/> no					<p style="text-align: center;">If yes, how many times?</p> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				
2b. had trouble getting or keeping housing?.....										<input type="checkbox"/> yes <input type="checkbox"/> no									
2c. had trouble getting or keeping a job or trouble with income or economic support?.....										<input type="checkbox"/> yes <input type="checkbox"/> no									
2d. had trouble getting health care or with health insurance?.....										<input type="checkbox"/> yes <input type="checkbox"/> no									
2e. had personal trouble with friends, family, or acquaintances?.....										<input type="checkbox"/> yes <input type="checkbox"/> no									
2f. had any other type of problem? Specify:										<input type="checkbox"/> yes <input type="checkbox"/> no									
_____															<p>total number of impacts <input type="text"/> <input type="text"/></p>				

<p>Complete a separate Social Impact Log (SIL) for each impact. ←</p>																			
<p>3. In the last 6 months, has your participation in this study had a positive or beneficial impact on your life? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> don't know → If no or don't know, end of form.</p>																			
<p>3a. If yes, please describe: Summarize participant's response.</p>																			

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02					SAMPLE—English					01 Language Staff Initials / Date									
/hivnet/forms/PTN_037/forms/social_impact_assessment.fm																			

6.14.16 Social Impact Log (SIL-1)

Description and Purpose

This log form is designed to compliment the Social Impact Assessment form. The log form details any 'impacts' noted on the assessment form, documents the action taken by study staff and/or the participant to address the issue, and denotes the current status of the social impact.

As a log form, the SIL-1 form is designed to be updated and re-submitted to SCHARP as the initial information collected changes at subsequent visits. If the social impact reported is resolved or unable to be resolved at initial reporting, that would be indicated in item 7, along with a closure date, and that form is submitted to SCHARP once. For on-going or unresolved social impacts, the log would be updated as needed at each subsequent study visit, and re-submitted ONLY if changes are made. At the end of the study, all social impacts must be reported as "Resolved," "Unable to resolve," or "Unresolved at end of study."

Form-specific Instructions

Use this log to record the occurrence and resolution of adverse social impacts reported on scheduled Social Impact Assessment form and those reported spontaneously at any time during the study.

Item 1 and Item 6: Provide a description of the social impact and then what was done by the staff and the participant to address the issue.

Item 2: Record the start (date) of the impact.

Item 3: If a participant reports a negative social impact outside of a regularly scheduled visit, complete this log only and not the Social Impact Assessment form. Code item 3 as an interim visit.

Item 4: Use the following definitions to code the social impact:

Code	Definition
01 Police/Legal Problems	Had problems with local law enforcement or government agencies because of participation in this study.
02 Housing	Had trouble getting or keeping housing, or had other problems related to housing.
03 Employment	Been turned down for a new job, lost a job, or experienced other problems at work.
04 Health Care/Health Insurance	Been refused medical or dental treatment, or treated negatively by a health care provider. Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
05 Friends/Family	Had difficulty in relationships with friends or family such as avoidance, anger, or dismay due to participation in the study.
06 Other	Had other problems not covered in the codes above.

Item 5: Indicate the most serious/worst level of impact as related to the participant's quality of life.

Item 6: Describe both participant and staff actions in response to the social impact identified in Item 1.

Item 7: When recording the current status, document the closure date if the issue cannot be resolved and no further action is taken, or if the issue is resolved.

Figure 6-24
Social Impact Log (SIL-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)	Social Impact Log (SIL-1)						
HPTN 037 IDU Networks (095) SIL-1 (181)							
Participant ID <input type="text"/> - <input type="text"/> - <input type="text"/> <small>Site Number Participant Number Chk</small>	Page <input type="text"/> <input type="text"/>						
Social Impact Log							
<p>Instructions: Fax this form to SCHARP DataFax whenever a new Social Impact is recorded or information on this form is updated. Fax only pages with new entries or revisions.</p>							
<p>1. Concisely describe social impact:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>6. Describe what was done by staff and participant to address social impact:</p> <p>6a. Participant: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>6b. Staff: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>						
<p>2. Onset Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="margin-left: 100px;"><small>dd MMM yy</small></p> <p>3. Reported at Visit: <input type="text"/> . <input type="text"/></p> <p>4. Social Impact Code: <input type="text"/> <input type="text"/></p>							
Social Impact Codes: <table style="margin: 0 auto; border: none;"> <tr> <td style="padding-right: 20px;">01 Police/Legal Problems</td> <td>04 Health Care/Insurance</td> </tr> <tr> <td>02 Housing</td> <td>05 Friends/Family</td> </tr> <tr> <td>03 Employment</td> <td>06 Other</td> </tr> </table>		01 Police/Legal Problems	04 Health Care/Insurance	02 Housing	05 Friends/Family	03 Employment	06 Other
01 Police/Legal Problems	04 Health Care/Insurance						
02 Housing	05 Friends/Family						
03 Employment	06 Other						
<p>Ask Participant:</p> <p>5. What impact has this situation had on your quality of life?</p> <p><input type="checkbox"/> Minimal disturbance</p> <p><input type="checkbox"/> Moderate disturbance. No significant impact.</p> <p><input type="checkbox"/> Major disturbance with significant impact.</p>	<p>7. Record current status:</p> <p><input type="checkbox"/> Unresolved</p> <p><input type="checkbox"/> Unresolved at end of study</p> <p><input type="checkbox"/> Unable to resolve. No further action taken.</p> <p><input type="checkbox"/> Resolved</p> <p>↓</p> <p>If either is marked, enter closure date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="margin-left: 100px;"><small>dd MMM yy</small></p>						
<p>Reviewed by Investigator: _____</p> <p style="margin-left: 100px;"><small>Principal Investigator (or designee) Signature</small></p> <p style="margin-left: 450px;"><small>Date</small></p>							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02	SAMPLE —English						
<small>/hivnet/forms/PTN_037/forms/social_impact_log.fm</small>	<table style="border: none;"> <tr> <td style="border: 1px solid black; padding: 2px 5px; text-align: center;">01</td> <td style="padding-left: 10px;"><small>Staff Initials / Date</small></td> </tr> <tr> <td style="border: none;"><small>Language</small></td> <td></td> </tr> </table>	01	<small>Staff Initials / Date</small>	<small>Language</small>			
01	<small>Staff Initials / Date</small>						
<small>Language</small>							

6.14.17 Missed Visit (MV-1)

Description and Purpose

The Missed Visit form documents when an enrolled participant misses a scheduled semi-annual follow-up pre-test and/or post-test visit. This form should be completed when the staff have determined that a participant will not complete a scheduled visit within the allowable time frame. Wait until the allowable window has passed before completing and faxing this form. There is no need to return this form for missed quarterly locator visits.

NOTE: The allowable visit window for all follow-up visits in HPTN 037 is 14 days before the target date to 30 days after the target date. All activities related to the visit should be completed within this window.

Form-specific Instructions

Mark the reason that best describes why the visit was missed. Mark only one reason. Include any additional information in the comments section at the bottom of the form. If the participant has permanently withdrawn from the study, or if the participant has died, also complete a Termination form.

If a visit is completed within the window but after a Missed Visit form has been faxed to DataFax, draw a large X across the front of the previously submitted Missed Visit form. Write “delete” on the top of the form, date and initial the change, and then re-fax the form to DataFax.

6.14.18 Termination (TM-1)

Description and Purpose

The Termination Form documents when the participant completes the study or withdraws from the study before completing a minimum of 18 months and a maximum of 30 months (depending on date of enrollment) of follow-up. This form should be completed for every participant when their study participation has ended. This form should not be completed for screened participants who did not enroll in the study.

Form-specific Instructions

Item 1: Record the date that the participant is no longer in the study.

Item 2: Indicate the reason for termination from the study by marking one box.

Item 2a: Mark this box only if the participant has completed his or her scheduled exit visit.

Item 2b: Mark this box only if the participant died before completing all study visits. Indicate the cause of death (if known) and the date of death (if known).

Item 2c: Mark this box only if the participant has permanently left the study before completing all visits. Provide details in the comments section at the bottom of the form.

Item 2d: Mark this box only if the participant cannot attend scheduled visits within the target window.

Item 2e: Mark this box only if the participant has relocated permanently; the study does not allow for remote participation.

Item 2f: Mark this box only if the investigator elects to terminate the participant; note the reason in the space provided.


Item 2g: Mark the box only if the site has exhausted all efforts to contact the participant per protocol and local SOPs.

Item 2j: "Invalid ID due to duplicate screening/enrollment" refers to participants who are found to have enrolled twice, or enrolled after screening multiple times.

Item 2k: Mark this box only if the participant is terminated for a reason other than those listed; note the reason in the space provided.

Item 3: Mark this box to indicate if a social impact is associated with the reason for study termination. If yes, explain in Item 3a. Also complete the Social Impact Assessment form and the Social Impact Log to further describe the influence on the participant.

Figure 6-26
Termination (TM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Termination (TM-1)
 HPTN 037 IDU Networks (095) TM-1 (490)		Page 1 of 1
Participant ID [][]-[][][][][][]-[] Site Number Participant Number Chk	Termination	Form Completion Date [][] [][][][] [][] dd MMM yy
<p>Instructions: Complete this form when a participant terminates from the study.</p>		
dd MMM yy		
1. Termination Date: [][] [][][][] [][] Date the site determined that the participant was no longer in the study.		
2. Reason for termination. Mark only one.		
<input type="checkbox"/> 2a. Scheduled exit visit/End of study. → If scheduled exit visit/end of study, end of form.		
<input type="checkbox"/> 2b. Death. Indicate date and cause if known.		
dd MMM yy		
2b1. Date of death: [][] [][][][] [][] OR <input type="checkbox"/> Date unknown		
2b2. Cause of death: _____ OR <input type="checkbox"/> Cause unknown _____		
<input type="checkbox"/> 2c. Participant refused further participation. Specify reason in Comments field.		
<input type="checkbox"/> 2d. Participant unable to adhere to visit schedule.		
<input type="checkbox"/> 2e. Participant relocated, no follow-up planned.		
<input type="checkbox"/> 2f. Investigator decision, please specify: _____		
<input type="checkbox"/> 2g. Unable to contact participant.		
2h. HIV infection.		
2i. Inappropriate enrollment.		
<input type="checkbox"/> 2j. Invalid ID due to duplicate screening/enrollment.		
<input type="checkbox"/> 2k. Other reason, please specify: _____		
3. Was the reason for termination associated with a social harm? yes no don't know <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
page # page # page #		
3a. Social Impact Log pages: [][] [][][][] [][]		
If no or don't know, end of form.		
Comments: _____ _____		
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 10-MAR-03 /hivnet/forms/PTN_037/forms/termination.fm	SAMPLE—English	[0] [1] Language Staff Initials / Date

6.14.19 Comments (COM-1)

Description and Purpose

The Comments form is used to record any additional information about a participant or to clarify information recorded on another form. This form can be used whenever it is needed.

Form-specific Instructions

Enter visit code in the boxes on the top of the page. The visit code on this form is the visit code of the visit or form that the additional comments relate to. This can be a regularly scheduled visit or an interim visit.

Enter Participant ID number in upper left corner of the page.

Enter the date the form is completed in upper right corner of the page.

Record the acronym of the form to which the written comments apply. The form acronym is located in the upper right corner of each form. For example, the acronym for the Comments form is COM-1. If the written comments apply to more than one form, enter all the acronyms. If the comments do not relate to any form, mark the “not applicable” box.

Print legibly on the Comments form; do not use cursive handwriting.

6.14.20 End of Study Inventory (ESI-1)

Description and Purpose

This form collects the date of the participant's last study visit and summarizes the number of Social Impact Log forms and unique Local Laboratory forms that have been completed. Comparison of total numbers recorded on the form and individual CRFs submitted to DataFax will insure that all of this data has been received.


Form-specific Instructions

Item 1: Record the visit code of the participant's last regularly scheduled visit or interim visit.

Item 2: Record the page number of the last Social Impact Log form submitted or mark 'none' if no log forms were submitted.

Item 3: Tally the number of unique Follow-Up Local Lab forms, including regularly scheduled, interim, and confirmatory tests, and record the total number of forms submitted.

Figure 6-28
End of Study Inventory (ESI-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)  HPTN 037 IDU Networks (095) ESI-1 (489)		End of Study Inventory (ESI-1) Page 1 of 1
Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <small>Site Number Participant Number Chk</small>		Form Completion Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>
End of Study Inventory		
1. What is the visit code of the participant's last visit?	Visit Code <input type="text"/> <input type="text"/> . <input type="text"/>	
2. What was the last Social Impact Log (SIL-1) page number submitted for this participant?	<input type="text"/> <input type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>none</i>	
3. How many Follow-up Local Lab Results forms (LL-1) were submitted for this participant?	<input type="text"/> <input type="text"/> <i># of LL-1</i>	
<div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="text-align: left;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 05-DEC-02 <small>/hivnet/forms/PTN_037/forms/end_of_study.fm</small> </div> <div style="text-align: center;"> SAMPLE—English </div> <div style="text-align: right;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">01</div> <small>Language Staff Initials / Date</small> </div> </div>		

6.14.21 Randomization List (RL-1)

Description and Purpose

The Randomization List serves to document the randomization arm assigned to each participant by randomization/enrollment cohort.

SCHARP provides each site with randomization lists prior to the first randomization/enrollment session. Each list comes in a sealed packet. Packets are defined and labeled by cluster size, whereby cluster size indicates the number of index participants to be randomized.

Refer to section 5.3 for a description of the study randomization procedures.

Form-specific Instructions

This form is completed as a part of the in-office randomization procedure and is filled out by the staff person charged with responsibility for randomization and witnessed by a second staff person.

Complete the group ID number and randomization date.

The body of the form consists of three columns - sequence number, assignment (treatment or control), and participant identification number (PTID). Both the six-digit sequence number (two-digit cluster number, two-digit packet number, and two-digit sequential number from 01 to 20) and the randomization assignment are pre-printed on the RL-1 form.

Record the list of PTIDs for eligible index participants, arranging them in order from lowest to highest, at the time of randomization.

Note any comments about the process in the space provided.

Submit the RL-1 form to SCHARP DataFax immediately following the in-office randomization.

Randomization List (RL-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Randomization List (RL-1)



HPTN 037 Sessions (105)

RL-1 (101)

Page 1 of 1

Group ID

-

Site Number

Group

Randomization List

Randomization Date

dd

MMM

yy

Sequence # Assignment

PTID

20-01-01	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-02	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-03	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-04	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-05	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-06	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-07	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-08	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-09	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-10	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-11	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-12	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-13	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-14	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-15	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-16	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-17	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-18	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-19	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>
20-01-20	TBD	<input type="text"/> - <input type="text"/> - <input type="text"/>

Instructions: Fax this form to SCHARP DataFax immediately after in-office randomization occurs.

Comments: _____

23-JAN-04

/hivnet/forms/PTN_037/forms/rando_list.fm

SAMPLE—English

-

Cluster

Packet

Language

Staff Initials / Date

6.14.22 Intervention Session Participation Log (IL-1)

Description and Purpose

This log form collects participant attendance at each of the six intervention group counseling sessions. Based on group number and the date of the session, this form documents the counseling session leaders, the session number, the length of the session, if the session was audio-taped, and whether or not each participant in the group attended the session.

Form-specific Instructions

This form is completed by study staff at the completion of each intervention session and submitted via DataFax to SCHARP.

Complete one IL-1 form for each intervention counseling session, using the designated intervention group number in the ID field. The intervention group number refers to a sequential number assigned locally to each group of participants. Also indicate the session date. *Note: As there may be more than one session scheduled on a given date, the accuracy of both the group number and the session date is critical.*

Record the ID numbers of the group leaders.

Record the session number, marking only one box of those numbered 1–6. If a session ends early due to unforeseen circumstances (such as weather or a technical failure), the session may be continued and completed at the next scheduled meeting date. Complete an IL-1 form for each session, marking the same session number on both forms and checking the “continued session” box on the second form. A session may only be “continued” once, and only one session may be conducted per meeting. *For example, session 1 is not completed at the first meeting and is carried over for completion at the second meeting. Two IL-1 forms are filled out for session 1, session dates are different, and the “continued” box is marked on the second form. At the end of the session 1 content, the group is concluded for the day; it is not permissible to conduct a split session and commence session 2 content.*

Record the ID numbers of all participants who are scheduled to attend the counseling session. For each participant, mark “yes” or “no” to indicate session attendance. If a participant misses both the first and second sessions with his/ her intended randomization group, he/she cannot attend the remaining sessions with that group. However, attendance for that participant should continue to be marked on all six session logs for the original group. If the participant is transferred to another intervention group prior to the 6-month follow-up visit, also record attendance for all sessions with the new group. In addition, an Intervention Cohort Participant Transfer form (IPT-1) should be completed.

Using the 24-hour clock, record the time that the counseling session started and when it ended. Refer to the 24-hour clock conversion table at the start of this section for assistance.

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped. Mark “no” to indicate no taping; provide details in the comments section at the end of the form.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of the page.

Figure 6-29
Intervention Session Participation Log (IL-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)
Intervention Session Participation Log (IL-1)

HPTN 037 Sessions (105)
IL-1 (201)
Page 1 of 1

Group ID

Site Number Group

Intervention Session Participation Log

Session Date

dd MMM yy

Group Leader #1 ID

Site Number Leader

Group Leader #2 ID

Site Number Leader

Session #

1 2 3 4 5 6

continued session

Participants expected to attend: <i>Enter Participant ID</i>	Did participant attend?	Session Start Time
1. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> yes no </div> <input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
2. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
3. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
4. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
5. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
6. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
7. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
8. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
9. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
10. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
11. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>
12. <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<div style="display: flex; justify-content: space-around; font-size: x-small;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> : <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <p style="font-size: x-small; text-align: center;">hr min</p>

Was the session audio-taped? yes no → *If no, record reason in Comments field below.*

Comments: _____

17-APR-03
 /hivnet/forms/PTN_037/forms/intervention_log.fm

SAMPLE—English

01

 Language Staff Initials / Date

6.14.23 Booster Session Participation Log (BL-1)

Description and Purpose

This log form collects participant attendance at the 6 and 12-month booster sessions. Based on group number and the date of the session, this form documents the booster session leaders, the type and length of the session, and the participants attending the session.

Form-specific Instructions

This form is completed by study staff at the completion of each booster session and submitted via DataFax to SCHARP.

Complete one BL-1 form for each booster session, using the designated group number in the ID field. The group number refers to a sequential number assigned locally to each group of participants. Also indicate the session date. *Note: As there may be more than one session scheduled on a given date, the accuracy of both the group number and the session date is critical.*

Record the ID numbers of the group leaders.

Record the type of booster session by marking either the 6-month or 12-month box.

Record the ID numbers of all participants who attended the booster session.

Using the 24-hour clock, record the time that the counseling session started and when it ended. Refer to the 24-hour clock conversion table at the start of this section for assistance.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of the page.

Figure 6-30
Booster Session Participation Log (BL-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Booster Session Participation Log (BL-1)	
HPTN 037 Sessions (105) BL-1 (301)		Page 1 of 1	
Booster ID <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Booster Session Participation Log	
Site Number Booster Session		Session Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	
Site Number Leader		Site Number Leader	
Group Leader #1 ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/>		Group Leader #2 ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/>	
Site Number Leader		Site Number Leader	
Participants who attended: Enter Participant ID		Session Start Time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
		hr min	
1. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>		Session End Time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
		hr min	
2. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
3. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
4. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
5. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
6. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
7. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
8. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
9. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
10. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
11. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
12. <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>			
Comments: _____ _____			
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> 06-MAY-04		SAMPLE—English	
/hivnet/forms/PTN_037/forms/booster_log.fm		<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	
		Language Staff Initials / Date	

6.14.24 Intervention Session 1 (INA-1–INA-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material completed in Intervention Session 1: Introduction. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one INA-1, 2 form for each counseling Intervention Session 1, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.


Items 1–10: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 11–19: After reviewing the entire session, rank each qualitative item as “not adequate,” or “acceptable”. The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-31
Intervention Session 1 (INA-1–INA-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 1 (INA-1)


 HPTN 037 Sessions (105) INA-1 (211)

Page 1 of 2

Group ID
 -
Site Number Group

**RTI Monitoring—
Intervention Session 1**

Session Date

dd MMM yy

Group Leader #1 ID
 -
Site Number Leader

Group Leader #2 ID
 -
Site Number Leader

Review Date

dd MMM yy

Session 1: Introduction

Was the session audio-taped? yes no → **If no, end of form.
Record reason in
Comments field below.**

Instructions: Mark “yes” or “no” to indicate whether each element of the intervention was completed.

	<small>yes</small>	<small>no</small>	<small>not taped</small>
1. Welcome and introduction of study/study goals.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Establish group rules.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Conduct Ice-Breaker: Helping Others.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Present myths and facts.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Conduct ribbon demonstration.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Define/discuss peer mentoring.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Present/discuss peer mentoring “In Action” video.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Present SPEAKK: Communication Tools for Peer Mentors.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Present homework assignment—mentoring activity.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Conduct session summary and wrap-up.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>


Comments: _____

29-APR-03 **SAMPLE—English** 01

/hivnet/forms/PTN_037/forms/session_1_rti.fm Language Staff Initials / Date

Figure 6-32
Intervention Session 1 (INA-1–INA-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 1 (INA-2)



HPTN 037 Sessions (105) INA-2 (212)

Page 2 of 2

Group ID

Site Number	-		Group				

**RTI Monitoring—
Intervention Session 1**

Instructions: Rate the session using the scale from 1–3 to indicate overall qualitative assessment.

	<i>not adequate</i>	<i>acceptable</i>	<i>good</i>	<i>could not evaluate</i>
11. Follows script	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Time management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Neutral/non-judgmental delivery.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Maintains focus on group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Listens and integrates participant comments with group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Uses suggested discussion questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Overall delivery of session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Attempted to include all participants in discussion.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Ensures accuracy of information discussed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

06-NOV-03
 /hivnet/forms/PTN_037/forms/session_1_rti.fm

SAMPLE—English

0	1
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 Language Staff Initials / Date

6.14.25 Intervention Session 2 (INB-1–INB-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material covered in Intervention Session 2: Peer Mentoring and Injection-Related HIV Risk Behaviors. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one INB-1, 2 form for each counseling Intervention Session 2, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.


Items 1-9: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 10-18: After reviewing the entire session, rank each qualitative item as “not adequate,” “acceptable”. The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-33
Intervention Session 2 (INB-1–INB-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 2 (INB-1)


 HPTN 037 Sessions (105) INB-1 (213)

Page 1 of 2

Group ID
 -
Site Number Group

**RTI Monitoring—
Intervention Session 2**

Session Date

dd MMM yy

Group Leader #1 ID
 -
Site Number Leader

Group Leader #2 ID
 -
Site Number Leader

Review Date

dd MMM yy

Session 2: Peer Mentoring and Injection-related HIV Risk Behaviors

Was the session audio-taped? yes no → **If no, end of form.
Record reason in
Comments field below.**

Instructions: Mark "yes" or "no" to indicate whether each element of the intervention was completed.

	<small>yes</small>	<small>no</small>	<small>not taped</small>
1. Welcome back and review homework/peer mentoring activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Present Harm Reduction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Present Injection Risk Ladder/Steps and safer injection video.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Present clean needle demonstration and video.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Practice needle cleaning skills.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Facilitator presents freeze frame role plays using SPEAKK.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Conduct small group role plays.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Present homework assignment—peer mentoring training activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Conduct wrap-up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

29-APR-03 **SAMPLE—English**
/hivnet/forms/PTN_037/forms/session_2_rti.fm Language Staff Initials / Date

Figure 6-34
Intervention Session 2 (INB-1–INB-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 2 (INB-2)																																																						
HPTN 037 Sessions (105) INB-2 (214)	Page 2 of 2																																																					
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Site Number	-			Group																																																		
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6.14.26 Intervention Session 3 (INC-1–INC-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material covered in Intervention Session 3: Safer Sex Practices and Communication Skills. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one INC-1, 2 form for each counseling Intervention Session 3, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.


Items 1-9: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 10-18: After reviewing the entire session, rank each qualitative item as “not adequate,” “acceptable”. The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-35
Intervention Session 3 (INC-1–INC-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 3 (INC-1)



HPTN 037 Sessions (105) INC-1 (215)

Page 1 of 2

Group ID

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Site Number Group

**RTI Monitoring—
Intervention Session 3**

Session Date

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dd MMM yy

Group Leader #1 ID

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Site Number Leader

Group Leader #2 ID

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Site Number Leader

Review Date

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dd MMM yy

Session 3: Safer Sex Practices and Communication Skills

Was the session audio-taped? yes no **→ If no, end of form. Record reason in Comments field below.**

Instructions: Mark "yes" or "no" to indicate whether each element of the intervention was completed.

	yes	no	not taped
1. Welcome back and review homework/peer mentoring activity.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Present Sex Risk Ladder/Steps.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Conduct male condom use demonstration.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Practice male condom use.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Philadelphia only: Conduct female condom use demonstration.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Philadelphia only: Practice female condom use.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Summarize condom use.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Present peer mentoring in action video using SPEAKK.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Present homework assignment (peer mentoring training activity) and wrap-up.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

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SAMPLE—English

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Language Staff Initials / Date

Figure 6-36
Intervention Session 3 (INC-1–INC-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 3 (INC-2)																																																						
HPTN 037 Sessions (105) INC-2 (216)	Page 2 of 2																																																					
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<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> 06-NOV-03 <small>/hivnet/forms/PTN_037/forms/session_3_rti.fm</small>	SAMPLE—English		<table style="border: 1px solid black; width: 40px; height: 20px; text-align: center; font-size: x-large;"> <tr> <td style="width: 20px;">0</td> <td style="width: 20px;">1</td> </tr> </table>	0	1	<small>Staff Initials / Date</small>																																																
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6.14.27 Intervention Session 4 (IND-1–IND-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material covered in Intervention Session 4: Personal Resistance to Change. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one IND-1, 2 form for each counseling Intervention Session 4, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.


Items 1-7: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 8-16: After reviewing the entire session, rank each qualitative item as “not adequate,” “acceptable.” The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-37
Intervention Session 4 (IND-1–IND-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 4 (IND-1)


 HPTN 037 Sessions (105) IND-1 (217)

Page 1 of 2

Group ID
 -
Site Number Group

**RTI Monitoring—
Intervention Session 4**

Session Date

dd MMM yy

Group Leader #1 ID
 -
Site Number Leader

Group Leader #2 ID
 -
Site Number Leader

Review Date

dd MMM yy

Session 4: Personal Resistance to Change

Was the session audio-taped? yes no **▶ If no, end of form.
Record reason in
Comments field below.**

Instructions: Mark "yes" or "no" to indicate whether each element of the intervention was completed.


	<small>yes</small>	<small>no</small>	<small>not taped</small>
1. Welcome back and review homework/peer mentoring activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Reflect on personal resistance to change.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Present dyad active listening.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Participant report on active listening exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Summarize dyad active listening exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Discuss problem solving impediments.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Present homework assignment (peer mentoring training activity) and wrap-up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

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Figure 6-38
Intervention Session 4 (IND-1–IND-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 4 (IND-2)



HPTN 037 Sessions (105) IND-2 (218)

Page 2 of 2

Group ID

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Site Number Group

**RTI Monitoring—
Intervention Session 4**

***Instructions:** Rate the session using the scale from 1–3 to indicate overall qualitative assessment.*

	<i>not adequate</i>	<i>acceptable</i>	<i>good</i>	<i>could not evaluate</i>
8. Follows script	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Time management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Neutral/non-judgemental delivery.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Maintains focus on group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Listens and integrates participant comments with group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Uses suggested discussion questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Overall delivery of session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Attempted to include all participants in discussion.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Ensures accuracy of information discussed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

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Language Staff Initials / Date

6.14.28 Intervention Session 5 (INE-1–INE-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material covered in Intervention Session 5: Interpersonal Barriers to Peer Mentoring. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one INE-1,2 form for each counseling Intervention Session 5, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*

Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.


Items 1-6: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 7-15: After reviewing the entire session, rank each qualitative item as “not adequate,” “acceptable.” The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-39
Intervention Session 5 (INE-1–INE-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 5 (INE-1)


 HPTN 037 Sessions (105) INE-1 (219)

Page 1 of 2

Group ID
 -
Site Number Group

**RTI Monitoring—
Intervention Session 5**

Session Date

dd MMM yy

Group Leader #1 ID **Group Leader #2 ID**
 - -
Site Number Leader Site Number Leader

Review Date

dd MMM yy

Session 5: Interpersonal Barriers to Peer Mentoring

Was the session audio-taped? yes no → **If no, end of form.
Record reason in
Comments field below.**

Instructions: Mark "yes" or "no" to indicate whether each element of the intervention was completed.

	<small>yes</small>	<small>no</small>	<small>not taped</small>
1. Welcome back and review homework/peer mentoring activity.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Reflect on interpersonal resistance to peer mentoring.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Present approaching others when doing peer mentoring.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Conduct small group freeze-frame role plays using SPEAKK with resistant networks.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Summarize dealing with interpersonal resistance.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Present homework assignment (peer mentoring activity) and wrap-up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

29-APR-03 **SAMPLE—English**
/hivnet/forms/PTN_037/forms/session_5_rti.fm Language Staff Initials / Date

Figure 6-40
Intervention Session 5 (INE-1–INE-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) RTI Monitoring—Intervention Session 5 (INE-2)																																																						
	HPTN 037 Sessions (105)	INE-2 (220)	Page 2 of 2																																																			
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<p><i>Instructions: Rate the session using the scale from 1–3 to indicate overall qualitative assessment.</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;"></th> <th style="width: 10%; text-align: center; font-size: small;"><i>not adequate</i></th> <th style="width: 10%; text-align: center; font-size: small;"><i>acceptable</i></th> <th style="width: 10%; text-align: center; font-size: small;"><i>good</i></th> <th style="width: 10%; text-align: center; font-size: small;"><i>could not evaluate</i></th> </tr> </thead> <tbody> <tr> <td>7. Follows script</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>8. Time management</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>9. Neutral/non-judgemental delivery.</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>10. Maintains focus on group activity</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>11. Listens and integrates participant comments with group activity</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>12. Uses suggested discussion questions</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>13. Overall delivery of session</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>14. Attempted to include all participants in discussion.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>15. Ensures accuracy of information discussed.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>						<i>not adequate</i>	<i>acceptable</i>	<i>good</i>	<i>could not evaluate</i>	7. Follows script	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Time management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Neutral/non-judgemental delivery.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Maintains focus on group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Listens and integrates participant comments with group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Uses suggested discussion questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Overall delivery of session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Attempted to include all participants in discussion.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Ensures accuracy of information discussed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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6.14.29 Intervention Session 6 (INF-1–INF-2)

Description and Purpose

Audio-tapes from all six intervention sessions for each randomized group will be bundled and shipped from the site(s) to the RTI monitor for quality assurance review. This form documents the counseling content and a qualitative assessment of the material covered in Intervention Session 6: Review, Mentor Plans, and Graduation. This form is completed by the RTI monitor to assess adherence to the intervention curriculum content and to assess the quality of delivery.

To further ensure adherence to the intervention curriculum, a second assessment of the counseling content will be performed by the study site supervisors using a similar non-DataFax form.

Form-specific Instructions

Complete one INF-1, 2 form for each counseling Intervention Session 6, using the designated intervention group number in the ID field as noted on the tape. The intervention group number refers to a sequential number assigned locally to each group of participants. Record the group leader ID numbers and the session date, also per the tape label. Also record the review date to indicate the completion of the monitoring review. *Note: As there may be more than one session scheduled on a given date, the accuracy of the group code and session date is critical.*


Indicate whether or not the session was audio-taped. Mark “yes” to indicate that the complete session or part of the session was taped and available for review. Mark “no” to indicate no taping and provide details in the comments section at the end of the form.

Items 1-5: For each element of the intervention session, mark “yes” or “no” to indicate whether all material in the counseling manual was covered. The focus of this section is to determine adherence to key elements of the curriculum. Mark “not taped” to indicate any element that is not covered because the taped was turned off or due to a taping error. “No” indicates that an element was missed, whereas “not taped” indicates that the element was covered during a time when the recorder was turned off (according to notes from the site facilitator).

Items 6-14: After reviewing the entire session, rank each qualitative item as “not adequate,” “acceptable.” The focus of this section is to assess the quality of the delivery and presentation to study participants. If there are items that cannot be assessed because only part of the session was taped, mark “could not evaluate.” If only a partial tape is available for review, rank those items that are evaluable; do not penalize for items that are not taped.

Record additional comments to more accurately describe the session, particularly in the event of unusual circumstances, in the space at the bottom of each page.

Figure 6-42
Intervention Session 6 (INF-1–INF-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		RTI Monitoring—Intervention Session 6 (INF-2)			
 HPTN 037 Sessions (105) INF-2 (222)	Page 2 of 2				
Group ID <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 8px; margin-top: 2px;"> Site Number Group </div>		RTI Monitoring— Intervention Session 6			
<p>Instructions: Rate the session using the scale from 1–3 to indicate overall qualitative assessment.</p>					
		<i>not adequate</i>	<i>acceptable</i>	<i>good</i>	<i>could not evaluate</i>
6. Follows script	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Time management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Neutral/non-judgemental delivery.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Maintains focus on group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Listens and integrates participant comments with group activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Uses suggested discussion questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Overall delivery of session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Attempted to include all participants in discussion.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Ensures accuracy of information discussed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Section 7. Visit Checklists

This section contains templates for visit and contact checklists for each scheduled study visit and contact. As noted in Section 3.2.2, these checklists are a convenient tool to guide staff in proper study procedures and sequence and help ensure that all required procedures are completed before participants leave the study site. Site-specific tailoring of the checklists may be undertaken. All checklists should bear a version number and date. 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.

Screening Procedures for Index Participants – Pre-test Visit (Visit 1.0)

Forms required at this visit:

- Index Consent for Screening (non-DataFax)
- Consent quiz (if used at pre-test)
- Screening Log and Database (non-DataFax)
- Index Screening Assessment
- Demographics Form
- Locator Form (non-DataFax)
- Risk Assessment Form
- LDMS Tracking Form (non-DataFax)
- Compensation Record, if required (non-DataFax)
- Signed and dated chart notes (non-DataFax)

- Introduce the study; explain the informed consent and screening process; provide a brief overview of the benefits and risks, procedures and requirements (study visits, intervention procedures, randomization process, blood draws, questions about drug use and sexual behavior, recruitment of network members, etc).
- Administer Index Consent for Screening; answer all questions; emphasize need for visit compliance; obtain volunteer's signature and offer the volunteer a copy of the consent form to keep. (Informed consent for study enrollment should be a process that begins at the initial screening visit and continues throughout screening and at every contact.)
- Assign PTID number; enter into Screening Log and Database as soon as possible.
- Complete **Index Screening Assessment** (If any response indicates ineligibility, stop - no further assessments are to be made; document the reason for ineligibility in a chart note).
- Complete **Demographics Form** on eligible volunteers.
- Collect identifying and contact information and complete Locator Form.
- Administer **Risk Assessment Form**. *Someone other than the HIV counselor* must administer the risk assessment prior to the delivery of HIV counseling.
- BEFORE participant goes to counselor, check consent for accurate signatures and dates; review data forms to ensure completion and accuracy.
- Provide HIV pre-test and risk reduction counseling; document in signed and dated chart note.
- Collect 4-8 mls of blood according to local procedures for HIV testing and plasma storage and complete the LDMS Tracking Form. If using rapid testing, perform rapid test per standard clinical procedures.
- If using non-rapid tests, schedule next screening and post-test counseling visit to occur in approximately 7 days. 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 post-test counseling visit. Document in a signed and dated chart note.

— If using rapid tests, proceed to post-test checklist when result is ready.

Screening Procedures for Index Participants – Pre-test Visit (cont'd)

— Document the visit in a signed and dated chart note.

— Provide compensation and document on Compensation Record (if using non-rapid test).

— Perform quality assurance measures on required data collection forms for accuracy.

Submit DataFax forms to SCHARP only after the index and their network members have been randomized.

Screening Procedures for Index Participants – Post-test Visit (Visit 1.0)

Forms required at this visit:

- Screening HIV Status Form
- Post-Test Visit Form
- Consent for Enrollment of Index Participants (non-DataFax)
- Consent quiz
- Network Inventory Survey (non-DataFax)
- Network Summary
- Network Norms
- Cards for prospective members
- LDMS Tracking Form (non-DataFax, if additional sample has been drawn)
- Compensation Record (non-DataFax)
- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart notes (non-DataFax)

Between initial pre-test and post-test screening visits:

- Receive the participant's HIV test results.
- Document results on the **Screening HIV Status Form**; if the HIV test is indeterminate, repeat the test; complete form when final status has been determined.
Note: Participant must have a negative ELISA in order to be eligible for the study.

Post-test counseling or subsequent screening visits:

- Confirm participant identity and PTID number (if using non-rapid test).
- Review/update participant contact and locator information (if using non-rapid test). Document any changes with a signed and dated note on the Locator Form.
- Provide HIV post-test and risk reduction counseling; document in signed and dated chart notes. *The same counselor that provided pre-test counseling should administer post-test counseling if possible.*
- Complete **Post-Test Visit Form**.
- Refer to local health care, social services, and/or other providers if needed.

If HIV infection is suspected (i.e., the ELISA is positive), the participant is ineligible:

- Discontinue the study screening and enrollment process and document reason for ineligibility on site source records.
- Provide counseling and referrals for confirmatory testing; document in a signed and dated chart note.
- Provide compensation and document on Compensation Record.

Screening Procedures for Index Participants – Post-test Visit (cont'd)

If HIV infection is ruled out (i.e. ELISA is negative), the volunteer can continue the screening process.

- Confirm volunteer's continued willingness to participate. If the volunteer is unwilling to continue the screening process, document reason for refusal or unwillingness in a signed and dated chart note and contact any network members who have presented for screening.
- Review the prospective visit schedule with the volunteer to confirm his/her availability.
- Explain the study and screening process; have the volunteer read the Consent for Enrollment of Index Participants (or read it to him/her) and carefully explain all aspects of the study and answer all questions.
- Administer Informed Consent Quiz. Document discussions in a signed and dated chart note.
- Administer Consent for Enrollment of Index Participants; obtain all signatures and dates and offer volunteer a copy of the consent form to keep. If the volunteer does not accept a copy, document this in a chart note.
- Administer Network Inventory Survey (record answers on grid).
- Complete **Network Summary Form**.
- Complete **Network Norms Form**.
- Assign Network ID Number; indicate on Network Grid. Add Network ID number to other data forms; initial and date when network ID is added to forms.
- Determine the network members that are eligible for recruitment by the index member. Assign network and member ID numbers to each prospective network member (record on Grid Form). Provide a recruitment card to the prospective index for each network member.
- Provide volunteer with instructions for contacting the site with questions or concerns.
- Inform participant that he/she will be contacted during the next 1 to 2 months (prior to Day – 60) to monitor the success in recruitment of their network members.
- BEFORE participant leaves, check consent for accurate signatures and dates; review data forms to ensure completion and accuracy.
- Document the visit in a signed and dated chart note.
- Provide compensation and document on Compensation Record.
- Perform quality assurance measures on required data collection forms for accuracy.

Submit DataFax forms to SCHARP only after the index and their network members have been randomized.

Screening Procedures for Network Members – Pre-test Visit (Visit 1.0)

Forms required at this visit:

- Network Member Consent for Screening and Enrollment (non-DataFax)
- Consent quiz
- Screening Log and Database (non-DataFax)
- Member Screening Assessment
- Demographics Form
- Locator Form (non-DataFax)
- Risk Assessment Form
- LDMS Tracking Form (non-DataFax)
- Compensation Record (non-DataFax)
- Signed and dated chart notes (non-DataFax)

- Confirm identity of volunteer with recruitment card bearing the network ID and member ID number and/or the description provided by their prospective index participant.
- Introduce the study; explain the informed consent and screening process; have the volunteer read the Network Member Consent for Screening and Enrollment (or read it to him/her) and carefully explain all aspects of the study and answer all questions.
- Administer Informed Consent Quiz. Document discussions in a signed and dated chart note.
- Administer Network Member Consent for Screening and Enrollment; obtain all signatures and dates and offer volunteer a copy of the consent form to keep. If the volunteer does not accept a copy, document this in a signed and dated chart note.
- Assign PTID number; enter into Screening Log and database.
- Complete **Member Screening Assessment** (If any response indicates ineligibility, stop - no further assessments are to be made; document the reason for ineligibility in a signed and dated chart note).
- Complete **Demographics Form**.
- Collect identifying and contact information and complete Locator Form.
- Administer **Risk Assessment Form**. *The risk assessment must be administered prior to the delivery of HIV counseling by someone other than the counselor.*
- BEFORE participant goes to counselor, check consent for accurate signatures and dates; review data forms to ensure completion and accuracy.
- Provide HIV pre-test and risk reduction counseling; document in a signed and dated chart note.
- Collect 4-8 mls of blood according to local procedures for HIV testing and plasma storage and complete the LDMS Tracking Form. If using rapid testing, perform rapid test per standard clinical procedures.

Screening Procedures for Network Members – Pre-test Visit (cont'd)

- If using non-rapid tests, schedule next screening and post-test counseling visit to occur in approximately 7 days. 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 post-test counseling visit.
- If using rapid tests, proceed to post-test checklist when results are available.
- Document the visit in a signed and dated chart note.
- Provide compensation and document on Compensation Record.
- Perform quality assurance measures on required data collection forms for accuracy.

Submit DataFax forms to SCHARP only after the index and their network members have been randomized.

Screening Procedures for Network Members – Post-test Visit (Visit 1.0)

Forms required at this visit:

- Screening HIV Status Form
- Post-Test Visit Form
- Network Norms Form
- Compensation Record (non-DataFax)
- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart notes (non-DataFax)

Between initial screening and post-test counseling visit:

- Receive the volunteer's HIV test results.
- Document results on the **Screening HIV Status Form**.

Post-test counseling visit:

- Confirm volunteer identity and PTID number (if using non-rapid test).
- Review/update volunteer contact and locator information (if using non-rapid test). Document any changes with a signed and dated note on the Locator Form.
- Disclose HIV test results and provide post-test and risk reduction counseling; document in a signed and dated chart note. *The same counselor that provided pre-test counseling should administer post-test counseling if possible.*
- Refer to local health care, social services, and/or other providers if needed.
 - If HIV infection is suspected (i.e., the test results are positive or indeterminate) provide counseling and referrals for confirmatory testing; document in a signed and dated chart note.

Regardless of HIV status

- Complete the **Post-Test Visit Form**.
- Review the study and screening process with the volunteer.
- Review the prospective visit schedule (dates of future visits if enrolled on this day) with the volunteer to confirm his/her availability.
- Confirm the volunteer's continued willingness to participate. If the volunteer is not able or unwilling to continue the screening process, document reason for refusal or unwillingness in a signed and dated chart note.
- Complete Network Norms Form. May be administered by counselor or interviewer.
- Document the visit in a signed and dated chart note.

Screening Procedures for Network Members – Post-test Visit (cont'd)

- BEFORE participant leaves, check consent for accurate signatures and dates; review data forms to ensure completion and accuracy.
- Provide compensation and document on Compensation Record.
- Inform Network member that the study staff may try to contact them in the next few weeks to inform them of their enrollment status.
- Perform quality assurance measures on required data collection forms for accuracy.

Submit DataFax forms to SCHARP only after the index and their network members have been randomized.

Enrollment Procedures for Index and Network Participants

Day 0 – Randomization (Network Enrollment)

Forms required at this visit:

- Index and Network Member Eligibility Checklist
- Randomization List
- Randomization/Enrollment Form (Index and Network Member)
- Signed and dated chart notes
- Signed and dated note in site administrative binder

Prior to Randomization:

- Review all source documents of each individual to ensure eligibility.
- Complete and/or review Index and Network Member Eligibility Checklists.
- Send e-mail to SCHARP at least 24 hours prior to randomization indicating the scheduled date of the randomization and the number of networks to be randomized.

On the Day of Randomization:

Note: The randomization procedure must be conducted by one staff member and witnessed by a second. These staff must not be interviewers who should remain blind to study arm assignment.

- Compile a list of PTIDS of eligible index participants in numerical order from lowest to highest PTID. Confirm that each index has successfully recruited at least one eligible network member.
- Select a randomization packet based on the number of participants to be randomized.
- Document PTID on the Randomization List. The second column of each line contains the assignment for that PTID.
- Confirm that PTID's are in ascending order.
- Submit the Randomization List to SCHARP using DataFax.
- Complete the **Randomization/Enrollment Form** for all Index and Network Members enrolled.
 - If the index participant is randomized to the intervention arm, schedule the next 6 intervention session appointments, 3-month locator contact and 6-month follow-up visit.
 - If the participant is randomized to the control arm, schedule the 3-month locator contact and 6-month follow-up visit.
- Store the lists and packets, which are source documents, in a separate confidential file (to prevent unblinding by staff). Return any un-opened randomization envelopes to SCHARP

via a traceable courier (i.e. FedEx) at the end of the study enrollment period.

Enrollment Procedures for Index and Network Participants

Day 0 – Randomization (Network Enrollment) cont'd

- Document the date and time of the randomization procedure in the site administrative binder. Include the name of the person conducting the randomization and the name of the witness.
- Contact index participants to notify them of their enrollment status and schedule of visits. Document in a signed and dated chart note.
- Inform the Network Members of their enrollment status and confirm appointments for 3-month locator contact and 6-month follow-up visit. Document this with a signed and dated chart note.
- Review all required screening forms for accuracy for both index and their network members and, if randomized, submit to SCHARP. Ensure that Network ID numbers have been added to all documents; **initial and date all added data**.

WITHIN 2 WORKING DAYS, submit the following DataFax forms to SCHARP for each randomized index and their network member(s):

Index Member:

- Index Screening Assessment
- Demographics Form
- Risk Assessment Form
- Screening HIV Status Form
- Post-Test Visit Form
- Network Summary
- Network Norms
- Index Eligibility Checklist
- Randomization/Enrollment Form

Network Member(s):

- Member Screening Assessment
- Demographics Form
- Risk Assessment Form
- Screening HIV Status Form
- Post-Test Visit Form
- Network Norms
- Member Eligibility Checklist
- Randomization/Enrollment Form

Intervention Session Visits for Index Members 1 Thru 6 Weekly Sessions (Day 0 To Week 4) And 6- And 12-Month Booster Sessions

Forms required at this visit:

- Attendance Sign-in Sheet
- Intervention Session Participation Log*
- Site Session Content Checklists (non-DataFax)
- Reminder cards if used
- Booster Session Participation Log**
- Compensation Record (non-DataFax)
- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart notes (non-DataFax)

- Confirm participant identity and PTID number.
- Review/update participant contact and locator information. Document any changes with a signed and dated note on the Locator Form.
- Complete Attendance Sign-in Sheet and document content delivered on Site Session Content Checklist.*
- Complete Site Session Content Checklists.*
- Complete **Intervention Session Participation Log**.*
- Complete **Booster Session Participation Log****
- Complete Compensation Record.
- Schedule next intervention session unless it is the 12-month booster session. If it is the 12-month booster session, confirm schedule for 15-month locator contact and 18-month follow-up visit.
- Document the visit in a signed and dated chart note.

WITHIN 2 WORKING DAYS, submit DataFax forms to SCHARP.

* 1-6 weeks sessions only

** Booster sessions only

Locator Contact (Month 3, 9, 15, 21, and 27) for Index and Network Members

Form required at this visit:

- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart notes (non-DataFax)

- Confirm participant identity and PTID number.
- Review/update participant contact and locator information. Document any changes with a signed and dated note on the Locator Form.
- Confirm appointment for the next Follow-up Pre-Test Visit.
- 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 next 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.

Follow-up Pre-Test Visit (Months 6, 12, 18, 24 and 30) for Index and Network Participants (Visits 3.0-7.0)

Forms required at this visit:

- Risk Assessment Form
- Network Inventory Survey (**Index Only** non-DataFax)
- Network Summary Form (**Index Only**)
- Network Norms Form (**12 and 24 months only**)
- Social Impact Assessment, if needed
- Social Impact Log, if needed
- Exposure/Contamination Assessment
- LDMS Tracking Form (non-DataFax)
- Compensation Record, if required (non-DataFax)
- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart notes (non-DataFax)

- Confirm participant identity and PTID number.
- Review/update participant contact and locator information. Document any changes with a signed and dated note on the Locator Form.
- Review elements of informed consent as needed. Remind participants of length of study and of how much has been completed. *NOTE: A new consent may have been issued since the last visit. If so, determine if participant needs to be re-consented.*
- Administer **Risk Assessment Form**. *The risk assessment must be administered prior to the delivery of HIV counseling by someone that is blinded to the participants study arm.*
- Administer Network Inventory Survey (record answers on grid) [**Index Only**].
- Complete **Network Summary Form** [**Index Only**].
- Complete **Network Norms Form (12 and 24 months only)**.
- Complete **Social Impact Assessment** as needed in response to participant report.
- Complete **Social Impact Log** as needed in response to participant report.
- Complete **Exposure/Contamination Assessment**.
- BEFORE participant goes to counselor, review consent, if needed, and data forms to ensure completion and accuracy.
- If participant is HIV infected based on prior testing, provide risk reduction counseling, **but do not collect blood**; document in a signed and dated chart note.
- If participant is HIV uninfected based on prior testing, provide HIV pre-test and risk reduction counseling; document in a signed and dated chart note.

Follow-up Pre-Test Visit (Months 6, 12, 18, 24 and 30) for Index and Network Participants (cont'd)

- Collect 4-8 mls of blood according to local procedures from HIV-uninfected participants for HIV testing and plasma storage and complete the LDMS Tracking Form. If using rapid testing, perform rapid test per standard clinical procedures.
- If using standard testing, schedule next post-test counseling visit to occur in approximately 7 days. For rapid tests, proceed with post-test checklist when test result is available.
- Schedule next locator contact and follow-up pre-test visits, as required.
- 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 next visit. Document in a signed and dated chart note.
- Provide compensation and document on Compensation Record (if using non-rapid test).
- Document the visit in a signed and dated chart note.
- Perform quality assurance measures on required data collection forms for accuracy.

WITHIN 2 WORKING DAYS, submit DataFax forms to SCHARP.

Follow-up Post-Test Visit (Months 6, 12, 18, 24 and 30) for Index and Network Participants (Visits 3.0-7.0)

Forms required at this visit:

- Follow-up Local Lab Results Form, if needed
- LDMS Tracking form, if needed (non-DataFax)
- Compensation Record (non-DataFax)
- Signed and dated chart notes (non-DataFax)

Between Pre-test and Post-Test Visits:

- Receive the participant's HIV test results, if needed.
- Document results on the **Follow-up Local Lab Results Form**, if needed.

During the Follow-up Post Test Visit:

- Confirm participant identity PTID number.
- Disclose HIV test results and provide post-HIV test and risk reduction counseling to HIV-uninfected participants; document in a signed and dated chart note. *The same counselor that provided pre-test counseling should administer post-test counseling if possible.*
- Refer to local health care, social services, and/or other providers if needed.
- If HIV infection is suspected (i.e., the Western Blot on the first sample is positive or indeterminate):
- Collect blood for confirmatory HIV WB and plasma storage. Complete LDMS tracking form.

After confirmation of test:

- Update the **Follow-up Local Lab Results Form** with results of any repeated tests.

Regardless of HIV test result:

- Confirm the date of the next contact and follow-up pre-test visits.
- 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 post-test counseling visit. Document in a signed and dated chart note.
- BEFORE participant leaves, review data forms to ensure completion and accuracy.
- Provide compensation and document on Compensation Record.
- Perform quality assurance measures on required data collection forms for accuracy.
- Document the visit in a signed and dated chart note.

WITHIN 2 WORKING DAYS, submit DataFax Forms to SCHARP.

Interim Contact Visit for Index and Network Members (Visit X.X)

Forms required:

- Follow-up Local Lab Results Form, if required
- LDMS Tracking Form, if required (non-DataFax)
- Social Impact Assessment, if needed
- Social Impact Log, if needed
- Comments Form, if needed
- Signed and dated Locator Form note, if needed (non-DataFax)
- Signed and dated chart note* (non-DataFax)

*Signed and dated chart note at a minimum is required for interim visits

- Confirm participant identity and PTID number.
- Review/update participant contact and locator information. Document any changes with a signed and dated note on the Locator Form.
- Confirm appointment for the next Follow-up Visit.
- 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 next Follow-up Visit; document in signed and dated chart note.
- Provide interim HIV counseling and testing as needed in response to the participant's concerns and reports of potential exposure to HIV. Complete LDMS Tracking Form if required. Document all test results on a **Follow-up Local Lab Results Form**.
- Complete **Social Impact Assessment** as needed in response to participant report.
- Complete **Social Impact Log** as needed in response to participant report.
- Refer participant to local healthcare, social service, and/or other providers if needed.
- Record any additional information on a Comments Form, if needed.
- Document the contact in a signed and dated chart note.
- Perform quality assurance measures on required data collection forms for completeness and accuracy.

WITHIN 2 WORKING DAYS, submit DataFax forms to SCHARP.

Section 8. Participant Retention

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.

8.1 Definitions of retention

The term “retention” refers in general to completion of study follow-up visits and procedures as specified in the study protocol at the specified timepoints. In HPTN 037, for follow-up visits, retention is based on whether participants complete scheduled follow-up visits. Participants who complete their visits will be considered “retained” for those visits. At the end of the study, retention is defined based on whether participants complete their last expected study visit. Participants who complete their last expected visits, and undergo HIV testing at these visits, if applicable, will be considered “retained.”

As indicated above, during the study, participants who do not complete a particular scheduled visit, but then complete the next scheduled visit, will not be considered retained for the missed visit, but will be considered retained for the next scheduled visit. Thus retention rates can fluctuate over time and across visits. Importantly, retention can be improved by ensuring that participants return for their next scheduled visit after missing a visit.

SCHARP will generate retention reports during the study presenting retention rates for key study visits designated by the Protocol Team. SCHARP will generate a final end-of-study retention rate for each site after the study is completed (see also Section 9).

8.2 Retention Requirements

Each study site will target retention of at least 90% of enrolled study participants annually. The purpose of this retention target is to ensure the accuracy of the study results. The primary objective of HPTN 037 is to estimate the rate of new HIV infections among IDUs at each study site. HIV infection rates are calculated as the number of study participants who become infected with HIV during a study divided by the total amount of participant follow-up time observed in a study. Follow-up time in a study is usually expressed in “person-years” and depends on the number of participants enrolled in a study, and how long each participant stays in a study. Low retention rates can have serious impacts on the HIV infection rates observed during a study because we cannot know if those who do not return for testing are HIV positive or negative. The observed rate could be higher or lower than the true rate, but it is not possible to determine the direction of the error. To avoid this problem, high rates of participant retention must be maintained throughout a study.

8.3 Obtaining and Updating Locator Information

Successful retention begins with collection of exhaustive locator information from each study participant. All study participants will be asked to provide locator information at the Screening/Enrollment 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.

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/her 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 caseworker, etc.
- Name, address, telephone number, and/or other contact information for support groups, shelters, food pantries, temples, etc. frequented by the participant.

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.

8.4 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 targeted 90% annual retention rate. The retention plan — including a copy of the study locator form — should be stored with the “local study-specific SOPs”.

It 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:

1. Work with local CAB and community members to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
2. 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).

3. Inform local service providers who interact with the local study population about the study, so that they also can express their support for it.
4. Dedicate adequate staff time and effort to retention efforts.
5. Emphasize the value of the participant's involvement in the study during the study informed consent process and subsequently at follow-up visits.
6. 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.
7. Prepare a calendar of scheduled contacts and visits for each enrolled participant, based on his/her enrollment date. Offer small calendar as an incentive. Maintain a copy in the participant's file for easy reference.
8. 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.
9. Always schedule the participant's next contact and/or visit before he/she completes the current contact or visit. Give the participant an appointment card with the scheduled contact or visit date and time noted.
10. 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.
11. 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.
12. 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.
13. 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 again later.
14. 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.
15. Post outreach workers at other local service organizations utilized by the study population.
16. Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
17. 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.
18. If a participant reports that he/she wishes to discontinue participation in the study, ask if he/she would be willing/interested to continue having semiannual HIV testing, or at least a final study test. If the participant refuses this level of involvement, explain that he/she is always welcome to come back if he/she wishes.

Section 9. Study Reporting Requirements

This section describes the routine reports that will be produced during HPTN 037 and the components of those reports, as well as the activities relating to data cleaning and quality control.

9.1 Reports

This section describes the various reports SCHARP and/or the study sites will produce. The following are described for each report: purpose, frequency, who will prepare the report, who will receive the report, and components of the report. Table 1 summarizes the reporting schedule.

Table 1: Reporting Schedule

Report	Frequency	
	Months 1-30	Months 30 to study end
Screening/Enrollment	Weekly	
Enrollment/Retention	Monthly	Monthly
Data QC Reports	Every 2 weeks	Every 2 weeks
Data Quality Summary	Quarterly	Quarterly

In general, routine reports generated from the SCHARP database (e.g., QC Reports, Enrollment/Retention Reports) will include data submitted by the sites up to 10 calendar days prior to the date of the report.

9.1.1 Screening/Enrollment Report

Purpose: To monitor the completion of screening visits and enrollments at each study site in real time.

Responsibility for Preparation: HPTN 037 Site Study Staff; Site Coordinators

Frequency: Weekly, during enrollment only.

Distribution List: Distributed by e-mail to HPTN 037 Protocol Team

Components: Minimally, by each site, the number of individuals screened, the number eligible, and the number enrolled into the study.

9.1.2 Enrollment/Retention Report

Purpose: To monitor participant accrual and retention by site as reflected by data submitted to SCHARP and entered into the study database.

Responsibility for Preparation: SCHARP HPTN 037 SAS Programmer

Frequency: Monthly for duration of the study.

Distribution List: Distributed by e-mail to HPTN 037 Protocol Team

Components:

Enrollment: For all sites, the number enrolled individually, the number of networks enrolled each week, and a comparison with enrollment targets.

Retention: For all sites by visit, the numbers of active participants, inactive participants, active participants expected for visit, active participants expected for visit who have had a visit.

9.1.3 Data Quality Control Reports

Purpose: To identify and correct missing and inconsistent data in the database.

Responsibility for Preparation: SCHARP HPTN 037 Data Coordinator and SAS Programmer.

Frequency: Reports are produced and distributed every two weeks.

Distribution List:

1. Site Coordinators or Site Data Managers via e-mail (site-specific report).
2. SCHARP HPTN 037 Data Coordinator
3. SCHARP HPTN 037 Protocol Operations Coordinator

Components:

1. Fax re fax list (identifies missing pages, overdue visits, missing data, and other data questions).
2. Questions and answers (addresses more complex problems).

9.1.4 Site QC Performance Report

Purpose: To summarize site performance regarding QCs and resolution of QCs.

Responsibility for Preparation: SCHARP HPTN 037 Protocol Operations Coordinator.

Frequency: Quarterly.

Distribution List:

1. Site Principal Investigators.
2. Site Coordinators and Site Data Managers.
3. Designated members of HPTN 037 Protocol Team.

Components: Site performance, including total number of records submitted, time to submission, total number of QC notes, average number of days to resolution, total number of “clean” records (those without queries), and rate of clean records.

Section 10. Laboratory Procedures

This section contains instructions related to laboratory procedures required by HPTN 037. Each study site will adhere to standards of good laboratory practice, the HPTN Laboratory Standard Operating Procedures and their site-specific Standard Operating Procedures for proper collection, processing, labeling, and transport of specimens. All specimens will be shipped in accordance with IATA specimen shipping regulations. Storage and shipping will be documented using the HPTN Laboratory Data Management System (LDMS).

HPTN 037 requires specimen collection and processing for HIV serology at the local laboratory (LL) as well as specimen storage for possible quality assurance (QA) testing at the HPTN Central Lab and possible future research testing. Identical procedures are followed at each HIV testing time point, as described below.

10.1 Biohazard Containment

As the transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions will be employed by all personnel in the drawing of blood and shipping and handling of all specimens for this study, as currently recommended by the Centers for Disease Control and Prevention (CDC). A copy of the CDC's guidelines entitled "Universal Precautions For Prevention Of Transmission Of HIV And Other Bloodborne Infections" can be found at:

<http://www.cdc.gov/ncidod/hip/Blood/universa.htm>. The WHO's guidelines, entitled "Universal Precautions, Including Injection Safety" can be downloaded at:
<http://www.who.int/hiv/topics/precautions/universal/en/>.

10.2 The Laboratory Data Management System (LDMS)

The LDMS is used to track the collection, storage, and shipment of laboratory specimens. A copy of the current LMDS manual can be obtained at <http://www.fstrf.org/ldms/ldms.html>. Questions about SCHARP pre-printed label supply and pre-LDMS-entry labeling procedures for this study can be directed to one of the SDMC/SCHARP Protocol Operations Coordinators, Tom Perdue or Eileen Hess. Questions about LDMS and specimen collection, shipping and storage should be raised with the HPTN Central Lab Manager, Estelle Piwowar-Manning (phone 410.614.6736, e-mail epiwowa@jhmi.edu). For problems or technical questions only about LDMS, contact the LDMS User Support (716-834-0900 x311 or hptn.ldms.usersupport@fstrf.org).

10.2.1 SCHARP-supplied Specimen Labels and Tracking Sheets

SCHARP will prepare and ship label sets and Specimen Tracking Sheets specific for 037 to each study site prior to the start of the protocol. Study staff will apply two labels – one with the participant ID and the other with the specimen collection date-- to each specimen tube prior to specimen collection. Staff will also attach two bar-coded labels corresponding to each specimen to the Specimen Tracking Sheet (See LDMS Figure 1). The date labels should be checked to ensure that the date is correct.

Participant ID labels:

- **Small non-barcoded participant identification (PTID) labels:** One or more pages of small labels will be prepared for each assigned participant ID. These labels will have the protocol number and participant ID printed on them and will be placed directly on the specimen collection container or tube at the time of collection. The labels are small enough to fit on all specimens.
- **Large barcoded participant identification (PTID) labels:** These labels will have the protocol number and participant ID embedded in the barcode, with readable information below each bar code. These bar coded labels will be applied to the top of the Specimen Tracking Sheet, which will accompany each specimen shipment to the local laboratory where the specimens will be stored.

Both the small and the large bar coded participant ID label sheets should be placed in the participant's folder (or chart) once a participant has been assigned an ID number. On the day of a participant visit when a blood draw is scheduled, the participant ID labels will be taken out of the participant's folder and brought to the phlebotomy location, where the date labels and blank Specimen Tracking Sheets are kept.

Specimen Collection Date labels:

- **Small non-barcoded specimen collection date labels:** One or more pages of small labels will be prepared for each potential study day. These labels will have the date printed on them and will be placed directly on the specimen collection container or tube at the time of collection. The labels are small enough to fit on all specimens. Enough date labels will be printed to accommodate the largest anticipated need for a peak participant visit day.
- **Large barcoded specimen collection date labels:** Larger size labels will have the date barcoded, with readable information below each barcode. These labels will be applied to the bottom of the Specimen Tracking Sheet, which will accompany each specimen shipment to the local laboratory where specimens will be stored. A sufficient supply of date labels will be printed to accommodate the largest anticipated need for a peak visit day.

All specimen collection date labels should be kept in the location where specimens will be labeled, prior to a participant visit. Each day, the clinic staff will confirm that the specimen collection date label sheets (both the small specimen collection date label sheet and the larger bar coded specimen date label sheet) are for the current date. At the end of each day, all unused date labels with that day's date should be destroyed to ensure the labels are not used in the future.

Specimen Tracking Sheet:

This sheet identifies and accompanies each specimen entered into LDMS. The purpose of the Specimen Tracking Sheet is to assist the local lab technician in entering the specimens received into LDMS.

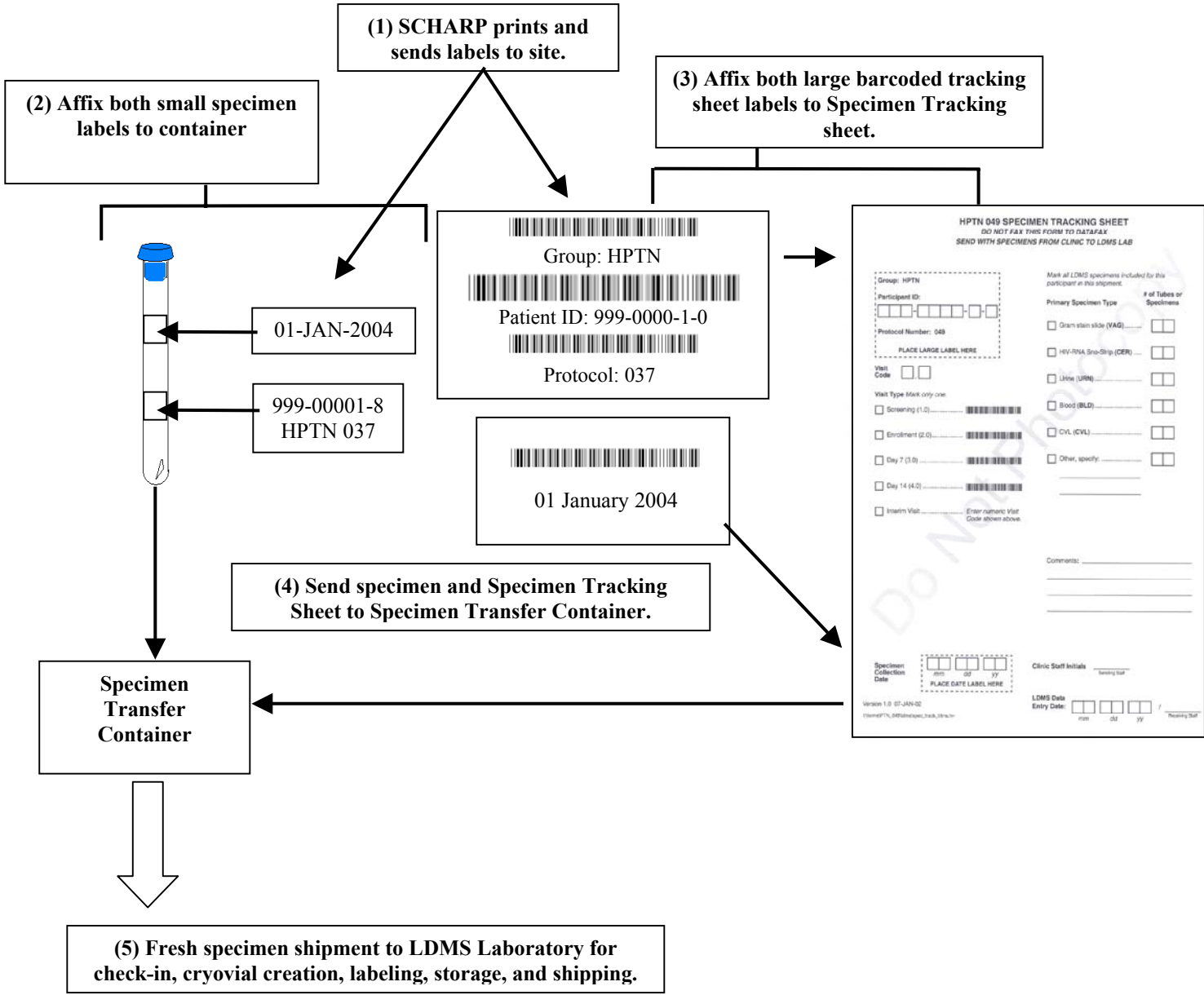
The Specimen Tracking Sheet should be prepared by placing one of the large barcoded participant ID labels on the top of a Specimen Tracking Sheet in the space shown on the sheet for a participant ID number. One of the large barcoded date labels will be applied at the bottom of the sheet over the location with the date boxes. The visit code will be written in the space provided, and the appropriate visit box/barcode will be checked. On the right side of the Specimen Tracking Sheet, the type of specimen sent to the local LDMS laboratory will be checked and the number of specimens sent will be written (for HPTN 037, only blood will be sent). All types of blood vacutainers are entered under the 'BLD' primary type.

The clinic staff will place all specimens collected at a participant visit into an appropriate specimen transfer container along with the Specimen Tracking Sheet that describes those specimens. If samples were collected from more than one participant, each set of specimens will be packaged together with its own Specimen Tracking Sheet. The LDMS laboratory should be notified that a specimen shipment is coming so that they will be ready for processing upon arrival.

See LDMS-Figure 1: 'Clinic Specimen Collection, Labeling and Storage' flow diagram for further clarification about LDMS Labels and Specimen Tracking Sheets.

LDMS-Figure 1

Clinic Specimen Collection, Labeling and Storage



10.2.2 LDMS Laboratory Specimen Processing and Storage

When the specimen shipment is received at the local laboratory, each package in the shipment will be checked to ensure that the all specimens in the package are for the same participant ID as the barcoded ID label on the Specimen Tracking Sheet and that the type and number of each specimen marked on the Specimen Tracking Sheet is correct. If discrepancies are noted, the clinic staff should be contacted and local procedures for QC and correction followed.

The LDMS laboratory tech will open the LDMS Specimen Management window and position the cursor at the Group box. Using the barcode scanner, the LDMS laboratory tech will scan the barcoded Group (HPTN) field on the Specimen Tracking Sheet. Next, the barcoded Participant ID number will be scanned followed by the protocol number. Scanning will automatically advance the cursor to the next field. At this point the cursor should be in the Visit box. The checked visit number will be scanned, which will enter the visit number and the type of visit ('VST').

This finishes entry of participant information and begins the primary specimen information entry. The barcoded specimen collection date will be scanned next. If the receipt date is the same as the specimen collection date then scan the collection date into the receipt date field, otherwise hand enter the receipt date. The rest of the information will be entered by hand, following the HPTN LDMS User Manual (Section 3, Specimen Management). Each type of specimen will then be logged in and the appropriate number of labels will be generated for that specimen type.

If the specimen is to be aliquoted and frozen, cryovial labels will be prepared using the LDMS system and printed on the LDMS printer using label stock certified for long term freezer storage and/or LN2 shipping. The Central Laboratory will specify all label stock to be used.

The LDMS-generated labels will be applied to each cryovial using standard procedures, which will be placed into a 9x9 freezer box that has already been logged into LDMS.

Each specimen in the box will be logged into the LDMS system using the Storage Management screen. The row and column of each specimen in the box will be entered into LDMS. The box will be added to the storage structure in LDMS.

Each container will then be placed into the LDMS-assigned freezer location or other assigned storage structure, according to LDMS specifications.

If specimens are designated by the protocol to be shipped either to the Central Laboratory, a specialty lab or to the NIAID Central Specimen Repository, the specimens will be checked out of the local freezer storage and placed into an appropriate shipping container using the LDMS system. The Central Laboratory will define shipping containers and packing and labeling procedures appropriate to the type of specimen. Shipments to the Central Lab or protocol specific labs will follow instructions in the protocol Study Specific Procedure manual.

An electronic shipping manifest will be created for each shipment by the LDMS system. The electronic manifest disk will be placed in the shipping container prior to final packing and pickup. After pickup, the electronic shipping manifest will also be sent as an e-mail

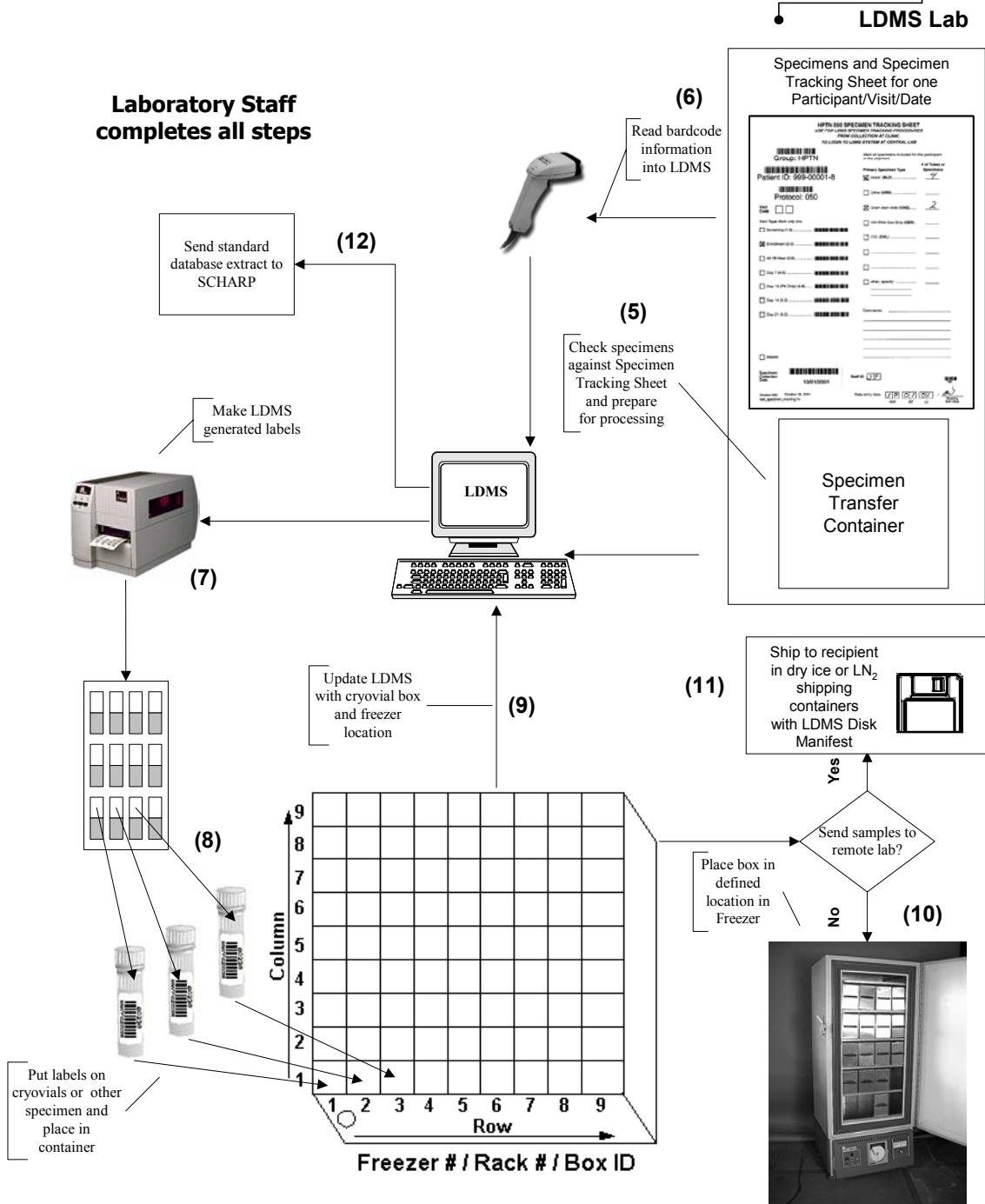
attachment to the intended recipient of the shipment. The email will include the name of the shipper and the shipment tracking number, so that the receiving laboratory can contact the shipper if the shipment does not arrive on schedule.

On a regular basis, at least monthly, the local LDMS laboratory data manager will create a standard database extract for shipment to the Statistics and Data Management center (SCHARP). This database extract, consisting of a set of database tables put inside of a PKZIP compatible format, will be sent to the Statistics and Data Management center either via direct dial modem, as an e-mail attachment, or on a floppy disk via courier (Fed. Ex, DHL). SCHARP will prepare a database of the current specimen collection for each local LDMS laboratory and of each specimen shipment. Prior to site monitoring, SCHARP will select a random selection of specimens presumed to be still in the local LDMS laboratory freezer so that the site monitor can conduct a specimen and LDMS data audit.

Refer to LDMS-Figure 2 for LDMS laboratory specimen processing.

LDMS-Figure 2

LDMS Laboratory Specimen Logging, Cryovialing, Storage and Shipping to Central Labs



10.3 Specimen Collection and Processing

This section describes how blood should be collected for immediate laboratory analysis and long-term storage. As a condition for study activation, each study site must establish an SOP for local specimen handling and maintenance of “chain of custody” related to testing for the primary study endpoints (safety and HIV). The CL must approve this SOP. The SOP should state how a sample is obtained, how the sample is transported from the clinic to the lab, what documentation accompanies each sample, how its departure from one place and arrival at another is documented, and how it is handled and processed once it reaches the lab. Specific information that must accompany the specimen includes the PTID, collection date, and visit code for each specimen. Specimen labels provided by the SDMC include this key information. Accountability for the samples must be maintained, with requirements for signatures of the involved parties (i.e., each individual who handled the specimen). The site SOP should also detail how the results are returned from the lab to the clinic as well as how problem samples are reported back to the clinic.

10.3.1 Screening

At the screening visit, blood samples will be collected for HIV testing and plasma storage. If using a standard EIA for HIV testing, site staff will collect eight mLs of blood from all participants using standard clinic practices. If using rapid testing, site staff may choose to perform *one* of the following procedures for all participants using standard clinic practices:

- Prick the participant’s finger for rapid testing and then collect four mLs of venous blood for specimen storage.
- Collect eight mLs of venous blood and use this specimen for both rapid testing and specimen storage.

HIV tests (EIA or rapid) will be performed according to local procedures. For non-rapid HIV tests, prospective index participants will be asked to return in approximately one week for their second counseling session and HIV test results. If using rapid testing, the potential participant will be asked to wait for the results. Those who test HIV-positive are not eligible for further screening and will receive post-test counseling and referrals.

All blood remaining after HIV testing will be processed for storage, as described in section 10.4.

10.3.2 Follow-up Visits

Four to eight mLs of blood will be collected from each participant for HIV testing and storage at the local laboratory at every follow-up visit as described above.

HIV infection status will be ascertained using one of the algorithms in Appendix I of the protocol. Sites may choose to use standard or rapid testing. If using rapid testing, study staff may choose to use one rapid test or two tests concurrently. All positive test results obtained during follow-up will be confirmed by Western Blot.

Refer to the package inserts included with the test kits used at each site for complete instructions. The site’s laboratory is responsible for reviewing the results and quality assuring all results.

All blood remaining after HIV testing will be processed for storage, as described in section 10.4.

10.4 Plasma Storage at the Local Lab

Participant plasma samples will come from the four to eight mL blood samples collected at screening and follow-up visits. The following steps should be followed to prepare the blood for storage:

- Log samples into the LDMS and generate LDMS labels.
- Process blood for plasma samples within 24 hours according to local procedures. Specimens can be stored at room temperature for up to 1 day, at 2–8° C for up to 5 days, or frozen at –80° C.
- Store 4 x 1.0 mL plasma aliquots using labeled [LDMS generated label] cryovials according to local procedures. Store any remaining plasma even if less than 1.0 mL aliquot.
- Store plasma aliquots in a -80° freezer at the local repository.

On a quarterly basis the HPTN CL will request shipment of specified stored plasma samples for QA testing at the CL. Within one week of receiving the CL request, retrieve the specific samples and ship them according to the instructions provided in section 10.6 to

**The Johns Hopkins University Hospital
c/o Estelle Piwowar-Manning
Department of Pathology
Pathology Building -Room 313
600 North Wolfe Street
Baltimore, Maryland 21287
USA**

Phone: +1 (410) 502-5296
Fax: +1 (410) 614-0430
email: epiwowa@jhmi.edu

10.5 Long Term Specimen Archive

All plasma specimens collected during the study will be stored on site throughout the study implementation period. The HPTN CL will provide instructions for long term specimen archive after the study is completed.

10.6 Shipping of Specimens to a Third Country or the US

Shipment of specimens outside the country will need to be in compliance with International Air Transport Association (IATA) Dangerous Goods Packing Instruction 602. The IATA Dangerous Goods Regulations are the worldwide gold standard for shipping. Each lab should have the current IATA manual (supplied by the HPTN Central Laboratory annually) and at least one person certified in IATA regulations; however, it is strongly suggested that more than person be certified. This certification needs to be renewed every two years.

All specimens need to be shipped in Infectious Substance Containers (ISC—either SAF-T-PAK-ISS-1 plastic containers or Sturdee Seal polypropylene canisters), small fiberboard boxes, overpack cartons and other packing materials as needed—all of which are in compliance with IATA Dangerous Goods Packing Instruction 602.

If specimens need to be shipped within the country, the site specific SOP should provide details for storage, packaging, and shipment.

10.7 JHU Shipping Instructions

1. The plasma samples should be placed in the cryovial box in the order of the shipping manifest for shipments greater than 15 vials. If less than 15 vials are to be sent, they can be placed in plastic shipping baggies inside the orange-topped shipping canister.
2. The orange-topped canister should have absorbent material included. This is then placed in the cardboard box, which is placed inside the polystyrene insulated box and the box filled with sufficient carbon dioxide (dry ice) to last at least 48 hours (either an ISS2, STP370 or STP 300). Likewise, the cryovial box should be wrapped in absorbent material and placed inside a shipping bag, sealed, and placed in the shipping container (either an ISS2, STP 370, or STP310).
3. Do not ship on Friday or the day before a holiday. Please call the laboratory around holiday times to check available days for shipping.
4. PAPERWORK: The appropriate CRF MUST accompany the shipment, as well as a LDMS shipping diskette, boxmap, and LDMS shipping manifest. The paperwork should NOT be placed in the dry ice, but between the polystyrene container and outer box. The shipping diskette should be placed in a diskette mailer.
5. Prior to shipment, please fax the Shipping Notice to Estelle Piwovar-Manning at 410-614-0430. If fax transmittal problems occur, please call the lab at 410-502-5296 to notify lab personnel that a shipment has been sent and provide the airway bill number. Any questions relating to specimen handling, shipping, or identification should be directed to Estelle Piwovar-Manning at 410-614-6736. Shipments may be made Monday through Thursday only by overnight courier service (Federal Express).

Section 11. Other Study Documents

This section contains:

- Network Interview Instructions
- Network Survey Screening
- Network Survey for Follow-up Visits
- Study Staff Roster and Signature Sheet
- DAIDS Investigator of Record Agreement

Network Interview Instructions

An important component of this study will include an interview that asks study participants questions about the people in their social and risk networks.

KEY POINTS WHILE CONDUCTING INTERVIEW:

- Allow sufficient time for participant to think through each of the questions.
- Use neutral, nonjudgmental probes and silence when needed.
- Remind participants that they will not be able to add names to this list after they leave today.

Network GRID:

The purpose of the Network GRID is to document the names (first name and initial of last name or nickname/street name) of people who are important to the Index participant in a number of functions. This GRID compiles all of the people mentioned by the Index participant so that it is a representation of the social network and a comprehensive representation of the Index participant's risk network participant.

The first section of the GRID (questions 1 - 9) is the name generating section. During this section the goal is to get the Index participant to identify as many people as applicable in response to the questions.

The second section of the GRID (questions 10-31) asks detailed questions about the network.

Description

Network GRID:

The Network GRID looks like a checkerboard with numbers sequentially running along the top and along the side.

- The numbers running along the top refer to the number of the **question** on the Network Section of the interview.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1														
2														
3														

1. If you wanted to talk to someone about things that are very personal and private or if a situation came up where you needed some advice, is there anybody you could talk to? Please tell me the first name and initial of the last name and nickname/street name of the people that you could talk to.

- The numbers running along the side of the table refer to the different names of the people identified by the Index participant.

	First name	Last Name	Nickname	1	2	3	4	5	6
1	James	P	JJ						
2	Roeina	M	Roe						
3	Stacy	J	Muffin						
4	Donny	G	Snoop Dog						
5	Dianne	T	Lady Di						
6	Tonya	J	Lil Bits						
7	Christine	B	Chrissy						
8	Denise	M	Neeceee						
9	Sabrina	M	Brina						

The Code

This code will be used to record the answers to questions 1-6 and 8-10.

Legend

[1]	one	YES
[0]	zero	NO
[7]	seven	Don't Know
[8]	eight	refused
[9]	nine	question does not apply
[-]	dash	person not named yet

Question 1: If you wanted to talk to someone about things that are very personal and private or if a situation came up where you needed some advice, is there anybody you could talk to? Please tell me the first name and initial of the last name and/or nickname/street name of the people that you could talk to.

	First name	Last Name	Nickname	1	2	3	4	5	6
1	James	P	JJ	1					
2	Roeina	M	Roe	1					
3	Stacy	J	Muffin	1					
4									
5									
6									
7									
8									
9									

After asking the question 1: the participant listed 3 people (James, Roeina, and Stacy). After writing down their names you indicate in the column 1 (for question 1) a "1" meaning that they are people they could talk to.

Question 2: If you needed to borrow \$25 or something valuable, is there anybody who you know would lend or give you \$25 or something that was valuable? Remember you might have listed these names before or they could be new names.

	First name	Last Name	Nickname	1	2	3	4	5	6
1	James	P	JJ	1	0				
2	Roeina	M	Roe	1	0				
3	Stacy	J	Muffin	1	1				
4	Donny	G	Snoop Dog	-	1				
5	Dianne	T	Lady Di	-	0				
6	Tonya	J	Lil Bits	-	1				
7	Christine	B	Chrissy	-	1				
8	Denise	MI	Neeceee	-	1				
9									

After asking question 2, the participant listed Stacy (again), and Donny, Dianne, Tonya, Christine and Denise (for the first time). You will enter a “1” for Stacy, Donny, Dianne, Tonya, Christine and Denise in column 2

The zero [0] indicates that James and Roeina were not mentioned in response for this question and the dashes [-] in column 2 indicate that Donny, Dianne, Tonya, Christine, and Denise were not indicated for the first questions.

Questions 3 and 4 are similar in the pattern that you use to collect and code the responses.

SEX NETWORK

Questions 5 – 7 are name generating questions pertaining to the participant’s sexual network.

Question 5: Have you had sex in the last 6 months? (even if it wasn’t with your primary partner) is to determine if the Index participant has been sexual active. If the participant responds “yes” enter a one “1” in column 5 for every one who has been listed as a network member for some function. This entry is used as a place holder and allows you to continue the interview without skipping a space.

Question 6: Of the people that listed so far whom did you have sex with in the last six months? [And ask] Who else did you have sex with in the past six months; [again this is to generate names and expand the list of sex network members]. Remember always probe for additional names. It is important to obtain a comprehensive list of all network members especially members in their drug use and sex networks.

The pattern that you use to collect and code the responses is the same as it was for Questions 1 – 4:

DRUG NETWORK

Questions 8 & 9 are name generating questions specifically pertaining to generating the names of participant’s drug network. **Remember, throughout the entire name generating phase of the network GRID; try to get the participant to name as many people as possible in response to the questions.**

END OF NAME GENERATING SECTION

Beginning with question 10, you will not be asking the client to identify any new names.

The remaining questions will be for the existing list of names, but the questions will not pertain to all of the names on the list.

The remaining questions follow similar response patterns as any other part of the survey.

For example: Some of the questions will have a: 0=NO or 1=YES response.
 Some questions have response categories 1=Everyday
 2=A few times a week
 3=A few times a month
 4=About once a month

Take Note:

- Question 10 & 11: Please tell me the age of each person you have listed?

	First name	Last Name	Nickname	10	11	12	13	14	15	16	17
1	James	P	JJ	4	4						
2	Roeina	M	Roe	3	0						
3	Stacy	J	Muffin	2	7						
4	Donny	G	Snoop Dog	4	0						
5	Dianne	T	Lady Di	3	2						
6	Tonya	J	Lil Bits	3	3						
7	Christine	B	Chrissy	3	5						
8	Denise	M	Neeceee	3	0						
9	Sabrina	M	Brina	3	0						

The response is a two digit age. Each digit of the age goes in a separate column.

- Question 12 - 15: What is each person's relationship to you, their gender & race?

	First name	Last Name	Nickname	8	9	10	11	12	13	14	15
1	James	P	JJ	0	0	4	4	0	2	M	W
2	Roeina	M	Roe	0	0	3	0	0	2	F	L
3	Stacy	J	Muffin	0	1	2	7	1	0	F	B
4	Donny	G	Snoop Dog	0	1	4	0	1	4	M	B
5	Dianne	T	Lady Di	0	0	3	2	1	7	F	W
6	Tonya	J	Lil Bits	0	1	3	3	2	0	F	W
7	Christine	B	Chrissy	0	1	3	5	3	1	F	B
8	Denise	M	Neeceee	0	0	3	0	2	1	F	B
9	Sabrina	M	Brina	0	1	3	0	3	1	F	W

The response is a combination of the relationship gender and race codes. Again, each digit gets entered into a separate column.

Relation Codes:

- | | | |
|----------------------------|------------------------|----------------------------|
| 1. husband/wife | 8. step-mother | 15. distant relative |
| 2. girlfriend/female lover | 9. step-father | 16. grandparent |
| 3. boyfriend/male lover | 10. sex client | 17. neighbor |
| 4. father | 11. casual sex partner | 18. shooting/running buddy |
| 5. mother | 12. uncle/aunt | 19. casual acquaintance |
| 6. daughter/son | 13. cousin | 20. drug/needle dealer |
| 7. sister/brother | 14. friend | 21. other (specify) _____ |

Race/Ethnic Codes:

White – “W”

African-American – “B”

Native American – “N”

Asian/Pacific Islander – “A”

Hispanic/Other – “L” if Hispanic “O” other

Question 16 - 18: I would like to know how long you have known each person you have listed?

The response for length of time is a combination of two digit numbers. First digit is entered in column 16 & second digit entered in column 17. The code for month or year is entered as “M” = month(s) & “Y” = year and entered in column 18.

	First name	Last Name	Nickname	12	13	14	15	16	17	18	19	20	21
1	James	P	JJ	4	0	2	M	0	5	Y			
2	Roeina	M	Roe	0	0	2	F	0	5	Y			
3	Stacy	J	Muffin	7	1	0	F	0	5	M			
4	Donny	G	Snoop Dog	0	1	4	M	0	4	Y			
5	Dianne	T	Lady Di	2	1	7	F	0	8	M			
6	Tonya	J	Lil Bits	3	2	0	F	0	4	M			
7	Christine	B	Chrissy	5	3	1	F	1	0	Y			
8	Denise	M	Neeceee	0	2	1	F	0	6	Y			
9	Sabrina	M	Brina	0	3	1	F	0	5	M			

Questions 26 – 29: Ask Questions 26 – 29 only for the Network members who **have used** drugs in the past six months [again use questions # 8 & 9 as a guide] Use the code pattern under each question to enter the appropriate response. Enter each response in the column that matches the question #. For Network members who HAVE NOT used drugs in the past six months enter a “9”

	First name	Last Name	Nickname	20	21	22	23	24	25	26	27	28	29
1	James	P	JJ	1	1	0	0	1	1	1	2	0	1
2	Roeina	M	Roe	0	1	1	0	1	1	0	1	0	0
3	Stacy	J	Muffin	0	0	0	0	0	0	0	9	1	0
4	Donny	G	Snoop Dog	0	0	0	0	0	0	0	9	0	0
5	Dianne	T	Lady Di	1	0	0	0	0	0	0	9	0	0
6	Tonya	J	Lil Bits	1	0	0	0	1	1	0	1	0	0
7	Christine	B	Chrissy	0	0	0	0	0	0	0	9	0	0
8	Denise	M	Neeceee	1	0	0	0	0	0	1	1	0	0
9	Sabrina	M	Brina	0	0	0	0	0	0	0	9	1	0

Questions #'s 30 & 31: For these questions enter the appropriate response according to the codes listed after each question and enter the response in the column number that matched the question #.

INSTRUCTIONS FOR DENSITY GRID

Q32: To code the density grid, put page one of the Network Grid on top. You have a list of all the people the participant mentioned in the names generating section. Now we want to find out who on this list is friends with who else on this list. Read the definition of friend. They do not need to be close friends. Relatives count as friends.

Definition of friend: These people might be friends, shooting or drinking buddies, family members, sex partners, professionals, or other people they know.

The numbers on the top refer to these number assigned to each name listed on the side. The numbers on the side refer to the names to the right of the numbers.

Starting with person 1 ask, “Is person 1 friends with person 2? Is person 1 friends with person 3?” and so on until the end of the list. Record “1” for yes and “0” for no. Then ask, “Is person 2 friends with person 3? Is person 2 friends with person 4?” and so on until the end of the list. Continue until you reach the next to last person. Ask if this person is friends with the last person on the list. At this point, you will have completed the density grid. **Never record 1 or 0 to the left of the black filled squares.**

Avoid going too fast through the density grid. Particularly if the participant has a large network, it can get tedious asking is this person friends with that person over and over again. You may feel tempted to rush along, but then you and the participant may make mistakes. So try to just keep up a steady pace and make sure the participant is really thinking about what you are asking. You can try to see if the responses given make sense based on the relationships you have recorded. If something seems wrong, it is fine to repeat the question. Be careful not to make assumptions. Sometimes brothers may not have ever met, for example.

Network Survey: (completed at Visit Code 1.0)

In this section I would like to get an idea of the people who are important to you in a number of different ways. I will be reading descriptions of ways that people may be important to you. After I read each description, I will be asking you to give me the first name and initial of the last name or the street name of each person in your life who fits the description. These people might be friends, shooting or drinking buddies, family members, sex partners, professionals, or other people you might know. We will keep all names and all information confidential.

Note to interviewers: this is a very important section of the survey. Give the respondents plenty of time to think about the types of people who fit these categories. Use pauses to allow for sufficient time for the respondents to recollect the names, especially for the risk network.

1. If you wanted to talk to someone about things that are very personal and private or if a situation came up where you needed some advice, is there anybody you could talk to? Please give me the first name and last name initial of all the people who **you would** talk to about things that are very personal and private?

Remember to probe, “is there anyone else?”

Code all listed network members as 1.

2. If you needed to borrow \$25 or something valuable, is there anybody you know **who would** lend or give you \$25 or more, or would give you something that was valuable?

Remember to go back to the people who were named in question #1 and ask “what about ...?”

Ask, “Is there anyone else who you can think of?” Always probe for additional people.

**Code all network members who Index would borrow \$25.00 from as 1 = YES
Code Network members on list who Index would not borrow \$25.00 from as 0 = NO**

3. Is there anybody that **you could** get together with to have fun or to relax **or just hang out with**? These could be new names or people you listed before.

Probe for additional names by asking, “Is there anyone else who you can think of?”

Code: 0 = No 1 = Yes

4. Is there anybody who **you could** ask for advice or help about health problems like: infections, gonorrhea, birth control, or AIDS? These might be people you have listed before or they could be new names.

Probe for additional names by asking, “Is there anyone else who you can think of?”

Code: 0 = No 1 = Yes

SEX NETWORK

5. Have you had sex in the last 6 months (even if it wasn't with your primary partner)?

No - code 0 (skip to q#8 – code 0 for all people listed on grid)

Yes - code 1 for everyone on the network list

6. Of the people that you listed so far whom **did you have sex with** in the last six (6) months?

Go down the network list and ask about each person on the list.

Remember to be eligible for this study you need to bring people into the study, the more people you name the more choices you have to bring people into the study. So think about if there are additional people who you have sex with, including people who may be casual sex partners. Since you will be asked to bring people into the study, the people you name should be people you see or talk to regularly.

Probe for additional names by asking, “Who else did you have sex with in the last six months?” Add the name(s) to the network list.

Code: 0 = No 1 = Yes 8 = Refused

7. How often do you use a condom with...?

Go down the network list & ask about each person on the list who they HAD sex with.

Code: 4 = All The Time

3 = Half the Time or More

2 = Less Than Half The Time

0 = Never

DRUG NETWORK

Now, I am going to ask you about another group of people, those who you do drugs with. These individuals may be close friends or casual acquaintances. The one requirement for listing them is that you have known them for at least one month. Remember whatever you say is completely confidential. You may give nicknames or street names. No one will know what you have said. If you have any questions about confidentiality please let us know.

Note: “Do drugs with” is defined as being in the same room when using drugs.

8. Who are the people that you do drugs with?

Go down the network list and ask about each person on the list.

Additional probes:

- Think about the places where you copped last week and the people who you were with. Do you buy or use drugs with any of those people regularly?

- Think about the all the different places where you used last week. These might be friends' places, abandoned houses, your place, or galleries. Who was there and are you usually with them when you use drugs?
- Sometimes people that you list are not available, they may be sick, locked up, or just not around. So can you think of anyone else that you did drugs with in the last six months?
- Look at the list. Is there anyone else you can think of that you do drugs with? These may be close friends, family members, running buddies, or acquaintances.
- Who else did you do drugs with last month?
- In the last three months who did you cop with?
- How about three months ago, who were you doing drugs with then?
- **(Interviewer use last holiday)** How about since Thanksgiving, Christmas, Easter, July 4th (holidays in the last 6 months), who have you used with since then?

Code: 0 = No 1 = Yes 8 = Refused

9. Are there any individuals who you have listed who do drugs but don't do them with you? Remember whatever you say is completely confidential.

[If Yes] Who is that person(s)?

Code: 0 = No 1 = Yes 7 = Don't Know 8 = Refused

PERSONAL CHARACTERISTICS OF NETWORK MEMBERS

Now, I would like to get some information about the people that you have on this list. For each person on the list, could you tell me:

10 -11. Please tell me the age of each person you have listed?

If participant is uncertain about an age, ask them for their best guess; code "00" if person is under 1 year.

<input type="text"/>	<input type="text"/>
First Digit	Second Digit

12 -15. What is each person's relationship to you? Are they male or female? What is their race?

Use relationship codes for columns 12 & 13; code "m" or "f" for gender in column 14 and use the code list for race in column 15.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
First Digit	Second Digit	M or F	Race

16 -18. I would like to know how long you have known each person you have listed? Let's start with **[Name 1]**. How about **[Name 2, etc.]**?

First
Digit

Second
Digit

Month/Year
M or Y

19. How often do you talk with or see each of the people you have listed?

- Code:**
- 1 = Everyday**
 - 2 = A few times a week**
 - 3 = About once a week**
 - 4 = Two or three times a month**
 - 5 = About once a month**
 - 6 = Five to ten times a year**
 - 7 = Less than five times a year**
 - 8 = Less than once a year**

20-25. For network members who have used drugs in the past 6 months only (look at questions #8 & #9)

In the past 6 months, has **[NAME each network member who has used drugs and ask q #'s 20 – 25 one at a time]**:

- 20. Injected speedball?
- 21. Injected just heroin?
- 22. Injected just cocaine?
- 23. Snorted heroin?
- 24. Snorted cocaine?
- 25. Smoked crack?

Code for questions 20. – 25.

- 0 = No**
- 1 = Yes**
- 7 = Don't Know**
- 8 = Refused**
- 9 = Person listed has not used drugs in past 6 months or ever**

26. In the past six months, how often does **[Name 1, Name 2, etc.]** use drugs?

- Code:**
- 0 = Do not use**
 - 1 = Everyday**
 - 2 = Less than everyday**

27. For each of the people you do drugs with, how often in the last six months have you shared drugs with them? **[Look at column #8]**

- Code:**
- 0 = None**
 - 1 = Daily**
 - 2 = Weekly**
 - 3 = Monthly**
 - 4 = Less than once a month**

28. In the last six months, how often have you shared cookers with them? **[Look at column #8]**

Code: 0 = None
1 = Daily
2 = Weekly
3 = Monthly
4 = Less than once a month

29. In the last six months, how often did you share needles with them? **[Look at column #8]**

Code: 0 = None
1 = Daily
2 = Weekly
3 = Monthly
4 = Less than once a month

30. In the past 6 months, did you talk to anyone on this list about not sharing or cleaning their works?

Code: 0 = No 1 = Yes 7 = Don't Know 8 = Refused

31. Did you talk to anyone on this list about using condoms in the past 6 months?

Code: 0 = No 1 = Yes 7 = Don't Know 8 = Refused

Before we go to the next set of questions, I'm going to review with you the people who you named who you use drugs with and/or have sex with (**name the list of network members Index just identified**). Now think about the last time you bought drugs/copped, used drugs, and had sex. Are there people who you did any of these things with that are not listed (**give Index time to think**)? **If Index names additional network members, return to the beginning of the questionnaire and ask all questions.**

DENSITY

32. Who in this list is a friend with whom else in the list?

Code Density Sheet

Network Survey for Follow-up Visits

Remember you completed this survey at your last study visit? I'm going to ask the same questions about the people who are important to you. I will ask about the people who you named the last time and if there are additional people who should be added to your list. I will be reading descriptions of ways that people may be important to you. After I read each description, I will be asking you to give me the first name and last name initial or the street name of each person in your life who fits the description. These people might be friends, shooting or drinking buddies, family members, sex partners, professionals, or other people you might know. Remember we will keep all names and all information confidential.

Instruction for interviewer – begin survey with asking about each Network Member listed on previous grid.

1. If you wanted to talk to someone about things that are very personal and private or if a situation came up where you needed some advice, is there anybody you could talk to? Please give me the first name, and last name initial of all the people who **you would** talk to about things that are very personal and private?

Code all listed network members as 1. Remember to go back to the names included on the last grid and ask “what about ...?” Remember to probe “is there anyone else?”

2. If you needed to borrow \$25 or something valuable, is there anybody you know **who would** lend or give you \$25, or more, or would give you something that was valuable?

Remember to ask about the people who were mentioned in question #1.

Always probe for additional people by asking, “Is there anyone else who you can think of?”

**Code all network members who Index would borrow \$25.00 from as 1 = YES
Code network members on list who Index would not borrow \$25.00 from as 0 =**

NO

3. Is there anybody that you **could get** together with to have fun or to relax **or just hang out with**? These could be new names or people you listed before.

Probe for additional names by asking, “Is there anyone else who you can think of?”

Code: 0 = No 1 = Yes

4. Is there anybody who **you could** ask for advice or help about health problems like: infections, gonorrhea, birth control, or AIDS? These might be people you have listed before or they could be new names.

Probe for additional names by asking, “Is there anyone else who you can think of?”

Code: 0 = No 1 = Yes

SEX NETWORK

5. Have you had sex in the last 6 months (even if it wasn't with your primary partner)?

No - code 0 (skip to q#8 – code 0 for all people listed on grid)

Yes - code 1 for everyone on the network list

6. Of the people that you listed so far whom did you have sex with in the last six (6) months?

Go down the network list and ask about each person on the list.

So think about if there are additional people who you have sex with, including people who maybe casual sex partners. The people you name should be people you see regularly.

Probe for additional names by asking, “Who else did you have sex with in the last six months?” Add the name(s) to the network list.

Code: 0 = No 1 = Yes 8 = Refused

7. How often do you use a condom with...?

Go down the network list & ask about each person on the list who they HAD sex with.

Code: 4 = All The Time

3 = Half the Time or More

2 = Less Than Half The Time

0 = Never

DRUG NETWORK

Now, I am going to ask you about another group of people, those who you do drugs with. These individuals may be close friends or casual acquaintances. The one requirement for listing them is that you have known them for at least one month. Remember whatever you say is completely confidential. You may give nicknames or street names. No one will know what you have said. If you have any questions about confidentiality please let us know.

8. Who are the people that you do drugs with?

Go down the network list and ask about each person on the list.

Additional probes:

- Think about the places where you copped last week and the people who you were with. Do you buy or use drugs with any of those people regularly?
- Think about the all the different places where you used last week. These might be friends' places, abandoned houses, your place, or galleries. Who was there and are you usually with them when you use drugs?
- Sometimes people that you list are not available, they may be sick, locked up, or just not around. So can you think of anyone else that you did drugs with in the last six months?

- Look at the list. Is there anyone else you can think of that you do drugs with? These may be close friends, family members, running buddies, or acquaintances.
- Who else did you do drugs with last month?
- In the last six months, who did you cop with?
- How about three months ago, who were you doing drugs with then?
- **(Interviewer use last holiday)** How about since Thanksgiving, Christmas, Easter, July 4th (holidays in the last 6 months), who have you used with since then?

Code: 0 = No 1 = Yes 8 = Refused

9. Are there any individuals who you have listed who do drugs but don't do them with you? Remember whatever you say is completely confidential.

[If Yes] Who is that person(s)?

Code: 0 = NO 1 = Yes 7 = Don't Know 8 = Refused

PERSONAL CHARACTERISTICS OF NETWORK MEMBERS

Now, I would like to get some information about the people that you have on this list. For each person on the list, could you tell me:

10 -11. Please tell me the age of each person you have listed?

If participant is uncertain about an age, ask them for their best guess; code "00" if person is under 1 year.

<input type="text"/>	<input type="text"/>
First Digit	Second Digit

12 -15. What is each person's relationship to you? Are they male or female? What is their race?

Use relationship codes for columns 12 & 13; code "m" or "f" for gender in column 14 and use the code list for race in column 15.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
First Digit	Second Digit	M or F	Race

16 -18. I would like to know how long you have known each person you have listed? Let's start with **[Name 1]**. How about **[Name 2, etc.]**?

<input type="text"/>	<input type="text"/>	<input type="text"/>
First Digit	Second Digit	Month/Year M or Y

19. How often do you talk with or see each of the people you have listed?

- Code:** 1 = Everyday
2 = A few times a week
3 = About once a week
4 = Two or three times a month
5 = About once a month
6 = Five to ten times a year
7 = Less than five times a year
8 = Less than once a year

20-25. For network members who have used drugs in the past 6 months only (look at questions #8 & #9)

In the past 6 months, has...[NAME each network member who has used drugs and ask q #'s 20 – 25 one at a time]:

20. Injected speedball?
21. Injected just heroin?
22. Injected just cocaine?
23. Snorted heroin?
24. Snorted cocaine?
25. Smoked crack?

Code for questions 20. – 25.

- 0 = No
1 = Yes
7 = Don't Know
8 = Refused
9 = Person listed has not used drugs in past 6 months or ever

26. In the past six months, how often does [Name 1, Name 2, etc.] use drugs?

- Code:** 0 = Do not use
1 = Everyday
2 = Less than everyday

27. For each of the people you do drugs with, how often in the last six months have you shared drugs with them? [Look at column #8]

- Code:** 0 = None
1 = Daily
2 = Weekly
3 = Monthly
4 = Less than once a month

28. In the last six months, how often have you shared cookers with them? [Look at column #8]

- Code:** 0 = None
1 = Daily
2 = Weekly
3 = Monthly
4 = Less than once a month

29. In the last six months, how often did you share needles with them? **[Look at column #8]**

Code: 0 = None
1 = Daily
2 = Weekly
3 = Monthly
4 = Less than once a month

30. In the past 6 months, did you talk to anyone on this list about not sharing or cleaning their works?

Code: 0 = No 1 = Yes 7 = Don't Know 8 = Refused

31. Did you talk to anyone on this list about using condoms in the past 6 months?

Code: 0 = No 1 = Yes 7 = Don't Know 8 = Refused

Before we go to the next set of questions, I'm going to review with you the people who you named who you use drugs with and/or have sex with (**name the list of network members Index just identified**). Now think about the last time you bought drugs/copped, used drugs, and had sex. Are there people who you did any of these things with that are not listed (**give Index time to think**)? **If Index names additional network members, return to the beginning of the questionnaire and ask all questions.**

DENSITY

32. Who in this list is a friend with whom else in the list?

Code Density Sheet

DAIDS INVESTIGATOR OF RECORD AGREEMENT

To participate in a Division of AIDS (DAIDS) non-IND, network affiliated study, an investigator must complete this agreement and submit it to the Protocol Registration Office (PRO) as part of a complete Protocol Registration Package.

1. Study name and protocol number:

2. Name and address of Investigator of Record (IoR):

3. Education, training, and experience that qualifies the investigator to conduct this study. Please indicate which of the following is attached.

Curriculum Vitae

Other Statement of Qualifications

4. Name and address of all facilities where the study will be conducted:

5. Name and address of any clinical laboratories to be used in the study (Mark *none* if no lab will be utilized for this study.)

None

DAIDS INVESTIGATOR OF RECORD AGREEMENT

6. Name(s) and address(es) of the institutional review board(s) or ethics committee(s) responsible for review of this study:

7. Name(s) of sub-investigator(s) who will assist the IoR in the conduct of this study (Mark *none* if no sub-investigators will be involved in this study.)

None

8. Commitments:

I agree to conduct the study in accordance with the relevant, current protocol(s) and will not make changes in the protocol without permission of the DAIDS, except when necessary to protect the safety, rights, or welfare of study participants.

I agree to personally conduct or supervise this study.

I will ensure that the requirements relating to obtaining informed consent and IRB or Ethics Committee (EC) review and approval (*insert relevant terms of assurance here, e.g. 45 CFR 46, ICH/GCP, etc.*) are met.

I agree to report to the sponsor adverse experiences that occur during the course of this study.

I agree to maintain adequate and accurate study records and to make those records available for inspection by DAIDS and/or DAIDS' authorized representatives.

I will ensure that an IRB or EC that complies with the requirements of 45 CFR Part 46 will complete initial and continuing review and approval of the study. I also agree to promptly report to the IRB/EC all changes in the study and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the study without DAIDS and IRB/EC approval, except where necessary to eliminate apparent immediate hazards to study participants.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Investigator of Record signature and date:

APPENDIX A 45 CFR, ICH Consolidated Guidelines for GCP

APPENDIX B DAIDS SOP for Essential Documents

APPENDIX C DAIDS SOP for Source Documentation
