

## Section 9. Data Management

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This SSP section describes general data management requirements for HPTN074, including how to complete, store, and transmit case report forms using DataFax, the data management system used by the Statistical and Data Management Center (SDMC) – SCHARP – for this study. This SSP section should be used in conjunction site SOPs when reviewing all aspects of data management related to HPTN074.

### 9.1 SDMC Contact Information

For information about this section of the SSP or about data management procedures for HPTN074, please contact the SDMC Clinical Data Manager:

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For questions about clinical queries, you may also contact the SDMC Clinical Affairs Safety Associate (CASA):

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For questions about QC Reports, you may also contact the DF/Net Data Manager:

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### 9.2 DataFax Overview

DataFax is the data management system used to receive and manage data collected at study sites. The site transmits an electronic image of each case report form (CRF) to DataFax, and the original hard copy CRF is retained by the site.

Case report forms can be transmitted to DataFax using a fax machine connected to the internet (fax in a TIFF or PDF) to the e-mail address:

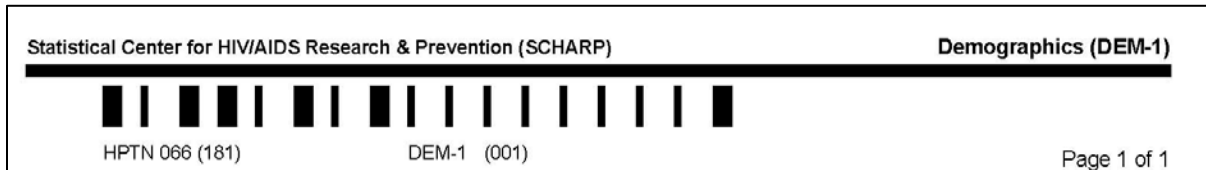
[hptn@dfnetresearch.com](mailto:hptn@dfnetresearch.com)

SCHARP is available to consult with the site to determine the best method for data transmission. The DataFax users support group should be contacted ([support@datafax.com](mailto:support@datafax.com)) anytime the site has technical questions or problems with their fax equipment.

### 9.2.1 Receiving CRFs

Once a CRF image is received, DataFax identifies the study to which each CRF belongs using the barcode at the top of the form (**Figure 1**) and saves the electronic copy of the CRF in the appropriate study database. Thus, it is important to not obscure, mark over, or punch holes through this barcode.

**Figure 1: Example of Barcode**



Using Intelligent Character Recognition (ICR), DataFax reads handwritten numbers, dates and check boxes recorded in each field.

### 9.2.2 Data Entry/Quality Control

When a CRF image is received by DataFax, the following occurs:

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form and saves the electronic copy in the appropriate study database.
- Using Intelligent Character Recognition (ICR), DataFax reads handwritten numbers, dates, and check boxes, recorded in each field.
- Next, each CRF image is reviewed for accuracy. Problems (such as missing or inconsistent data, invalid data values, and/or illegible data) are identified and marked with Quality Control notes (QCs) as necessary.
- QCs are compiled into study-specific QC Reports that are e-mailed, in Adobe Acrobat PDF format, to designated site staff on a routine basis. The QC Report may also show missing pages and overdue visits, based on protocol expectations.

### 9.2.3 DataFax Quality Control Reports

The first page of every QC report is the cover letter (**Figure 2**). The cover letter serves the following purposes:

- identifies the QC report
- alerts the site to trends in data quality that may need attention, and lists the individuals to whom the QC Report is being sent (this includes site staff and SDMC staff)



**Figure 3: Example of Fax/Refax List from QC Report**

VTN903 VPS Quality Control Report

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## 9.4 Case Report Forms

CRFs are technical documents that have been specifically designed to communicate with DataFax. An exact replica of the blank CRF is programmed into the database, facilitating the identification of data recorded on the CRF image received from sites.

### 9.4.1 CRF Distribution

Case report forms are distributed as a single PDF with all of the forms. When the CRFs are finalized, they will be posted to the SDMC Atlas web-portal, and/or emailed to the site. CRF printing instructions are included.

### 9.4.2 Updates to Case Report Forms

If it becomes necessary to modify or add an individual CRF or entire form set after it has been released to the sites, SCHARP will make the revision, change the version date on only the specific CRF(s) with the edit(s). SCHARP will email the HPTN LOC and sites once the updated forms are available. The site must destroy all unused copies of the old version of the form.

### 9.4.3 Standard CRF Elements

Most case report forms contain standard CRF elements such as a line for recording staff initials and dates, and boxes for recording participant identification numbers, visit codes or page numbers. The format of these elements may vary from study to study, so it is important to pay attention when completing these items.

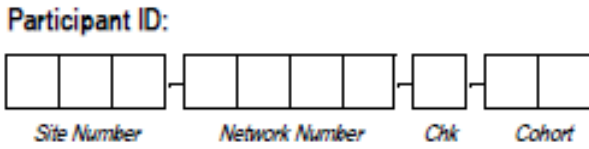
#### 9.4.3.1 Participant IDs

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The PTIDs will either be posted on study-specific pages of the Atlas portal or emailed to the sites by the SDMC Clinical Data Manager. Once a participant has signed the informed consent form for a given protocol, a PTID can be assigned. PTIDs should be assigned in sequential order, and each PTID should be crossed out after it has been assigned to ensure that it is used only once. If a participant re-screens for the study (e.g. if an index participant screens out once but comes back again to screen as an index), the participant is re-screened with the same PTID that was assigned at their first screening visit. A new PTID is not assigned.

PTID boxes are located near the upper left corner of each DataFax CRF. On multiple page CRFs, the PTID must be filled in on each page.

Below (**Figure 4**) is the PTID structure used for this study:

**Figure 4: HPTN 074 PTID Structure**



**Site Number** = Unique site specific number assigned by SCHARP

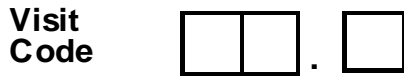
**Network Number** = Unique number assigned to each index/network partner(s) unit or “network”

**Check Digit (Chk)** = Algorithmically generated number that ensures accuracy of PTID

**Cohort** = Number assigned to identify participants as index (00) or network partner (01,02,03...)

**9.4.3.2 Visit Codes**

Most CRFs include boxes in the upper right corner for a visit code. DataFax uses this number to identify the visit at which the CRF was completed.



However, not all CRFs include boxes for visit codes. If a form is only completed and transmitted once during a study (e.g., Enrollment or Demographics), no visit code box will be provided; the visit code will be automatically assigned by DataFax.

All study visit codes for HPTN074 are listed in the **Table 1** below:

**Table 1.** Listing of study visits, time points and associated visit codes.

Study Visit	Time Point	Visit Code
Screening	Day -60 to 0	01.0
Enrollment	Day 0	02.0
One month visit	Week 4	03.0
Quarterly visit 1	Week 13	04.0
Quarterly visit 2	Week 26	05.0
Quarterly visit 3	Week 39	06.0
Quarterly visit 4	Week 52*	07.0
Quarterly visit 5	Week 65*	08.0
Quarterly visit 6	Week 78*	09.0
Quarterly visit 7	Week 91*	10.0
Exit Visit	Week 104*	11.0

\*Weeks 52, 65, 78, 91, or 104 may be an Exit Visit for some participants, depending on the timing of the participant’s enrollment relative to the enrollment period at the site.

**Table 1a.** Listing of study extension visits and associated visit codes.

Study Extension Visit	Visit Code
Visit 1	41.0
Visit 2	42.0
Visit 3	43.0
Visit 4	44.0

#### 9.4.3.3 Page Numbers

Some CRFs, such as log forms (e.g., Adverse Experience Log, Social Impact Log, or Agency Contact Log), may include boxes in the upper right corner for page numbers, as shown below:

Page

Page numbers should be assigned in sequential ascending order and should never be changed unless instructed by the SDMC. In the example of the AE Log, the participant’s first AE reported would be page 001, the second AE reported would be 002, etc. This numbering is followed throughout a participant’s entire duration in the study, regardless of the visit when the adverse experience was reported.

The Systems Navigator Encounter and Psychosocial Encounter forms contain a box in the upper right hand corner for an “Encounter number”.

**Encounter #:**

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The encounter number is used to count each unique encounter the participant has with either the systems navigator or the psychosocial counselor. For example, mark the encounter number on the SNE 001 the first time the participant meets with the Systems Navigator. Mark the encounter number 002 the second time the participant meets with the Systems Navigator, and so forth. Each encounter (with the Systems Navigator and the Psychosocial Counselor) is numbered separately. Encounter numbers should not be skipped on these forms. This means that encounter number 001 on the SNE may be a different date than encounter number 001 on the PSY.

#### **9.4.3.4 Staff Initials and Date**

Most DataFax CRFs include a line in the lower-right corner of each page for a staff member's initials and the date when the form was completed. The site staff person who initially completes the form must record his/her initials and the date in the space provided. When more than one staff member records data on a CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/date field should write his/her initials and date next to each data element for which he/she is responsible. It is acceptable to bracket a section an initial and date once for that entire section.

#### **9.4.4 CRF Completion Guidelines**

Based on the use of electronic transmission of case report forms and Good Clinical Data Management Practices (GCDMPs), the following guidelines should be used for completing DataFax CRFs:

1. Read and follow all form instructions carefully.
2. Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool.
3. Use only one color pen per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
4. Press firmly when recording data or writing comments.
5. Print all data and comments legibly by hand.
6. Do not use cursive/script handwriting, as it can be difficult to read.
7. Write numbers as large as possible while staying within the boundaries of the boxes.
8. Use the units of measurement that are requested on the form.
9. Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
10. Record a response for every item unless instructed otherwise by a skip pattern.
11. Record notes or comments in the local language and provide the English translation.



12. If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
13. Mark only one answer except when given the instruction “Mark all that apply.”
14. In general, do not record data or make marks in the margins at the top, bottom, or sides of the CRF.
15. Do not type data onto CRFs.
16. Do not obscure, mark over, or punch holes through the barcode at the top of each CRF.
17. Never use correction fluid (“white-out”) or correction tape on CRFs.
18. The site staff member who initially completes the CRF must record his/her initials and the date in the space provided in the bottom right-hand corner of each CRF page.
19. Remove any paper clips, staples, or other attachments before transmitting CRFs.

#### 9.4.4.1 Marking Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.



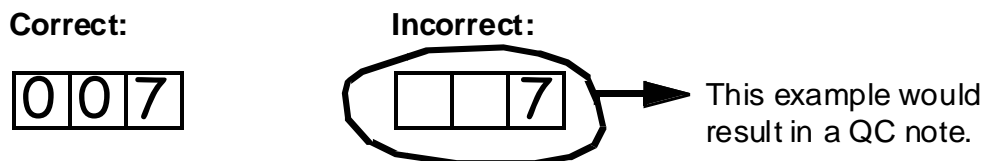
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

#### 9.4.4.2 Recording Numbers

Some questions on CRFs include boxes for recording a numeric response. DataFax can only read the numbers in these boxes if they are recorded clearly. The instructions below should be followed when recording numeric responses:

1. Right justify all numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

The following example shows how a value of 7 is recorded in three response boxes:



- Write the number as large as possible while staying within the boundaries of the box.

In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

**Correct:**



**Incorrect:**



- Write the number simply, with as few loops as possible.

The following example shows the format in which numbers will be most easily read by DataFax. Also included are some commonly used formats that may be difficult for DataFax to identify.

**Easily Identified:**



**Difficult to Identify:**



#### 9.4.4.3 Recording Dates

Dates are recorded using the “dd MMM yy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yy” represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English* in order for the date to be read in DataFax. Abbreviations for the months in English are shown below:

**Table 2.** Listing of month abbreviations

Month	Abbreviation
January	JAN
February	FEB
March	MAR
April	APR
May	MAY

June	JUN
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

For example, June 1, 2010 would be recorded as follows:

0	1	J	U	N	1	0
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

Sometimes, only a month and a year are required, in which case the response boxes will look like this:

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

A dosing date of October, 2010, would be recorded as follows:

O	C	T	1	0
<i>MMM</i>			<i>yy</i>	

#### 9.4.4.4 Recording Time

Time is recorded on CRFs using the 24-hour clock, in which hours are designated from 00 to 23. For example, in the 24-hour clock, 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

1	4	:	2	5
<i>hr</i>			<i>min</i>	

**Note:** Midnight is recorded as 00:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

**Table 3.** 12-hour and 24-hour clock translation table

12-hour clock (a.m.)	24-hour clock		12-hour clock (p.m.)	24-hour clock
Midnight	00:00		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

**9.4.5 Data Corrections and Additions to CRFs**

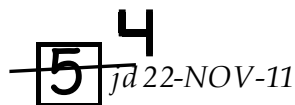
Sometimes data on a DataFax CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before transmission. It is important to make these changes to the original CRF— *never* overwrite an entry once it is recorded and *never* copy data onto a new form. After making the change, the CRF must be retransmitted to DataFax.

If a correction or addition is made to one page of a multiple-page CRF, only retransmit the page that was changed.

Whenever an entry on a DataFax CRF is changed, clarified, or amended, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs)
- place the correct or clarified answer near the box
- initial and date the correction as shown below

**Correct:**



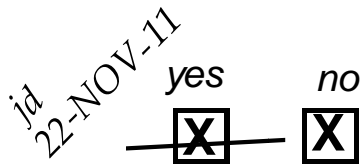
**Incorrect:**



If an **X** is marked in the wrong response box, correct it by doing the following:

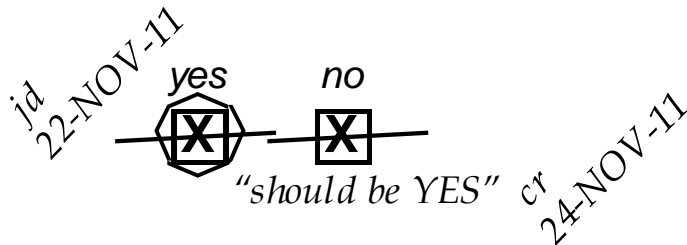
- draw a single horizontal line through the incorrectly marked box (do not obscure the entry or make it un-readable with multiple cross-outs)

- mark the correct box
- initial and date the correction and shown below



If the correct answer has previously been crossed out, do the following:

- circle the correct item
- write an explanation in the white space near the item
- initial and date all corrections as shown below



Please note that it is helpful to write in the final answer (e.g. “should be yes”) on the CRF when multiple corrections to one item have been made.

If an *entire* CRF needs to be deleted from the database, do the following:

- draw a single diagonal line across the entire page that needs to be deleted and write “delete”
- include a brief note of explanation, initial and date the deletion, and transmit this changed CRF to DataFax

The standards above must always be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed for the first time.

#### 9.4.5.1 Correcting a Participant Identification Number (PTID) Error

If a CRF with an incorrect PTID is submitted, notify the SDMC Clinical Data Manager right away in addition to making the correction on the original CRF.

#### 9.4.5.2 Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. Include a brief note of explanation such as “don’t know” (or “DK”), “refuses to answer” (or “REF”), “unknown” (or “UNK”), or “not applicable” (or “N/A”) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the “dd” boxes and write “don’t know” next to the response boxes, as shown below:

The diagram shows a date response form with two blank boxes followed by 'APR' and '12'. A horizontal line is drawn through the two blank boxes. Below the line, the text 'UNK' and 'LAF 26-JAN-12' is written.

If an answer is *no longer unknown*, line through any previously lined-through boxes (using a diagonal line) and update the form with the new response, as shown below:

The diagram shows a date response form with two blank boxes followed by 'APR' and '12'. A diagonal line is drawn through the two blank boxes. Above the line, the text 'Should be: 15' and 'LAF 10-FEB-12' is written. Below the line, the text 'UNK' and 'LAF 26-JAN-12' is written.

A skip instruction is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion or as an update to the form.

#### 9.4.6 Site Review of CRFs

Each form must be reviewed for completeness and legibility, ideally twice: once before the participant leaves the site and once again, by a second reviewer, before being transmitted to DataFax. As part of these reviews, the site should check to ensure that:

- Other than the PTID, there is no information on the form that could uniquely identify the participant (e.g., no name, phone number, national identification number, or any other personal identifiers)
- A response has been recorded for each item, unless the item has been skipped as instructed by a skip pattern, or the item has been marked as unknown/refused
- All text responses are clearly recorded
- There are no marks on or above the DataFax barcode at the top of each CRF page.

- There are no missing dates, missing visit codes, incorrect PTIDs, incorrect visit codes, missing data for items beginning a series of skip patterns or inconsistent or discrepant data

Reviewers can make edits/updates to forms completed by another staff member, so long as they mark their corrections with their own initials and the date of the change. While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is helpful to have a system to identify when a CRF was last transmitted to DataFax. Such a system may include using a stamp to date the back of the CRF.

Sites should thoroughly describe their CRF review process (including who performs the review and how it is conducted) as well as timeframes for review in their HPTN074Data Management SOP.

### **9.5 Faxing CRFs**

To streamline the submission of DataFax CRFs, the site should identify which staff member(s) will be responsible for transmitting forms to DataFax and which staff member(s) will be responsible for receiving and responding to QC reports.

Forms should be transmitted as soon as possible after they have been completed and reviewed. Ideally, completed forms will be submitted within 1-2 days of a participant completing the visit, though up to 5 days is allowed. AE Log forms should be faxed to DataFax within 1 calendar day of the date reported to site (i.e. within 24 hours of the site learning about the AE). Additionally, sites should respond promptly to requests for clarifications and corrections included in the QC Reports. Early detection of recurrent issues provides an opportunity to reduce errors and improve data quality.

It is necessary to have a system to identify whether a CRF has been transmitted to DataFax. Such a system may include using a stamp to date the back of the CRF. If a date stamp is used, it is important to remember to use *only* the back of the CRF for a date stamp, *never* the front, and to date stamp the back of the CRF each time it is transmitted, including retransmissions.

Once transmitted, keep all CRFs for every participant, even if the CRF was completed in error and/or has been marked for deletion from the database. *Never* destroy a form once it has been transmitted

In the rare event that a CRF is lost after being transmitted, contact the SCHARP Clinical Data Manager for a copy of the electronic image saved in DataFax. This version will become the new “primary” CRF and should be kept in the participant’s file. This CRF can be updated and retransmitted to as needed. If the original is ever found, it should also be kept in the participant’s file for documentation purposes only.

## 9.6 Visit Scheduling

### 9.6.1 Target Days

A target date is the day in which a visit should ideally occur. Target dates for index participants are based on their date of enrollment, Day 0, and do not change even if a visit takes place before or after the target date. **The target dates for study extension visits are based on the date the participant re-consents to be in the study extension, not the participant's original date of enrollment into the main study.**

### 9.6.2 Visit Windows

**Table 4** lists the visit codes, target days and visit windows for each study visit. All windows are listed in days.

There are two types of visit windows. The target visit window is the range of days in which the visit should ideally occur. It is used by DataFax to query for an “overdue” visit and by the Retention Reports to determine whether a visit has been conducted “early” or “late” (Visits are defined as “early” if the participant completed the follow-up visit within the allowable window but before the target window opened. Visits are defined as “late” if the participant completed the follow-up visit within the allowable window but after the target window closed). The target window around the Week 4 Visit is +/- 7 days and the target window around subsequent Follow-up Visits is +/- 14 days.

If it is not possible to complete visits within the target window, visits may be completed within the allowable window. The allowable visit window is an extension of the target window and is the timeframe within which each visit must take place. The allowable windows are continuous, meaning there are no gaps between each visit. The allowable window around Follow-up Visits, starting with the Week 26 Visit, is fairly wide. Participants have -28 days and + 61, 62 or 63 days to complete each Follow-up visit within the allowable window. Visits that occur outside the allowable visit window are considered “missed”.

**Table 4:** HPTN074 Target Days and Visit Windows

Visit Number	Visit Type ( <i>optional</i> )	Lower Allowable Window (-)	Lower Target Window (-)	Target Day	Upper Target Window (+)	Upper Allowable Window (+)
1.0	Screening	-56	n/a	n/a	n/a	n/a
2.0	Enrollment	n/a	n/a	0	n/a	n/a
3.0	Week 4	21 (-7)	21 (-7)	28	35 (+7)	76 (+48)
4.0	Week 13	77 (-14)	77 (-14)	91	105 (+14)	153 (+62)
5.0	Week 26	154 (-28)	168 (-14)	182	196 (+14)	244 (+62)
6.0	Week 39	245 (-28)	259 (-14)	273	287 (+14)	336 (+63)
7.0	Week 52	337 (-28)	351 (-14)	365	379 (+14)	426 (+61)
8.0	Week 65	427 (-28)	441 (-14)	455	469 (+14)	517 (+62)
9.0	Week 78	518 (-28)	532 (-14)	546	569 (+14)	608 (+62)
10.0	Week 91	609 (-28)	623 (-14)	637	651 (+14)	699 (+62)



11.0	Week 104	700 (-28)	714 (-14)	728	742 (+14)	790 (+62)
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**Table 4a.** HPTN074 Target days and Visit Windows for Study Extension

Visit Number	Visit Type	Lower Allowable Window (-)	Lower Target Window (-)	Target Day	Upper Target Window (+)	Upper Allowable Window (+)
41.0	Visit 1			N/A		
42.0	Visit 2	77 (-14)	77 (-14)	<b>91</b>	105 (+14)	153 (+62)
43.0	Visit 3	154 (-28)	168 (-14)	<b>182</b>	196 (+14)	244 (+62)
44.0	Visit 4	245 (-28)	259 (-14)	<b>273</b>	287 (+14)	336 (+63)

Network injection partners who enroll into the study at the index’s Enrollment Visit will follow the same exact visit schedule as the index participant. Late-entry partners will first complete their Week 4 Visit (visit 3.0) based off of *their own* date of enrollment before assuming the visit schedule of the corresponding index participant.

Which Follow-up Visit the late-entry partner completes first, as he/she assumes the index participant’s visit schedule, depends on when the late-entry partner actually completes their Week 4 Visit. If the late-entry partner’s Week 4 Visit occurs more than 2 weeks prior to the target date for the index’s next scheduled Follow-up Visit, then the partner would also complete that Follow-up Visit. If the late-entry partner’s Week 4 Visit occurs less than 2 weeks from the index’s next scheduled visit, the partner would not complete that visit, as his/her Week 4 Visit date would be too close and provide mostly redundant information. If the late-entry partner’s Week 4 Visit occurs after the target date for a Follow-up Visit, that Follow-up Visit will be skipped. Any Follow-up Visit that is skipped by the late-entry partner should be documented with a Missed Visit CRF. See Data Communique #2 for more information.

### 9.6.3 Missed Visits

A scheduled visit is considered missed if it is not completed within the allowable visit window in the tables above. Missed visits must be documented by completing a Missed Visit CRF.

If a visit happens to be completed within the allowable visit window after a Missed Visit form has already been submitted to SCHARP, draw a diagonal line through the previously submitted Missed Visit form, include a brief note of explanation, initial and date the changes, and re-submit the form to DataFax. Complete all of the scheduled visit procedures, code all forms with the appropriate visit code, and send the forms to DataFax.

### 9.6.4 Split Visits

In cases where a participant is not able to complete all required visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day, as long as the evaluations are completed within the same allowable visit window for that visit. When split visits occur, case report forms completed for the visit are all assigned

the same visit code (even though some forms and evaluations will have different visit dates).

For example, a network partner comes to the study clinic for her Week 39 Visit on day 276 but forgets to provide a urine sample for a drug screen. She comes back the next day, day 277, to provide one. The Week 39 Visit is considered to be “split” since the participant is completing a required study procedure for the Week 39 Visit on day 277 that she was not able to complete on day 276. All DataFax forms filled out on days 276 and 277 would be completed using the same visit code, 06.0.

### 9.6.5 Interim Visits

In addition to the scheduled, protocol-required visits, Interim Visits may occur after enrollment into the trial. Interim visits occur when a participant visits the study clinic outside of the regular study schedule (e.g. for HIV testing or to report a Social Impact).

Interim visit codes should only be assigned if CRFs are completed and submitted to document that interim visit. If no CRF pages are required to document the visit, then an Interim Visit code should not be assigned.

#### 9.6.5.1 Interim Visit Codes

Interim visit codes are assigned using the following guidelines:

- In the box to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit (even if this visit was missed).
- Use the guide below to complete the box to the right of the decimal point:

1 = the first interim visit after the most recent scheduled visit,  
2 = the second interim visit after the most recent scheduled visit,  
3 = the third interim visit after the most recent scheduled visit, and so on.

For example, the first interim visit after the Week 10 Visit would be recorded as follows:

Visit Code 

1	0	.	1
---	---	---	---

The second interim visit after the Week 10 Visit would be recorded as follows:

Visit Code 

1	0	.	2
---	---	---	---

An example of an interim visit is as follows: a network partner completes all his required study procedures for Visit 07.0, Week 52. Two weeks later, the participant calls to report a potential exposure to HIV and wants to come in for an HIV test. The participant comes back to the clinic 2 days later. This visit would be considered an Interim Visit since the participant had already completed the required study procedures for Visit 07.0. The

Follow-up Visit CRF is completed indicating the visit is an Interim Visit, and the Adverse Experience Log and Partner HIV Test Results CRFs would be completed using visit code 07.1.

### **9.7 Termination and Reactivation**

Participants are terminated from study participation when they have completed the final study visit; died; refused further participation in the study; relocated; study site staff can no longer contact the participant (lost-to-follow-up); or if the investigator has decided the participant can or should no longer participate. When an index participant is terminated from the study early, each network injection partner is expected to be terminated from the study early as well.

Participants who have been terminated from the study due to lost-to-follow-up, refusal, incarceration, or relocation, who then return to the study site before the close of the allowable visit window of their final visit, may be allowed to rejoin the study, and should be encouraged to do so. Participants are reactivated by writing “delete” on the previously submitted Termination form and retransmitting the form to SCHARP. Please note that a Missed Visit form must be completed for each missed visit or phone contact during the period the participant was not in contact with the site.

## 9.8 Schedule of Forms

### 9.8.1 Schedule of Forms- Index Participant

<b>SCREENING (DAY -60 to 0)</b>		<b>VISIT CODE: 01.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
DEM 1-4	Demographics*	001, 002, 003, 004
DVI	Demographics- Vietnam**	007
DIN	Demographics- Indonesia**	009
DUK	Demographics- Ukraine**	011
IPT	Index PTID Tracker*	019
ISO 1-2	Index Screening Outcome*	020, 021
SS	Specimen Storage***	230
CDF	CD4+ Count and Viral Load	330
<p><i>All CRFs listed above are required to be faxed to DataFax if the participant enrolls in the study. *Fax the Index PTID Tracker, Index Screening Outcome, and Demographics (including site-specific page) CRFs even if the participant does not enroll in the study.</i></p> <p><i>**Only complete and fax the site-specific page that corresponds to your site.</i></p> <p><i>***Fax the Specimen Storage CRF for all index participants who end up enrolling into the study. If a participant does not enroll in the study, fax in the Specimen Storage CRF only if they agreed to long term specimen storage of the Screening Visit samples.</i></p>		
<b>ENROLLMENT (DAY 0)</b>		<b>VISIT CODE: 02.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
BBA 1-8	Baseline Behavior Assessment	071, 072, 073, 074, 075, 076, 077, 078
IBH 1-6	Index Baseline HIV Care and ART Questionnaire	085, 086, 087, 088, 089, 090
IE	Index Enrollment	091
INS	Index Network Status	111
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
SS	Specimen Storage	230
<i>CONDITIONAL (Required only for indexes randomized to the intervention arm)</i>		
SNE 1-3	Systems Navigator Encounter	210, 211, 212
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030

SUT	Substance Use Treatment Initiation	040
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm.</i>		
<b>WEEK 4 VISIT (DAY 28)</b>		<b>VISIT CODE: 03.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>WEEK 13 VISIT (DAY 91)</b>		<b>VISIT CODE: 04.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230

<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡ Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>WEEK 26 VISIT (DAY 182)</b>		<b>VISIT CODE: 05.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡ Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>WEEK 39 VISIT (DAY 273)</b>		<b>VISIT CODE: 06.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165

FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter‡	210, 211, 212
PSY 1-4	Psychosocial Encounter‡	225, 226, 227, 228
ACL	Agency Contact Log‡	232
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>WEEK 52 VISIT (DAY 364)</b>		<b>VISIT CODE: 07.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter‡	210, 211, 212
PSY 1-4	Psychosocial Encounter‡	225, 226, 227, 228
ACL	Agency Contact Log‡	232
TM	Termination§	490
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<i>§ If this visit is an exit visit, fax the Termination CRF as well.</i>		
<b>WEEK 65 VISIT (DAY 455)</b>		<b>VISIT CODE: 08.0</b>

<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<b>REQUIRED</b>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<b>AS NEEDED</b>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
TM	Termination <sup>§</sup>	490
<i><sup>‡</sup>Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<i><sup>§</sup>If this visit is an exit visit, fax the Termination CRF as well.</i>		
<b>WEEK 78 VISIT (DAY 546)</b>		<b>VISIT CODE: 09.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<b>REQUIRED</b>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
CDF	CD4+ Count and Viral Load	330
<b>AS NEEDED</b>		
IAI	Index ART Initiation	030



SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
TM	Termination <sup>§</sup>	490
<i>‡ Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<i>§ If this visit is an exit visit, fax the Termination CRF as well.</i>		
<b>WEEK 91 VISIT (DAY 637)</b>		<b>VISIT CODE: 10.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
TM	Termination <sup>§</sup>	490
<i>‡ Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<i>§ If this visit is an exit visit, fax the Termination CRF as well.</i>		
<b>WEEK 104 VISIT (DAY 728)</b>		<b>VISIT CODE: 11.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
INS	Index Network Status	111
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165

FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
CDF	CD4+ Count and Viral Load	330
TM	Termination	490
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm.</i>		

### 9.8.2 Schedule of Forms – Network Partner Participants

<b>SCREENING</b>		<b>VISIT CODE: 01.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
PPT	Partner PTID Tracker*	024
PSO	Partner Screening Outcome*	025
DEM 1-4	Demographics*	001, 002, 003, 004
DVI	Demographics- Vietnam**	007
DIN	Demographics- Indonesia**	009
DUK	Demographics- Ukraine**	011
PHT	Partner HIV Test Results*	181
SS	Specimen Storage***	230
	<p><i>All CRFs listed above are required to be faxed to DataFax if the participant enrolls in the study. *Fax the Partner PTID Tracker, Partner Screening Outcome, Demographics (including site-specific page), and Partner HIV Test Results CRF even if the partner does not enroll in the study.</i></p> <p><i>**Only complete and fax the site-specific page that corresponds to your site.</i></p> <p><i>***Fax the Specimen Storage CRF for all partners who end up enrolling into the study. If a partner does not enroll in the study, fax in the Specimen Storage CRF only if they agreed to long term specimen storage of the Screening Visit samples.</i></p>	
<b>ENROLLMENT</b>		<b>VISIT CODE: 02.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
BBA 1-8	Baseline Behavior Assessment	071, 072, 073, 074, 075, 076, 077, 078
PE	Partner Enrollment	095
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
PHT	Partner HIV Test Results	181
SS	Specimen Storage	230
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
<b>WEEK 4 VISIT</b>		<b>VISIT CODE: 03.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165

FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
<b>WEEK 13 VISIT</b>		<b>VISIT CODE: 04.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
<i>†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit.</i>		
<b>WEEK 26 VISIT</b>		<b>VISIT CODE: 05.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>CONDITIONAL (Required only if HIV infection was confirmed at a previous visit)</i>		
CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
<i>†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit.</i>		
<b>WEEK 39 VISIT</b>		<b>VISIT CODE: 06.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		

FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
<i>†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit.</i>		
<b>WEEK 52 VISIT</b>		<b>VISIT CODE: 07.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>CONDITIONAL (Required only if HIV infection was confirmed at a previous visit)</i>		
CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
TM	Termination§	490
<i>†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit.</i>		
<i>§ If this visit is an exit visit, fax the Termination CRF as well.</i>		
<b>WEEK 65 VISIT</b>		<b>VISIT CODE: 08.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230

AS NEEDED		
SUT	Substance Use Treatment Initiation	040
TM	Termination§	490
†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit. § If this visit is an exit visit, fax the Termination CRF as well.		
<b>WEEK 78 VISIT</b>		<b>VISIT CODE: 09.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>CONDITIONAL (Required only if HIV infection was confirmed at a previous visit)</i>		
CDF	CD4+ Count and Viral Load	330
AS NEEDED		
SUT	Substance Use Treatment Initiation	040
TM	Termination§	490
†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit. § If this visit is an exit visit, fax the Termination CRF as well.		
<b>WEEK 91 VISIT</b>		<b>VISIT CODE: 10.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS-1	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT-1	Partner HIV Test Results†	181
FSU-1,2,3	Follow-up Substance Use Treatment	201, 202, 203
SS-1	Specimen Storage	230
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
TM	Termination§	490
†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit. § If this visit is an exit visit, fax the Termination CRF as well.		
<b>WEEK 104 VISIT</b>		<b>VISIT CODE: 11.0</b>

<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
PHT	Partner HIV Test Results†	181
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
TM	Termination	490
<i>CONDITIONAL (Required only if HIV infection was confirmed at a previous visit)</i>		
CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
SUT	Substance Use Treatment Initiation	040
†HIV testing (and the PHT) is not required if HIV infection was confirmed at a previous visit.		

### 9.8.3 Other Administrative Forms

<i>AS NEEDED, applicable to all visits</i>		
SIL	Social Impact Log	151
AE	Adverse Experience Log	460
MV	Missed Visit	463
TM	Termination <sup>∞</sup>	490
PDL	Protocol Deviation Log	495
<i>∞The Termination CRF is listed again, as it will need to be faxed to DataFax if a participant terminates early from the study. This may occur at any time during follow-up.</i>		

### 9.8.3 Schedule of Forms – Additional Forms Requirements

<b>Other Administrative Forms</b>		
<i>AS NEEDED</i>		
MV-1	Missed Visit	463
AE-1	Adverse Experience Log	460
PDL-1	Protocol Deviation Log	495
SIL-1	Social Impact Log	151
TM-1	Termination	490
	<i>Weeks 52, 65, 78, 91 or 104 may be an exit visit for participants. Follow alternative procedures as indicated if it is an Exit visit.</i>	
<b><i>CRFs REQUIRED FOR INDEX PARTICIPANTS IN THE TREATMENT ARM</i></b>		
SNE-1, 2, 3	Systems Navigator Encounter	210, 211, 212
	<i>Required at Enrollment, as needed thereafter</i>	
PSY-1-4	Psychosocial Encounter	225, 226, 227, 228
ACL-1	Agency Contact Log	232
<b><i>CRFs REQUIRED FOR PARTNERS WHO ACQUIRE HIV DURING THE STUDY</i></b>		
SS-1	Specimen Storage	230
CDF-1	CD4+ Count and Viral Load	330
	<sup>+</sup> CD4+ cell count testing will be performed at the HIV confirmatory visit and at weeks 26, 52, 78 and 104 (if HIV infection is confirmed prior to those visits).	



#### 9.8.4 Schedule of Forms – Study Extension Visits – Index Participant

<b>STUDY EXTENSION VISIT 1 (“Re-enrollment” - DAY 0)</b>		<b>VISIT CODE: 41.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
EXT	Study Extension**	315
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<p><b>**Complete the Study Extension CRF for all Index participants, regardless if they re-enroll in the study extension.</b></p> <p><sup>‡</sup>Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</p>		
<b>STUDY EXTENSION VISIT 2 (DAY 91)</b>		<b>VISIT CODE: 42.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230

CDF	CD4+ Count and Viral Load	330
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>STUDY EXTENSION VISIT 3 (DAY 182)</b>		<b>VISIT CODE: 43.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178
IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		
<b>STUDY EXTENSION VISIT 4/FINAL VISIT* (DAY 273)</b>		<b>VISIT CODE: 44.0</b>
<b>Acronym</b>	<b>Form Name</b>	<b>Plate #</b>
<i>REQUIRED</i>		
FUV	Follow-up Visit	120
SIA 1-2	Social Impact Assessment	152, 153
STG 1-2	Social Support and Stigma Questionnaire	155, 156
ITB	Index Treatment Belief Questionnaire	158
UDS	Urine Drug Screen	165
FBA 1-8	Follow-up Behavior Assessment	171, 172, 173, 174, 175, 176, 177, 178

IFH 1-6	Index Follow-up HIV Care and ART	185, 186, 187, 188, 189, 190
FSU 1-3	Follow-up Substance Use Treatment	201, 202, 203
SS	Specimen Storage	230
CDF	CD4+ Count and Viral Load	330
ETM	Study Extension Termination	491
<i>AS NEEDED</i>		
IAI	Index ART Initiation	030
SUT	Substance Use Treatment Initiation	040
SNE 1-3	Systems Navigator Encounter <sup>‡</sup>	210, 211, 212
PSY 1-4	Psychosocial Encounter <sup>‡</sup>	225, 226, 227, 228
ACL	Agency Contact Log <sup>‡</sup>	232
<i>‡Only for indexes randomized to the intervention arm. Note that these forms can be faxed at any time other than this visit.</i>		

**\*If the final study extension visit is a visit other than Study Extension Visit 4, please conduct all procedures that would normally be conducted at Visit 4 at that time. For example, if a participant decided to end study participation at what is considered to be Visit 2, please follow visit procedures and schedule of forms associated with Visit 4/Final Visit at this time.**

### Other Administrative Forms

<i>AS NEEDED, applicable to all visits</i>		
SIL	Social Impact Log	151
AE	Adverse Experience Log	460
MV	Missed Visit	463
PDL	Protocol Deviation Log	495