

Section 9. Data Management

This section describes data management for HPTN062 and DataFax, the data management system used by SCHARP. DataFax is a tool that allows for the collection and processing of accurate data for statistical analysis. The success of DataFax depends on the people who use it—both at the sites and at SCHARP. The purpose of this section is to provide site staff with the information they need to successfully complete and transmit DataFax forms for HPTN062.

9.1. Data Management Contact Information

For information about this section of the SSP or about data management procedures for HPTN062, please contact the HPTN062 SCHARP Project Manager:

Diana Lynn phone: 1-206-667-4980
e-mail: dlynn@scharp.org

For questions about QC reports, please contact the HPTN062 Data Coordinator:

Debbie Lands phone: 1-206-667-6149
e-mail: dlands@scharp.org

9.2. DataFax Overview

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

CRF Transmission

SCHARP's Information Technology (IT) Group works with each site to determine the best solution for data transmission on a site-by-site basis.

Data Entry/Quality Control

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

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.
- Next, each CRF is reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control (QC) notes.
- QC notes are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and retransmit the corrected CRFs to SCHARP DataFax.
- When the retransmitted pages are received, SCHARP staff review the corrected pages and resolve the QC notes.

Note: If a change is made to a CRF but the updated page is not retransmitted to SCHARP DataFax, the change will not be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC note, the note will continue to appear on subsequent QC reports until the modified CRF is received at SCHARP. Therefore, it is very important that the site retransmit updated CRF pages to SCHARP DataFax **any time** a change is made to data, regardless of whether or not the change was made in response to a QC report.

9.3. DataFax Form Completion

9.3.1. Guidelines

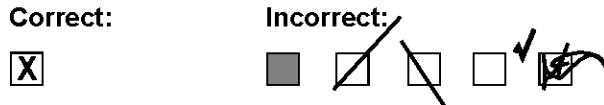
Based on the use of fax technology and Good Clinical Practice (GCP), the following guidelines should be used for completing DataFax CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color 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.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- Never obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- Never use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before transmitting CRFs.
- Because some CRFs are source documents, the site staff person who initially completes the form must record his/her initials and the date in the space provided in the bottom right-hand corner of each CRF page.

- Transmit forms as soon as possible after they have been completed and reviewed (within the time period specified for the study).

9.3.2. How to Mark 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.



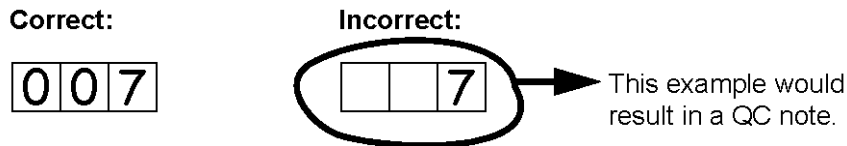
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

9.3.3. How to Record Numbers

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

- 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 when three response boxes are provided:



- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside 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:



- Write the number(s) simply, with few loops.

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:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

Ø 1 2 3 4 7

9.3.4. How to Record 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* for the date to be read in DataFax. Abbreviations are shown below:

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, 2009 would be recorded as follows:

01 JUN 09
dd MMM yy

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 date of October, 2009, would be recorded as follows:

O	C	T	0	9
<i>MMM</i>			<i>yy</i>	

9.3.5. How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock, in which hours are designated from 0–24. 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:

12-hour clock (a.m.)	24-hour clock	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

9.3.6. Data Corrections and Additions

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 transmitting.

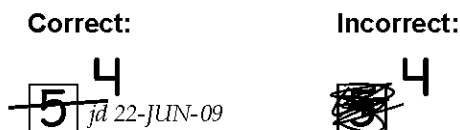
It is important to make these changes to the original CRF—*never* copy data onto a new form. After making the change, the CRF *must* be retransmitted to SCHARP DataFax.

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

Note: Never write over an entry once it is recorded. Use the standards outlined below when changing, clarifying, or amending data.

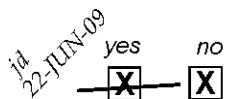
Whenever an entry on a DataFax CRF is changed, do the following:

- 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, and initial and date the correction as shown below:



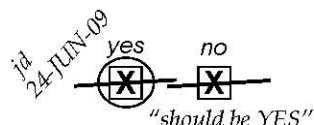
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and
- initial and date the correction as 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, and
- initial and date all corrections as shown below:



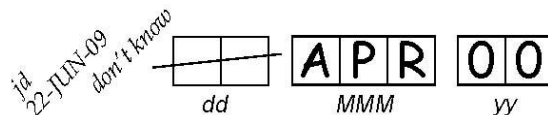
Note: The standards above must be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed to SCHARP for the first time.

9.3.7. How to Handle 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. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the blank boxes, in addition to initialing and dating the entry.

Note: A skip pattern is the only valid reason to leave a response blank.

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:



9.3.8. Staff Initials/Date

Every DataFax CRF includes a line in the lower-right corner for a staff member’s initials and the date on which the form was completed. 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 writes his/her initials and date next to each data element for which he/she is responsible.

9.4. Site Review of DataFax Forms

Each form must be reviewed for completeness and legibility before being transmitted to SCHARP DataFax. As part of the review, the site should check the following:

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., 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.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no: -missing dates, -missing visit codes, -incorrect PTIDs, -incorrect visit codes, and/or -missing data for items beginning a series of skip patterns.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been

transmitted to SCHARP DataFAX. Such a system may include using a stamp to date the back of the CRF.

Important: Use *only* the back of the CRF for a date stamp, *never* the front. Be sure to date stamp the back of the CRF each time it is transmitted, including retransmissions.

9.5. Faxing DataFAX Forms

To streamline the submission of DataFAX forms, the site should identify which staff members will be responsible for transmitting forms to SCHARP DataFAX and receiving and responding to QC reports.

It is important that the site transmits completed CRFs to SCHARP within 24-48 hours whenever possible, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

9.6. Participant IDs

DataFAX uses a unique participant identification number (PTID) to identify each study participant in the database. HPTN 062 will use the same PTID assigned to the participant when they enrolled in CHAVI 001. The site should carefully verify that the correct PTID is assigned for each participant.

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 is the PTID structure used for HPTN062:

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text" value="0"/>	<input type="text" value="1"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Protocol			Participant Number				Chk

Site Number/Unit ID = assigned by SCHARP
Participant Number = unique number assigned to each participant
Check Digit (Chk) = ensures accuracy of PTID

9.7. Visit Codes

DataFAX 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.

Visit Code .

In the above example, the week 1 visit would be recorded as 03.0. All study visit codes are listed in the table below:

Study Visit	Visit Code
Enrollment	01.0
Day 3 (Intervention Arm Only)	02.0
Week 1	03.0
Week 2	04.0
Week 4	05.0
Week 8	06.0
Week 12	07.0
Week 16	08.0
Week 20	09.0
Week 24	10.0

9.7.1. Interim Visit Codes

In addition to the scheduled, protocol-required visits listed above, Interim Visits may occur after enrollment into the trial. Interim visits occur when the participant visits the study clinic outside of the regular study schedule (e.g., for counseling in addition to what is provided in the standard CHAVI or intervention sessions 1 - 5). Interim visit codes should only be assigned if extra counseling is provided, otherwise the interim visit does not need to be reported on a DataFax CRF and reported to SCHARP DataFax.

Note: If no DataFax CRF pages are required to document the visit, then an Interim Visit code should not be assigned because skipping of Interim Visit codes is not allowed in the DataFax database at SCHARP and would cause a QC note to be added to the QC report.

Interim visit codes are assigned using the following guidelines:

- In the box(es) 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 4 Week scheduled study visit would be:

Visit Code

0	5	.	1
---	---	---	---

The second interim visit after the 4 Week scheduled study visit would be::

Visit Code

0	5	.	2
---	---	---	---

9.8. Visit Timing

All visits after enrollment and randomization are based on the CHAVI 001 enrollment date, which is considered to be Day 0. The table below lists the visit target dates and window periods.

Study Visit	Visit Code	Target Day	Allowable Visit Window
Enrollment	01.0	Day 0	Day 0 - 3
Day 3 (Intervention Arm Only)	02.0	Day 3	Day 1 - 6
Week 1	03.0	Day 7	Day 4 - 10
Week 2	04.0	Day 14	Day 11 - 21
Week 4	05.0	Day 28	Day 22 - 42
Week 8	06.0	Day 56	Day 43 - 70
Week 12	07.0	Day 84	Day 71 - 98
Week 16	08.0	Day 112	Day 99 - 126
Week 20	09.0	Day 140	Day 127 - 154
Week 24	10.0	Day 168	Day 155 - 182

9.8.1. Missed Visits

A scheduled visit is considered to be missed if not completed within the visit windows in the table above.

If it happens that a visit can be completed within the Allowable Window after a Missed Visit form has been submitted, draw a line through the previously submitted Missed Visit form, add a note that it should be deleted and why, initial and date, and resubmit it to SCHARP DataFax. Complete all of the scheduled visit procedures, code all visit forms with the scheduled visit code, and fax the CRF pages.

9.9. 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; or the investigator has decided they can or should no longer participate (however, see HPTN Operations Policy HPTN006); or the study site staff can no longer contact the participant (lost-to-follow-up). Participants who have been terminated from the study due to lost-to-follow-up, refusal, or relocation, who return to the study site before the end of the Allowable Visit window for their exit visit may be allowed to rejoin the study, and should be encouraged to do so. Participants are reactivated by writing “unterminate” or “delete” on the previously submitted Termination form and refaxing to SCHARP. Please note that a Missed Visit form must be completed for each missed visit during the period the participant was not in contact with the site.

9.10. Participant Randomization

Randomization is the process whereby a participant is assigned to a treatment arm for the study. There are three steps in the randomization process:

1. log in
2. enter the participant ID (PTID)
3. receive randomization confirmation notice

9.10.1. Requesting Randomization

CTU clinic staff request randomization for a participant via the web-based Randomization system once the participant has been confirmed eligible and consented to participate in HPTN 062.

To request randomization for a participant:

1. Log onto the HPTN 062 Randomization system (see Figure 1-1) located [on](http://www.hptn.org/research_studies/hptn062.asp) the HPTN 062 Web Page at: http://www.hptn.org/research_studies/hptn062.asp. There is a Randomization link in the left margin under the heading “HPTN 062 Quick Links”.
2. You will be asked to enter your site-specific Randomization username and password which will be assigned by SCHARP prior to study start (not the same as your username and password used to access Atlas).
3. This will link to the Randomization Request Form (see Figure 1-2).
4. Enter the PTID
5. Click the “Randomize” button

The following reminder message will appear on the screen during the registration process:

Eligibility criteria must be reviewed prior to randomization. If review of the criteria is complete and the volunteer meets eligibility criteria, RANDOMIZE. Otherwise CANCEL.

The randomization request will be submitted to SCHARP, the randomization assignment will be displayed on the screen and an email notification will be sent to the study coordinator. This notification must be printed and kept in the participant file. Site staff are cautioned that although the system is available 24 hours a day / 7 days a week, there may be unexpected delays due to poor internet connections or other technical difficulties. If such a delay is encountered the participant can be asked to return at a later time within the enrollment window (up to day 3 from enrollment in CHAVI 001) or see section 9.11.1 below for backup randomization procedures.

9.10.2. Randomization Confirmation Notices

Once the request has been processed and the participant has been randomized, the randomization system will automatically send randomization confirmation notices via e-mail to:

- Study coordinator (see Figure 9-1 for an example).

The Randomization Confirmation Notice contains the participant's ID and study arm assignment and must be printed and kept in the participant file.

Figure 9-1: Sample Randomization Confirmation Notice to Clinic Staff

RANDOMIZATION CONFIRMATION NOTICE
HPTN PROTOCOL 062

This notice confirms that the following participant has been randomized into HPTN Protocol 062.

Site: University of North Carolina Lilongwe Clinical Research Site

CRS ID: 12001

Date: 03 Feb 2010

Participant ID: 703019156

Arm: Standard Counseling Arm (standard counseling only)

Treatment: Standard HIV post-test counseling at enrollment (baseline) and standard risk-reduction counseling at follow-up

Please print this notice and file it with the participant record.

CONFIDENTIALITY NOTICE: This e-mail message and any attachments may be confidential and privileged. If you received this message in error, please destroy it and notify the sender. Thank you.

9.11. Releasing a Randomized Participant

In the unlikely event that a participant is mistakenly randomized, they must be released from randomization as soon as possible in order to make that slot available to another participant. A randomized participant should not be released without first consulting the protocol chair and the statistician (cc the SCHARP Project Manager). To request release of a participant:

1. Log onto the Randomization page.
2. Enter the PTID of the participant you wish to release from randomization
3. Click the "Release" button..
4. You will be asked to confirm that you really intend to release the participant. If so click "yes".

An automated e-mail will be sent to the site staff requesting confirmation of, and rationale for the release request. Sites must respond to this confirmation request before the participant can be released. After SCHARP receives the confirmation and rationale from the site, SCHARP

will release the participant. The release procedure automatically e-mails notification to study coordinator of the change in randomization status.

9.11.1. Back-up Randomization Procedures

In circumstances where CTU staff need to randomize a participant, but are unable to access Atlas due to technical problems, the site should do one of the following:

- If the technical problems are expected to resolve quickly, determine if the participant is able to wait at the site until another attempt can be made, or
- Arrange for the participant to return within the randomization/enrollment window to be randomized

If neither of the above is possible and the participant is a good candidate for continued study participation, call the SCHARP emergency contact:

Diana Lynn, HPTN 062 Project Manager
+1-425-941-8087 (personal cell phone)

The SCHARP emergency contact will log onto the HPTN 062 Randomization Calendar and randomize the participant for the site.

9.12. How to Complete Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted in a non-biased, non-judgmental manner.

9.12.1. Interviewing Techniques

An interviewer uses both verbal and non-verbal techniques to obtain the most honest, accurate, and thorough responses from participants. Some techniques to remember:

- Always remain neutral
- Ask all questions in the order presented in the questionnaire
- Ask all questions exactly as worded
- Discourage unrelated conversation while asking questions

These techniques are discussed in the sections below.

9.12.2. Welcoming the Participant

Introduce yourself, and try to create rapport (connection) between yourself and the participant to help him/her feel comfortable during the interview.

- Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions as they appear on the forms.

9.12.3. Asking Sensitive Questions

This study is about a very sensitive subject: HIV and sexual behavior. Gaining an understanding of participants' quality of life and sexual behavior patterns can affect the transmission of HIV and the development of prevention methods. Your level of comfort with asking sensitive questions will affect the participant's comfort and answers. If you ask the questions in a confident and supportive manner, the participant will feel more confident and comfortable answering the questions. Make eye contact with the participant to let them know you are listening and are aware that she/he is being asked difficult questions. Avoid apologizing for questions or making facial gestures that might show you feel any way but neutral about a question or the participant's response.

9.12.4. Recording Participants' Responses Verbatim

Interviewer-administered questions usually have a list of response categories provided to capture the participant's response. Sometimes an "other, specify" box is included as one of the response categories in order to capture participant responses that do not fit into one of the categories listed. When a participant's response does not match or fit into one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "local language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, translate the text recorded on the "local language" line into English, and record the English translation of the response on the "English" line. If the participant's response was originally in English, leave the "English" line blank.

9.12.5. Pacing the Interview

You need to be attentive to both the needs of the participant and the constraints of your schedule. It is important that the participant not feel rushed. Pace your reading of the questions according to the assessment of the participant's ability to comprehend. Let the participant finish speaking before you record his/her response and go on to the next item.

9.12.6. Reading Items Aloud

Read all items to the participant **exactly as worded**, and speak clearly. Do not rephrase an item because this can change its meaning, making it inconsistent with another participant's interview. Provide explanation or interpretation if necessary only after reading the item word-for-word. Discourage unrelated conversation during data collection. When applicable, acknowledge questions and concerns raised by the participant during the interview, and state that the subject can be discussed at the end of the interview.

9.12.7. Instructions to the Interviewer

In addition to the questions that are read to the participant, the questionnaire contains interviewer instructions. All interviewer instructions are in *italic letters*. These instructions are not read to the participant.

9.12.8. Show Cards

Laminated “show cards” are provided for questions containing multiple responses or subitems to aid questionnaire administration. Before reading the question to the participant, hand the corresponding card to the participant or place it on a table in front of the participant. Remove the card after the question is answered.

9.12.9. Probing

One of the major goals of the interviews is to obtain accurate information on many behaviors related to HIV and drug use. These interviews ask participants to recall many aspects of personal behaviors. However, participants may not remember or know the answer to every question. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called “probing.”

Effective probing helps a participant think more about a question or refine an answer that is too general, however, probing must not bias or otherwise direct participant responses.

9.13. Schedule of Forms

Acronym	Form Name	Plate #
ENROLLMENT (DAY 0)		VISIT CODE: 01.0
<i>REQUIRED FOR ALL</i>		
DEM-1-3	Demographics	
ENR-1	Enrollment and Randomization	
BSH-1, 2, 3, 4, 5, 6, 7, 8	Sexual History Baseline	021, 022, 023, 024, 025, 026, 027, 028
BDA-1-2	Drug-Alcohol Baseline	031, 032
BPV-1-2	Partner Violence Baseline	037, 038
BSS-1	Social Support	044
BAD-1, 2	Depression	045, 046
AHK-1	Acute HIV Knowledge	071
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
<i>STANDARD ARM REQUIRED</i>		
STE-1, 2	Standard Topics - Enrollment	210, 211
CPS-1, 2	Standard Post-session Counselor Assessment	241, 242
<i>INTERVENTION ARM REQUIRED</i>		
ITA-1, 2	Intervention Topics - Session 1	221, 222
CPA-1, 2	Intervention Post-session Counselor Assessment - Session 1	245, 246

AS NEEDED

Acronym	Form Name	Plate #
COC-1, 2, 3	Intervention Counselor Observation Checklist	267, 268, 269
MV-1	Missed Visit	463
DAY 3 (DAY 3) INTERVENTION ARM ONLY		VISIT CODE: 02.0
<i>INTERVENTION ARM REQUIRED</i>		
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
ITB-1,2	Intervention Topics - Session 2	225, 226
CPB-1,2	Intervention Post-session Counselor Assessment - Session 2	249, 250
FU-1	Follow-up Visit	101
AS NEEDED FOR ALL		
COC-1, 2, 3	Intervention Counselor Observation Checklist	267, 268, 269
MV-1	Missed Visit	463
WEEK 1 (DAY 7)		VISIT CODE: 03.0
<i>REQUIRED FOR ALL</i>		
AHK-1	Acute HIV Knowledge	071
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
FU-1	Follow-up Visit	101
<i>STANDARD ARM REQUIRED</i>		
STW-1, 2	Standard Topics - Weeks 1 and 2	215, 216
CPS-1, 2	Standard Post-session Counselor Assessment	241, 242
<i>INTERVENTION ARM REQUIRED</i>		
ITC-1, 2	Intervention Topics - Session 3	229, 230
CPC-1,2	Intervention Post-session Counselor Assessment - Session 3	255, 256
<i>AS NEEDED FOR ALL</i>		
COC-1, 2, 3	Intervention Counselor Observation Checklist	267, 268, 269
MV-1	Missed Visit	463
WEEK 2 (DAY14)		VISIT CODE: 04.0
<i>REQUIRED FOR ALL</i>		
FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128, 129
BAD-1, 2	Depression	045, 046
SDC-1, 2, 3, 4	Post-traumatic Stress Disorder and Coping	055, 056, 057, 058,

Acronym	Form Name	Plate #
DIS-1	Disclosure	061
AHK-1	Acute HIV Knowledge	071
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
FU-1	Follow-up Visit	101

STANDARD ARM REQUIRED

STW-1, 2	Standard Topics - Weeks 1 and 2	215, 216
CPS-1, 2	Standard Post-session Counselor Assessment	241, 242

INTERVENTION ARM REQUIRED

ITD-1, 2, 3, 4	Intervention Topics - Session 4	233, 234, 235, 236
CPD-1,2	Intervention Post-session Counselor Assessment - Session 4	259, 260
<i>AS NEEDED FOR ALL</i>		
COC-1, 2, 3	Intervention Counselor Observation Checklist	267, 268, 269
MV-1	Missed Visit	463

WEEK 4 (Day 28)

VISIT CODE: 05.0

REQUIRED FOR ALL

FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
DIS-1	Disclosure	061
AHK-1	Acute HIV Knowledge	071
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
FU-1	Follow-up Visit	101

AS NEEDED FOR ALL

MV-1	Missed Visit	463
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WEEK 8 (DAY56)

VISIT CODE: 06.0

REQUIRED FOR ALL

FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
FDA-1	Drug-Alcohol Use Follow-up	131
FPV-1, 2	Partner Violence Follow-up	137, 138
BSS-1	Social Support	044
BAD-1, 2	Depression	045
SDC-1, 2, 3, 4	Post-traumatic Stress Disorder and Coping	055, 056, 057, 058,
DIS-1	Disclosure	061
AHK-1	Acute HIV Knowledge	071
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077

Acronym	Form Name	Plate #
EHK-1	Established HIV Knowledge	078
FU-1	Follow-up Visit	101
<i>INTERVENTION ARM REQUIRED</i>		
AAA-1, 2	Acceptability (Intervention and Standard)	201, 202
ITE-1, 2	Intervention Topics - Session 5 (Booster)	238, 239
CPE-1,2	Intervention Post-session Counselor Assessment - Session 5	263, 264
<i>AS NEEDED FOR ALL</i>		
COC-1, 2, 3	Intervention Counselor Observation Checklist	267, 268, 269
MV-1	Missed Visit	463
WEEK 12 (Day 84)		VISIT CODE: 07.0
<i>REQUIRED FOR ALL</i>		
FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
FU-1	Follow-up Visit	101
WEEK 12 (Day 84) cont.		VISIT CODE: 07.0
<i>AS NEEDED FOR ALL</i>		
MV-1	Missed Visit	463
WEEK 16 (DAY112)		VISIT CODE: 08.0
<i>REQUIRED FOR ALL</i>		
FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
EHK-1	Established HIV Knowledge	078
FU-1	Follow-up Visit	101
<i>AS NEEDED FOR ALL</i>		
MV-1	Missed Visit	463
WEEK 20 (Day 140)		VISIT CODE: 09.0
<i>REQUIRED FOR ALL</i>		
FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
FU-1	Follow-up Visit	101
<i>AS NEEDED FOR ALL</i>		
MV-1	Missed Visit	463
WEEK 24 (Day 168)		VISIT CODE: 10.0
<i>REQUIRED FOR ALL</i>		
FSH-1, 2, 3, 4, 5, 6, 7, 8, 9	Sexual History Follow-up	121, 122, 123, 124, 125, 126, 127, 128
FDA-1	Drug-Alcohol Use Follow-up	131
FPV-1, 2	Partner Violence Follow-up	137, 138
BSS-1	Social Support	044

Acronym	Form Name	Plate #
BAD-1, 2	Depression	045
SDC-1, 2, 3, 4	Post-traumatic Stress Disorder and Coping	055, 056, 057, 058,
DIS-1	Disclosure	061
RSM-1, 2, 3, 4, 5, 6	Risk, Self-efficacy, and Motivation	072, 073, 074, 075, 076, 077
EHK-1	Established HIV Knowledge	078
<i>REQUIRED FOR ALL (cont.)</i>		
FU-1	Follow-up Visit	101
<i>AS NEEDED FOR ALL</i>		
MV-1	Missed Visit	463

9.14. Qualitative Data Collection

An in-depth interview (semi-structured interview) will be conducted with participants at weeks 2 (or 3), 8, 12, and 24, in both arms. At the week 2/3 interview, questions will primarily focus on the participants' perceptions of the format, content, and effectiveness of the counseling sessions, experimental or standard. Questions about sexual behavior will also be asked. At the week 8 interview, questions will primarily focus on gathering more in-depth information on sexual behavior and on risk behavior, particularly on perceptions as participants transition out of the acute/early phase of HIV infection. At the week 12 and 24 interviews, questions will primarily focus on risk dishibition. Acceptability questions may also be asked at week 8, 12, and 24. All qualitative interviews will be audio taped if permission is granted by the participant.

In addition, counselors will also be interviewed to assess their perceptions of the acceptability and perceived impact of the intervention over the course of the study as well as on implementation of the intervention. Two qualitative interviews will be conducted with each counselor. The first interview will be completed with each counselor when the counselor completes sessions 1-4 of the 062 intervention with 10 clients. The second interview will be completed when all sessions (sessions 1-5) are completed for all intervention participants. NOTE: The timing of these interviews must remain flexible in order to adapt to unanticipated changes in the sample size. Any change to the interview schedule will be discussed with the site team and protocol co-chairs prior to implementation. These will be audio taped with consent.

All qualitative interviews will have a question guide that interviewers will follow during the interview. The transcripts of interviews will be sent to FHI where qualitative analysis will be conducted.

Each site will have an SOP and work instructions detailing the process of data collection. The SOP will contain at a minimum the following information:

- Data collection procedures
- Labeling and storing tapes and transcripts

- Tracking the number of completed interviews
- Transcribing audio tapes
- Reporting data to FHI