



(HPTN 074) DF/Net 074

(DEM-1) 001

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>				

Form Completion Date:

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

Demographics

Thank you for being a part of our research. People live in different places, with different customs, cultures, sexual practices and beliefs. We hope to include people from different communities in our research. We respect all people, regardless of their differences. Not all questions we ask in our research will apply to you. Because we do not want to make assumptions, we ask the same questions of everyone. We want you to be comfortable in speaking with us. You do not have to answer any question that makes you uncomfortable.

Now I am going to ask you some questions about yourself. The answer to these questions will tell us more about who you are, such as your age and ethnicity (what cultural group you come from). I will also ask you about your sex and gender. Please feel free to ask any questions about things that you don't understand.

1	What is your date of birth?	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> <tr> <td colspan="2" style="text-align: center;"><i>dd</i></td> <td colspan="2" style="text-align: center;"><i>MMM</i></td> <td colspan="2" style="text-align: center;"><i>yy</i></td> </tr> </table>							<i>dd</i>		<i>MMM</i>		<i>yy</i>		OR	<i>If unknown, record age:</i> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table> <i>years</i>		
<i>dd</i>		<i>MMM</i>		<i>yy</i>														
2	What is your sex at birth?	<input type="checkbox"/> <i>Male</i> <input type="checkbox"/> <i>Female</i>																
3	How do you identify your gender? <i>Mark all that apply.</i>	<input type="checkbox"/> <i>Male</i> <input type="checkbox"/> <i>Female</i> <input type="checkbox"/> <i>Other, specify:</i> <i>Local language:</i> _____ <i>English:</i> _____																
4	Are you currently a student?	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>																

This interviewer-administered form is used to collect participants' demographic information.

This form is completed for all participants who were assigned a Participant ID during screening. Submit this CRF with **Screening Outcome** form for those participants who do not enroll. Submit after the enrollment visit only for those participants who enroll.

Item-specific Instructions:

Item 1	If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
Item 3	This item must be self-reported by the participant. Site staff is encouraged to document in chart notes if the participant, during study participation, prefers to be referred to by a specific pronoun or gender.

This interviewer-administered form is used to collect participants' demographic information.

This form is completed for all participants who were assigned a Participant ID during screening. Submit this CRF with **Screening Outcome** form for those participants who do not enroll. Submit after the enrollment visit only for those participants who enroll.



(HPTN 074) DF/Net 074

(DEM-3) 003

Participant ID:

Site Number			Network Number				Chk		Cohort										

Demographics

8 How would you describe your current living situation? *Mark all that apply.*

- 8a. Live in a house that I own or rent
- 8b. Live in parent's home
- 8c. Live in other relative's home (e.g. sibling, cousin, aunt and/or uncle)
- 8d. Rent a room or space in someone else's house or apartment
- 8e. Stay with someone else for free (don't pay regular room and board)
- 8f. Live on the street, in a park, alley or abandoned building
- 8g. Live in a homeless shelter
- 8h. Stay at more than two different places a week
- 8i. Live in a drug recovery or any transitional house
- 8j. Refuse to answer
- 8k. Other place, specify:

Local language: _____

English: _____

9 Who lives with you? *Mark all that apply.*

- 9a. Spouse/partner/girl-boyfriend
- 9b. Own children
- 9c. Parents
- 9d. Other family members
- 9e. Friends
- 9f. Others (e.g., roommates, tenants)
- 9g. Live alone
- 9h. Refuse to answer

This interviewer-administered form is used to collect participants' demographic information.

This form is completed for all participants who were assigned a Participant ID during screening. Submit this CRF with **Screening Outcome** form for those participants who do not enroll. Submit after the enrollment visit only for those participants who enroll.

This interviewer-administered form is used to collect participants' demographic information.

This form is completed for all participants who were assigned a Participant ID during screening. Submit this CRF with **Screening Outcome** form for those participants who do not enroll. Submit after the enrollment visit only for those participants who enroll.

Item-specific Instructions:

Items 11-12	Employment is self-defined by the participant. Document any activity for which the participant is receiving payment for doing work, whether or not it is considered legal employment.
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(HPTN 074) DF/Net 074

(DVI) 007

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>				

Form Completion Date:

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

Demographics - Vietnam

1 What does the participant report as his/her ethnicity/nationality? *Mark all that apply.*

- 1a. Kinh
- 1b. Tay
- 1c. Nung
- 1d. San diu
- 1e. H'Mong
- 1f. San chi (Trail)
- 1g. Hoa
- 1h. Dao (Man)
- 1i. Cao Lan
- 1j. Ngai
- 1k. Thai
- 1l. Other, specify:

Local language: _____

English: _____

No instructions necessary.



(HPTN 074) DF/Net 074

(DIN) 009

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>		

Form Completion Date:

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

Demographics - Indonesia

1 What does the participant report as his/her ethnicity/nationality? *Mark all that apply.*

- 1a. *Betawi*
- 1b. *Jawa*
- 1c. *Sunda*
- 1d. *Minang*
- 1e. *Batak*
- 1f. *Bugis*
- 1g. *Ambon*
- 1h. *Tionghoa*
- 1i. *Other, specify:*

Local language: _____

English: _____

No additional instructions needed.



(HPTN 074) DF/Net 074

(DUK) 011

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>				

Form Completion Date:

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

Demographics - Ukraine

1 What does the participant report as his/her ethnicity/nationality? *Mark all that apply.*

1a. *Ukrainian*

1b. *Russian*

1c. *Other, specify:*

Local language: _____

English: _____

No additional instructions needed.



(HPTN 074) DF/Net 074

(IPT) 019

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>	

Screening Visit Date:

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

Index PTID Tracker

1 Was the participant's identity checked (e.g. fingerprint, unique identification card, etc.)? Yes No
 If yes, go to item 2.

1a. If no, reason: _____

2 Has this participant been seen before for HPTN 074? Yes No
 If no, end of form.

2a. List all prior PTIDs associated with this participant:

	<i>Site Number</i>	<i>Network Number</i>	<i>Chk</i>	<i>Cohort</i>		<i>Site Number</i>	<i>Network Number</i>	<i>Chk</i>	<i>Cohort</i>
PTID #1:					PTID #4:				
PTID #2:					PTID #5:				
PTID #3:									

This form is completed for all participants who were assigned a participant ID during screening and is submitted for all screened participants.

Item-specific Instructions:

Screening Visit Date	The screening visit date is the date which the participant provided a screening blood sample for HIV testing. A complete date is required.
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(HPTN 074) DF/Net 074

(ISO-1) 020

Participant ID:

Site Number			Network Number				Chk	Cohort			

Screening Visit Date:

dd		MMM		yy	

Index Screening Outcome

1 Did the participant agree to have samples of blood collected at screening stored and used for future testing related to HIV infection?

- Yes
- No

2 How was this participant recruited? *Mark all that apply.*

- 2a. From another drug injector
- 2b. From an HPTN 074 participant
- 2c. From a drug user outside of their network
- 2d. Social media (e.g., Facebook) or other internet
- 2e. Print media
- 2f. TV or radio media
- 2g. Harm reduction sites/center
- 2h. Hot spots
- 2i. HIV clinics
- 2j. MAT clinics
- 2k. Drug sales locations
- 2l. Outreach
- 2m. Other, specify: _____

Local language: _____

English: _____

3 Did the participant enroll in the study?

- Yes —▶ *If yes, end of form. Do not submit page 2.*
- No

The **Index Screening Outcome** CRF documents participant screening and collects information about recruitment and reasons why participants may not enroll in the study.

This form is completed for all participants who were assigned a participant ID during screening and is submitted for all screened participants.

Item-specific Instructions:

Screening Visit Date	The screening visit date is the date which the participant provided a screening blood sample for HIV testing. A complete date is required.
Item 1	Document the participant's decision regarding screening specimen storage as documented on the screening consent form.



(HPTN 074) DF/Net 074

(ISO-2) 021

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>				

Index Screening Outcome

4 Why was the participant not enrolled in the study? *Mark all that apply.*

- 4a. Current participation in an HIV prevention study or previous/current participation in an HIV vaccine study
- 4b. Serious and active medical or mental illness
- 4c. Previously screened as a potential network partner of another index participant in this study
- 4d. Currently or previously a partner of an index participant
- 4e. Unwilling to adhere to study procedures
- 4f. Withdrew consent/refused to participate
- 4g. Unable to recruit network partner within window after screening blood draw
- 4h. Viral load < 1,000 copies/mL
- 4i. Does not meet the criteria for active injection drug user per protocol
- 4j. Not HIV positive
- 4k. Does not report sharing needles/syringes or drug solutions at least once in the last month
- 4l. Did not complete screening procedures

4m. Other, specify: _____ Local language: _____
 English: _____

The **Index Screening Outcome** CRF documents participant screening and collects information about recruitment and reasons why participants may not enroll in the study.

This form is completed for all participants who were assigned a participant ID during screening and is submitted for all screened participants.

Item-specific Instructions:

Screening Visit Date	The screening visit date is the date which the participant provided a screening blood sample for HIV testing. A complete date is required.
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(HPTN 074) DF/Net 074

(PPT) 024

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>	

Screening Visit Date:

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

Partner PTID Tracker

1 Was the participant's identity checked (e.g. fingerprint, unique identification card, etc.)? Yes No
 If yes, go to item 2.

1a. If no, reason: _____

2 Has this participant been seen before for HPTN 074? Yes No
 If no, end of form.

2a. List all prior PTIDs associated with this participant:

	<i>Site Number</i>	<i>Network Number</i>	<i>Chk</i>	<i>Cohort</i>		<i>Site Number</i>	<i>Network Number</i>	<i>Chk</i>	<i>Cohort</i>
PTID #1:					PTID #4:				
PTID #2:					PTID #5:				
PTID #3:									

This form is completed for all participants who were assigned a participant ID during screening and is submitted for all screened participants.

Item-specific Instructions:

Screening Visit Date	The screening visit date is the date which the participant provided a screening blood sample for HIV testing. A complete date is required.
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(HPTN 074) DF/Net 074

(PSO) 025

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>					

Screening Visit Date:

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

Partner Screening Outcome

1 Did the participant agree to have samples of blood collected at screening stored and used for future testing related to HIV infection?

- Yes
- No

2 Did the participant enroll in the study?

- Yes → *If yes, end of form.*
- No

3 Why was the participant not enrolled in the study? *Mark all that apply.*

- 3a. Any reactive or positive HIV rapid or HIV EIA test
- 3b. Current participation in an HIV prevention study or previous/current participation in an HIV vaccine study
- 3c. Serious and active medical or mental illness
- 3d. Previously screened as a potential network member of another index participant in this study
- 3e. Previously named and enrolled as a partner of another index partner
- 3f. Unwilling to adhere to study procedures
- 3g. Withdrew consent/refused to participate
- 3h. Does not meet the criteria for active injection drug user per protocol
- 3i. Could not confirm injection relationship with index
- 3j. Did not complete screening procedures
- 3k. Other, specify: _____

Local language: _____

English: _____

The **Partner Screening Outcome** CRF documents participant screening and reasons why participants may not enroll in the study.

This form is completed for all participants who were assigned a participant ID during screening and is submitted for all screened participants.

Item-specific Instructions:

Screening Visit Date	The screening visit date is the date which the participant provided a screening blood sample for HIV testing.
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(HPTN 074) DF/Net 074

(IAI) 030

Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Visit Date:

dd MMM yy

Index ART Initiation

1 When did the participant indicate that s/he had initiated ART?

dd MMM yy

2 How was ART use determined? *Mark all that apply.*

2a. Participant self-report

2b. Outside clinic report/documentation

2c. Other, specify: *Local language:* _____

English: _____

3 Is the participant willing/able to provide documentation?

Yes

No → *If no, end of form.*

4 Record ART medications prescribed for the participant:

	ART Medication Code	Date Started		
		<i>dd</i>	<i>MMM</i>	<i>yy</i>
4a.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
4b.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
4c.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
4d.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
4e.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Comments (*Local language*): _____

Comments (*English*): _____

This form documents an Index participant's initiation of ART during the course of the study. This CRF should only be completed once.

Item-specific Instructions:

Visit Date	Record the date of the study visit.
Item 1	Record the date that the participant indicates that he/she initiated ART.
Item 3	Details about the use of ART means a specific listing of medications prescribed. Use source documentation (clinic notes, prescription bottles, etc.). If participant reports ART use by self-report, mark "no."
Items 4a-4e	<ul style="list-style-type: none">• ART Medication Code: Refer to the HPTN 074 website for the list of ART Medication Codes.• Date Started: When possible, record the complete date (day, month, year). If the exact date is unavailable, record the month and year.



(HPTN 074) DF/Net 074

(SUT) 040

Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Visit Date:

dd MMM yy

Substance Use Treatment Initiation

1 When did the participant indicate that s/he had initiated substance use treatment?

dd MMM yy

2 How was substance use treatment determined? *Mark all that apply.*

2a. Participant self-report

2b. Outside clinic report/documentation

2c. Other, specify: *Local language:* _____

English: _____

3 Is the participant willing/able to provide details about his/her substance use treatment?

Yes No → *If no, end of form.*

4 Record the types of substance use treatment the participant is involved in.

	Yes	No	If yes, date of most recent visit:		
			dd	MMM	yy
4a. Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4b. Buprenorphine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4c. Other medication (MAT), specify: <i>Local Language:</i> _____ <i>English:</i> _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4d. Detoxification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4e. Community treatment/religious, specify: <i>Local Language:</i> _____ <i>English:</i> _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4f. Other specify: <i>Local Language:</i> _____ <i>English:</i> _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comments (*Local language*): _____

Comments (*English*): _____

This form documents a participant's initiation of substance use treatment during the course of the study. This CRF should be completed only once.

Item-specific Instructions:

Visit Date	Record the date of the study visit.
Item 1	Record the date that the participant reports that s/he initiated substance use treatment. If the participant has started treatment more than once, indicate the most recent start date.
Item 3	Details about the use of substance use treatment means a specific listing of any intervention (MMT, detox, religious, etc.) the participant is engaged in. Use source documentation (clinic notes, prescription bottles, etc.) if possible.
Items 4a-4f	Date Started: When possible, record the complete date (day, month, year). If the exact date is unavailable, record the month and year.



(HPTN 074) DF/Net 074

(BBA-1) 071

Participant ID:

Site Number			Network Number				Chk	Cohort			

Assessment Date:

dd		MMM		yy	

Baseline Behavior Assessment

A broad range of participants are taking part in this study. So some questions may not apply to you. We ask the same questions of all participants.

In this interview, you will be asked about your sexual behaviors and possible alcohol and drug use. Some of the questions may seem very personal. Please remember that all of your answers will be kept private. Your responses are linked only to your study number, not to your name.

We need you to answer these questions honestly. We do not judge about alcohol or drug use. We make no judgments about how you have sex or the number of times or with whom.

These questions help us understand the type of behaviors our participants are doing while on study. Your honesty will help us understand these differences in behaviors.

HIV TESTING HISTORY

1 Prior to participating in this study, did you ever have an HIV test? Yes No → If no, go to item 2.

1a. How many times have you had an HIV test in your lifetime? # of times

1b. When was your most recent HIV test?
dd MMM yy

1c. What was the result of that test? Negative Positive Don't know

INCARCERATION

2 In the last 3 months, how many different times were you in...

2a. Jail/prison? # of times

2b. Involuntary detoxification/detention? # of times

2c. Other incarceration, specify: # of times

Local language: _____ English: _____

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 1b	When possible record the complete date (day, month, year). If the exact date is unknown, record month and year.
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(HPTN 074) DF/Net 074

(BBA-2) 072

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>				

Baseline Behavior Assessment

ALCOHOL USE (Audit C) Answer questions to reflect your behavior over the past 3 months.

3 How often do you have a drink containing alcohol?

Never **→** *If never, go to item 6.* *2-3 times a week*
 Monthly or less *4 or more times a week*
 2-4 times a month

4 How many standard drinks containing alcohol do you have on a typical day?

1 or 2 *7 to 9*
 3 or 4 *10 or more*
 5 or 6

5 How often do you have six or more drinks on one occasion?

Never *Weekly*
 Less than monthly *Daily or almost daily*
 Monthly

NON-INJECTION DRUG USE

6 In the last 3 months, did you...

	<i>Yes</i>	<i>No</i>
6a. Use marijuana?	<input type="checkbox"/>	<input type="checkbox"/>
6b. Use stimulants (cocaine, methamphetamines)?	<input type="checkbox"/>	<input type="checkbox"/>
6c. Use opiates (heroin, opium)?	<input type="checkbox"/>	<input type="checkbox"/>
6d. Use other drugs (<i>as indicated by sites</i>), specify:	<input type="checkbox"/>	<input type="checkbox"/>

Local language: _____

English: _____

7 When was the last time you used marijuana, amphetamines, methadone, opiates or benzodiazepines that you did not inject?

Never
 OR

dd MMM yy

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 6	Record any non-injected use of the drugs indicated (smoke, ingest, sniff, etc.). If appropriate, use local or street name of the drug.
Item 7	If the participant has never used these drugs in a non-injected method, mark "never." When possible record the complete date (day, month, year), if the exact date is unknown record month and year. If appropriate, use local or street name of the drug.



(HPTN 074) DF/Net 074

(BBA-3) 073

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>				

Baseline Behavior Assessment

INJECTION DRUG USE

8	How old were you when you first injected drugs?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>years</i>							
9	What is the longest time you have not injected drugs, voluntarily (e.g. when you were not incarcerated), since you started using injection drugs?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>months</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>days</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>years</i>			
10	In the last 3 months, which of the following did you inject?	<i>Yes</i>	<i>No</i>	<i>Yes</i>	<i>No</i>					
	10a. Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	10i. Ketamine	<input type="checkbox"/>	<input type="checkbox"/>				
	10b. Methamphetamines	<input type="checkbox"/>	<input type="checkbox"/>	10j. Homemade opioids	<input type="checkbox"/>	<input type="checkbox"/>				
	10c. Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	10k. Short and long action stimulants	<input type="checkbox"/>	<input type="checkbox"/>				
	10d. Heroin	<input type="checkbox"/>	<input type="checkbox"/>	10l. Dezomorphine	<input type="checkbox"/>	<input type="checkbox"/>				
	10e. Opium	<input type="checkbox"/>	<input type="checkbox"/>	10m. Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>				
	10f. Buprenorphine	<input type="checkbox"/>	<input type="checkbox"/>	<i>Local language:</i> _____						
	10g. Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<i>English:</i> _____						
	10h. Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>							
11	In the last month, on how many days did you inject drugs?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i># of days</i>							
12	In the last month, on days that you injected, how many times a day did you usually inject drugs?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i># of times a day</i>							
13	When was the last day you injected (including today)?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>dd</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>MMM</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>yy</i>	OR	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i># of months ago</i>

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 9	Record the longest period of time the participant has abstained from injecting drugs since he/she first began injecting drugs.
Item 10	If appropriate, use local or street name of the drug.
Item 13	When possible, record the complete date (day, month & year). If the exact date is unknown, record month and year.



(HPTN 074) DF/Net 074

(BBA-4) 074

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>				

Baseline Behavior Assessment

SHARING

Often people share syringes and other equipment because they are in a rush, they are concerned about the police, feeling sick or for a variety of other reasons.

		<i>Yes</i>	<i>No</i>	<i>Don't know</i>
14	Have you shared rinse water in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	14a. The last time you injected, did you share rinse water?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Have you shared a cooker/container in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	15a. The last time you injected, did you share a cooker/container?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Have you shared filter cotton in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16a. The last time you injected, did you share filter cotton?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CLEANING

17	How often do you clean your needle before injecting?	<input type="checkbox"/> <i>Always</i> <input type="checkbox"/> <i>More than half the time</i> <input type="checkbox"/> <i>Less than half the time</i> <input type="checkbox"/> <i>Never</i>			
18	The last time you injected, did you clean the needle before you injected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19	The last time you injected, did you use a new needle?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20	How often do you clean your needle after injecting?	<input type="checkbox"/> <i>Always</i> <input type="checkbox"/> <i>More than half the time</i> <input type="checkbox"/> <i>Less than half the time</i> <input type="checkbox"/> <i>Never</i>			
21	The last time you injected, did you clean the needle after you injected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.



(HPTN 074) DF/Net 074

(BBA-5) 075

Participant ID:

<i>Site Number</i>			<i>Network Number</i>			<i>Chk</i>		<i>Cohort</i>	

Baseline Behavior Assessment

PRE-FILLING AND BACKLOADING SYRINGES

22 The last time you injected, did you use a pre-filled syringe? Yes No Don't know

23 The last time you injected, did you inject drugs that were frontloaded or backloaded into the syringe or needle that you used? Yes No Don't know

24 In the last 3 months, how many different people did you use injection drugs with? # of people → If 000, go to item 30.

25 In the last 3 months, how many times did you even once pass on a needle or syringe to someone else after you used it? # of times → If 000, go to item 27.

26 In the last 3 months, with how many different people did you pass on a needle or syringe after you had used it? # of people

27 In the last 3 months, how many times did you ever, even once, use a needle or syringe after someone else used it? # of times → If 000, go to item 29.

28 In the last 3 months, with how many different people did you use a needle or syringe after someone else used it? # of people

29 In the past 3 months, when you shared syringes, how often did you inject last?

Always Most times Sometimes
 Rarely Never I have not shared in the past 3 months

30 In the last 3 months, did you get your new needles/syringes from a...

30a. I did not get new needles in the last 3 months → Go to item 32 on page 6.

	Yes	No
30b. Pharmacy or health center?	<input type="checkbox"/>	<input type="checkbox"/>
30c. Needle seller?	<input type="checkbox"/>	<input type="checkbox"/>
30d. Needle exchange?	<input type="checkbox"/>	<input type="checkbox"/>
30e. Other drug injectors?	<input type="checkbox"/>	<input type="checkbox"/>
30f. Other, specify?	<input type="checkbox"/>	<input type="checkbox"/>

Local language: _____ English: _____

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.



(HPTN 074) DF/Net 074

(BBA-6) 076

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>				

Baseline Behavior Assessment

PRE-FILLING AND BACKLOADING SYRINGES

31 In the last 3 months, when you obtained new needles, typically, how many did you buy at one time?

 # of needles

DRUG TREATMENT PROGRAMS *Indicate which types of treatment you have participated in.*

32 Have you ever participated in any type of drug treatment program? Yes No → *If no, go to item 36 on page 7.*

33 Methadone maintenance or any other medication assisted treatment program (MMT/MAT)? Yes No → *If no, go to item 34 on page 7.*

33a. What type of MMT/MAT program have you been on? **Mark all that apply.**

- | | |
|--|--|
| <input type="checkbox"/> 33a1. Methadone | <input type="checkbox"/> 33a3. Other, specify:
(Local language) _____ |
| <input type="checkbox"/> 33a2. Buprenorphine | (English) _____ |

33b. How many times have you enrolled in MMT/MAT?

 # of times

33c. What is the longest period of time you have been in MMT/MAT?

 months

 days

33d. Have you participated in MMT/MAT in the last 3 months? Yes No → *If no, go to item 34 on page 7.*

33e. What type of MMT/MAT program have you been on in the last 3 months? **Mark all that apply.**

- | | |
|--|--|
| <input type="checkbox"/> 33e1. Methadone | <input type="checkbox"/> 33e3. Other, specify:
(Local language) _____ |
| <input type="checkbox"/> 33e2. Buprenorphine | (English) _____ |

33f. Are you currently in MMT/MAT? Yes No
→ *If yes, complete the Substance Use Treatment Initiation CRF.*

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 31	If the participant has not obtained his/her own needles or cannot remember, enter "000."
Item 33c	Enter both the number of months <u>and</u> days participant was in MMT/MAT. Do not leave any boxes blank. For example, 3 years is 36 months and 00 days. 6 weeks would be recorded as 01 months and 14 days.



(HPTN 074) DF/Net 074

(BBA-7) 077

Participant ID:

Site Number			Network Number				Chk	Cohort				

Baseline Behavior Assessment

DRUG TREATMENT PROGRAMS

34	A health care provider supported drug detoxification program?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	→ If no, go to item 35.
	34a. How many times have you enrolled in detoxification?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> # of times		
	34b. What is the longest period of time you have been in detoxification?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> months <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> days		
	34c. Have you participated in detoxification in the last 3 months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	→ If no, go to item 35.
	34d. Are you currently in detoxification?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
35	Any type of other drug treatment program (e.g. community treatment/religious)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	→ If no, go to item 36.
	35a. How many times have you enrolled in any other type of drug treatment?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> # of times		
	35b. What is the longest period of time you have been in this type of program?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> months <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> days		
	35c. Have you participated in this type of program in the last 3 months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	→ If no, go to item 36.
	35d. Are you currently in this type of program?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

SEXUAL BEHAVIOR QUESTIONS

The next few questions are about sexual behavior. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.

36	In the last 3 months, did you have vaginal or anal sex?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	→ If no, go to item 42 on page 8.
37	In the last month, how many different female sex partners have you had?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> # of female sex partners		
38	In the last month, how many different male sex partners have you had?	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> # of male sex partners		

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 34	Health care provider supported drug detoxification program can be voluntary or involuntary, in-patient or out-patient. Do not include alcohol-only detoxification programs.
Item 34b	Enter both the number of months <u>and</u> days participant was in detoxification. Do not leave any boxes blank. For example, 3 years is 36 months and 00 days. 6 weeks would be recorded as 01 months and 14 days.
Item 35	Other includes any secular, religious-based, or home based programs that are not supported by a healthcare provider.
Item 35b	Enter both the number of months and days participant was in MMT/MAT. Do not leave any boxes blank. For example, 3 years is 36 months and 00 days. 6 weeks would be recorded as 01 months and 14 days.



(HPTN 074) DF/Net 074

(BBA-8) 078

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>		

Baseline Behavior Assessment

39 Do you have a main partner such as a husband/wife or boyfriend/girlfriend? Yes No → *If no, go to item 41.*

39a. Is your main partner male or female?

Male Female Other, specify: *(Local language)* _____
(English) _____

40 In the last month, how many times did you have vaginal or anal sex with your main partner? # of times → *If 000, go to item 41.*

40a. How many of these times did you (or your partner) use a condom? # of times

41 In the last month, how many times did you have vaginal or anal sex with someone other than a main partner? # of times → *If 000, go to item 42.*

41a. How many of these times did you (or your partner) use a condom? # of times

Next I am going to ask about your sex trade (paid or paying) partners. By sex trade partners, I mean people that you had oral, vaginal or anal sex with in exchange for money, drugs, food or a place to stay.

42 In the last month, how many times did you give sex partners money or drugs in exchange for sex? # of times

43 In the last month, how many times did a sex partner give you money or drugs in exchange for sex? # of times

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 39	"Main partner" is someone you consider your wife/husband/boyfriend/girlfriend, have oral, vaginal or anal sex with, have been in a relationship with for at least 3 weeks. Do not include anyone you have had sex with casually or in exchange for money, drugs, food or a place to stay.
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(HPTN 074) DF/Net 074

(IBH-1) 085

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>	

Assessment Date:

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

Index Baseline HIV Care and ART

The next few questions are about anti-HIV medicines called antiretroviral therapy that you may be taking. These questions are not about drugs you may be taking to treat substance use. We need to know what is really happening, not what you think we "want to hear." Many people find it hard to take their medications all of the time.

1 When did you first find out that you were HIV positive?

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

2 With whom have you shared that you are living with HIV? *Mark all that apply.*

<input type="checkbox"/> 2a. Spouse/partner/girl-boyfriend	<input type="checkbox"/> 2d. Other family members	<input type="checkbox"/> 2g. No one
<input type="checkbox"/> 2b. Own children	<input type="checkbox"/> 2e. Friends	<input type="checkbox"/> 2h. Refuse to answer
<input type="checkbox"/> 2c. Parents	<input type="checkbox"/> 2f. Others	

3 How many of your drug partners (the people you inject drugs with) know that you have HIV?

- All of my partners
- More than half of my partners
- Less than half of my partners
- None of my partners

This is an interviewer-administered form.



(HPTN 074) DF/Net 074

(IBH-2) 086

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>		

Index Baseline HIV Care and ART

4 Who is the most supportive in helping you with your HIV care and treatment?

- Health care providers (such as doctors or nurses)
- Your spouse/live-in partner/long-term partner
- Casual sexual partner (i.e., friends or associates who you just met and had sex with)
- Injecting partners
- Commercial sex workers
- Your mother and father
- Your in-laws
- Other family members
- Priests/religious leaders
- Your neighbors or community members
- Friends
- Your employers
- Other, specify: *(Local language)* _____
(English) _____

5 How often have you talked to your family or support person about your HIV medications?

- More than once per week
- 2-3 times a month
- One time
- Once a week
- Once a month
- Never

6 Since you found out you were living with HIV, have you seen an HIV clinician?

- Yes
- No

→ If no, go to item 8 on page 3.

6a. If yes, on what date was your most recent visit?

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

7 Has any HIV clinician ever told you that you should initiate ART treatment for your own health?

- Yes
- No

This is an interviewer-administered form.



(HPTN 074) DF/Net 074

(IBH-3) 087

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>		

Index Baseline HIV Care and ART

8 Have you ever visited an HIV clinic or pharmacy with the intention of starting ART? Yes No

9 Have you ever been on ART treatment? Yes No

10 Are you currently taking ART medications? *If yes, complete Index ART Initiation CRF.* Yes No
If no, go to Item 16 on page 5.

11 We know that it is very difficult to take your HIV medications all the time. When was the last time you missed taking any doses of your ART medication?

Within the past week *3-4 weeks ago* *Never missed taking medications in past 3 months*
 1-2 weeks ago *1-3 months ago* *End of form.*

12 In the last month, on about how many days did you miss at least one tablet? days

13 Did you miss at least one tablet in the last four days? Yes No
If no, go to Item 15 on page 4.

13a. In the last four days, on how many days did you miss at least one tablet? days

14 Did you miss at least one tablet yesterday? Yes No

This is an interviewer-administered form.



(HPTN 074) DF/Net 074

(IBH-4) 088

No data recorded on this page

Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Site Number			Network Number				Chk	Cohort		

Index Baseline HIV Care and ART

15 The last time you missed at least one tablet, which of these best describes the reason why? *Mark only one. End of form.*

- I forgot
- I did not have the medication with me at the time I needed to take it
- I did not want person(s) nearby to see me taking the medication
- I was trying to avoid side effects
- I felt healthy
- I was drunk
- I am not engaging in any behaviors that can transmit HIV to others
- I do not believe the medicines are beneficial
- Not applicable
- Other, specify: (Local language) _____
(English) _____

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(IBH-5) 089

No data recorded on this page

Participant ID:

<i>Site Number</i>			<i>Network Number</i>			<i>Chk</i>		<i>Cohort</i>	

Index Baseline HIV Care and ART

	Sometimes people have trouble starting HIV treatment (ART) because of personal situations or circumstances. What are the reasons you have not started taking ART?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not Applicable</i>
16	Sometimes people have trouble starting HIV treatment (ART) because of personal situations or circumstances. What are the reasons you have not started taking ART?			
	16a. You don't think that you need it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16b. You don't have time to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16c. You don't have the energy or motivation to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16d. You missed an appointment, so it is difficult to go back.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16e. You have been too sick to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16f. Your drug use got in the way of going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16g. You are worried about the unwanted side effects or complications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16h. You don't understand when you are supposed to take each pill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16i. You sold or lost your medicine or your medicine was stolen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16j. Your drinking (alcohol) got in the way of you going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16k. You had to wait too long, so you left without being seen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Sometimes people find it difficult to start taking ART because of their family or friends. What are the reasons you have not started taking ART?			
	17a. You don't have enough support from family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	17b. You don't want others to know you have HIV (e.g., see me take medication).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(IBH-6) 090

No data recorded on this page

Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number		Network Number			Chk	Cohort	

Index Baseline HIV Care and ART

18	Many people find it difficult to start taking ART, even if they have previously tried, because of challenges in the health systems/health care process. What were the reasons you have not started taking ART?	Agree	Disagree	Not relevant/ Not Applicable
18a.	You do not have the necessary materials (e.g. paperwork, identification, test results) needed by the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18b.	ART is too expensive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18c.	ART was not available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18d.	HIV care provider would not continue your medicine or prescription.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18e.	You do not know how or where to get ART.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18f.	You find transport/travel to the clinic is difficult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18g.	You have been traveling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18h.	You have been in jail or incarcerated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18i.	You are scared of being arrested for your drug use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18j.	You will need to register with the government as being a drug user.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19 Are there any other reasons you find it difficult to start taking ART?

Local language: _____

English: _____

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(IE) 091

Participant ID:

<i>Site Number</i>	<i>Network Number</i>	<i>Chk</i>	<i>Cohort</i>						

Enrollment Date:

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

Index Enrollment

1 Did the participant agree to have their samples of blood collected at enrollment used for future testing related to HIV infection?

Yes

No

2 Did the participant agree to have their samples of urine collected at enrollment used for future testing related to drug use?

Yes

No

3 To which study arm is the participant assigned?

Standard of care

Intervention

This form is completed at Enrollment only.

Item-specific Instructions:

Items 1 and 2	Document the index participant's decision regarding enrollment specimen storage as documented on the enrollment consent form.
----------------------	---



(HPTN 074) DF/Net 074

(PE) 095

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>		

Enrollment Date:

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

Partner Enrollment

1 Did the participant agree to have their samples of blood collected at enrollment used for future testing related to HIV infection?

Yes

No

2 Did the participant agree to have their samples of urine collected at enrollment used for future testing related to drug use?

Yes

No

3 At which index visit was this network partner enrolled?

Index Visit Code:

--	--

 .

--

3a. Index enrollment date:

Date:

--	--

--	--	--	--

--	--

dd *MMM* *yy*

This form is completed at Enrollment only.

Item-specific Instructions:

Items 1 and 2	Document the participant's decision regarding enrollment specimen storage as documented on the enrollment consent form.
Items 3 and 3a	For network partners that are enrolled after their index partners enrollment visit, indicate the index visit code at which the partner enrolled and enter the index participant's enrollment date.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Visit Date:

dd MMM yy

Index Network Status

1	How many total injection partners are listed on the Social/Sexual Network List?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of partners</i>
2	How many new injection partners were added to the partner list as of this visit? By new, we mean they had not been in the list prior to this visit.	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of new partners</i>
3	Is a new partner enrolling at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No	} If both 3 and 3a are no, end of form.
3a.	Does the index currently have an enrolled partner with whom they are currently (within the last month) sharing needles, water, cookers, etc?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	List the enrolled partners with whom the participant has shared needles, water, cookers etc. in the last 3 months (include partners enrolled at this visit).		
	Partner's Initials or Nickname:	Participant ID:	
		<i>Site Number</i>	<i>Network Number</i> <i>Chk</i> <i>Cohort</i>
4a.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4b.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4c.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4d.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4e.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4f.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4g.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4h.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
4i.	_____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Comments (*Local Language*): _____

Comments (*English*): _____

This form is used to document new or returning network partners at follow-up visits.

The index may enroll additional network partners over the course of the study if the relationship and the partner meet protocol eligibility criteria. The index may end a relationship with a network partner, begin a relationship with a network partner or re-establish a relationship with a previous network partner. However, an index participant may only have up to 5 active network partners at any given time.

Item-specific Instructions:

Item 1	If no partners are listed on the Social/Sexual Network List (non-CRF), enter 000.
Item 2	If no new partners were added, enter 000.
Item 4	Returning partners who had previously enrolled in the study maintain his/her original Partner ID.



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(FUV) 120

Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Visit Date:

dd MMM yy

Follow-up Visit

1 Is this an interim visit? Yes No → *If no, go to item 2.*

1a. Reason for interim visit. **Mark all that apply.**

- 1a1. Report a new AE(s) 1a5. Repeat laboratory work
- 1a2. Report a social impact 1a6. Other, specify:
- 1a3. HIV testing (Local language) _____
- 1a4. New injection partner (English) _____

1b. Besides this form, what other DataFax forms were completed at this visit? **Mark all that apply.**

- 1b1. Partner HIV Test Results 1b6. CD4+/Viral Load Results
- 1b2. Index ART Initiation 1b7. Adverse Experience Log (new)
- 1b3. Substance Use Treatment Initiation 1b8. Social Impact Log (new)
- 1b4. Urine Drug Screen 1b9. Other, specify:
- 1b5. Specimen Storage (Local language) _____
- (English) _____

2 At this visit, how many new Adverse Experiences (AEs) have been reported? → *Complete a separate AE Log page for each AE. If none, enter 00.*

3 At this visit, how many new social impacts have been reported? → *Complete a separate Social Impact Log page for each event. If none, enter 00.*

This form is used to summarize information from each participant follow-up study visit (including interim visits).

Item-specific Instructions:

Visit Code	If this form is used for an interim visit, use an interim visit code. If it is used for a scheduled visit, use the visit code required for that visit. If this form is used for an interim visit, all other forms completed for this visit must have the same visit code as the one on this Follow-up Visit form.
Item 1b	Mark the newly completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronym(s) in the space provided.



Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>		

Social Impact Log

- 1 Concisely describe social impact: _____

- 2 Onset date:
dd MMM yy
- 3 Reported at visit: .
- 4 Social impact code: → *See back for definitions of Social Impact Codes.*

Complete this form when recording the occurrence and resolution of adverse social impacts reported on scheduled Social Impact Assessment Questionnaire forms and those reported spontaneously at any time during the study.

Social impacts are events that the participant thinks are related to participation in this study.

Item-specific Instructions:

Item 3	If a participant reports a negative social impact outside of a regularly scheduled visit, complete this Log and the Interim Visit form. Record the same interim visit code on both forms.	
Item 4	Use the following definitions to code the social impact.	
	Code	Definition
01	Personal Relationships	Had negative experiences with family, friends, significant others, or sex partners.
02	Travel/Immigration	Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.
03	Employment	Been turned down for a new job, lost a job, or experienced other problems at work.
04	Education	Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.
05	Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider.
06	Health Insurance	Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
07	Life Insurance	Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.
08	Housing	Had trouble getting or keeping housing, or had other problems related to housing.
09	Military/Other Government Agency	Had a problem with the military or any other government agencies.
10	Other	Had other problems not covered in the codes above.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Contact Date:

dd MMM yy

Social Impact Assessment

1	Because of your participation in this study, did anything negative or bad happen to you that you have not reported to us already?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 4.</i>
2	Because of your participation in this study, have you...			
	2a. been arrested or had trouble with the police or other legal problems?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 2b.</i>
	2a1. If yes how many times?	<input type="text"/> <input type="text"/> # of times		
	2b. had trouble getting or keeping housing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 2c.</i>
	2b1. If yes how many times?	<input type="text"/> <input type="text"/> # of times		
	2c. had trouble getting or keeping a job or trouble with income or economic support?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 2d.</i>
	2c1. If yes how many times?	<input type="text"/> <input type="text"/> # of times		
	2d. had trouble getting health care or with health insurance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 2e.</i>
	2d1. If yes how many times?	<input type="text"/> <input type="text"/> # of times		
	2e. had personal trouble with friends, family, or acquaintances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>→ If no, go to item 2f.</i>
	2e1. If yes how many times?	<input type="text"/> <input type="text"/> # of times		
	2f. had any other type of problem?	<input type="checkbox"/> Yes, <i>specify:</i>	<input type="checkbox"/> No	<i>→ If no, go to item 3.</i>
	<i>Local language:</i> _____	<i>English:</i> _____		
3	Indicate the total number of impacts:	<input type="text"/> <input type="text"/> # of impacts <i>Complete a separate Social Impact Log (SIL) for each impact.</i>		
4	Has your participation in this study had any positive or beneficial impact on your life?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't know <i>If no, end of form. Do not fax page 2.</i>

Complete this form when documenting information on any social impact, whether positive or negative, that a participant experiences as a result of being in this HIV prevention trial.

Adverse social impacts associated with study participation must be reported and followed until their resolution using the Social Impact Log. Only report new experiences on this form that have not already been documented on a Social Impact Log. Worsening or continuation of a situation previously reported is not considered a “new” experience.

Item-specific Instructions:

Items 1-3	<p>Read all sub-items to the participant and mark a response for each. If the participant refuses any, write “refused” and line through the response box.</p> <ul style="list-style-type: none"> • If the participant answers “yes” to any responses in item 2, a Social Impact Log page must be completed. • Total the number of social impacts reported and enter the number in the boxes labeled “total number of impacts.” Complete one Social Impact Log page for each impact reported. • If two separate occurrences of the same type of social impact are reported, (e.g., two separate episodes of personal relationship problems), mark the “yes” box for that social impact, and include both episodes in the total. Complete one Social Impact Log page for each episode.
Item 4	A “beneficial” impact means anything good or that has improved the participant’s quality of life.



Visit Code: .

Participant ID:

- - -

Site Number *Network Number* *Chk* *Cohort*

Social Impact Assessment

5	Because of your participation in this study, have you experienced...	<i>Yes</i>	<i>No</i>
5a.	Employment improvement?	<input type="checkbox"/>	<input type="checkbox"/>
5b.	Financial improvement?	<input type="checkbox"/>	<input type="checkbox"/>
5c.	Reduction in drug use?	<input type="checkbox"/>	<input type="checkbox"/>
5d.	Reduction in cravings/withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
5e.	Gained knowledge?	<input type="checkbox"/>	<input type="checkbox"/>
5f.	Life improvement?	<input type="checkbox"/>	<input type="checkbox"/>
5g.	Physical health improvement?	<input type="checkbox"/>	<input type="checkbox"/>
5h.	Improved relationships?	<input type="checkbox"/>	<input type="checkbox"/>
5i.	Reduced stigma?	<input type="checkbox"/>	<input type="checkbox"/>
5j.	Improved mental health?	<input type="checkbox"/>	<input type="checkbox"/>
5k.	Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>

Local language: _____

English: _____

Complete this form when documenting information on any social impact, whether positive or negative, that a participant experiences as a result of being in this HIV prevention trial.

Adverse social impacts associated with study participation must be reported and followed until their resolution using the Social Impact Log. Only report new experiences on this form that have not already been documented on a Social Impact Log. Worsening or continuation of a situation previously reported is not considered a “new” experience.



(HPTN 074) DF/Net 074

(STG-1) 155

Visit Code: .

Participant ID:

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Site Number Network Number Chk Cohort

Contact Date:

dd MMM yy

Social Support and Stigma Questionnaire

In this section, I am going to read you statements about how you may feel about yourself, your injection drug use, and your HIV/AIDS infection. I would like you to tell me if you agree strongly, agree, disagree, or disagree strongly with each statement.

INTERNALIZED STIGMA AND SHAME

		<i>Agree strongly</i>	<i>Agree</i>	<i>Disagree</i>	<i>Disagree strongly</i>
1	I think less of myself or I have felt ashamed because:				
	1a. I inject drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1b. I am living with HIV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EXPERIENCED STIGMA

		<i>Agree strongly</i>	<i>Agree</i>	<i>Disagree</i>	<i>Disagree strongly</i>
2	I have become isolated from my family because:				
	2a. I inject drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	2b. I am living with HIV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

ANTICIPATED STIGMA

		<i>Agree strongly</i>	<i>Agree</i>	<i>Disagree</i>	<i>Disagree strongly</i>
3	I fear that if I disclosed my HIV status to my family, they would exclude me from usual family activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	I fear that if I disclosed my HIV status to others, I would find it hard to find work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	I fear that if I go to an MMT or buprenorphine clinic to treat my substance use I will be treated poorly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I fear that if I go to an HIV clinic I will be treated poorly because I inject drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	I do not feel comfortable talking to health care providers as I feel they would judge me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

No instructions necessary.



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(STG-2) 156

Visit Code: .

Participant ID:

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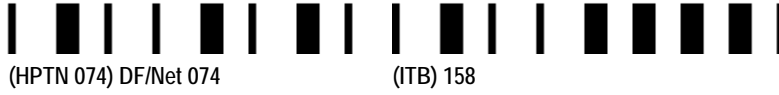
Site Number Network Number Chk Cohort

Social Support and Stigma Questionnaire

8	Over the last 2 weeks, how often have you been bothered by any of the following problems?	<i>Not at all</i>	<i>Several days</i>	<i>More than half of the days</i>	<i>Nearly every day</i>
	8a. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8b. Feeling down, depressed or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8c. Trouble falling or staying asleep or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8d. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8e. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8f. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8g. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8h. Moving or speaking so slowly that other people have noticed; or the opposite—being so fidgety or restless that you have to be moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8i. Thoughts that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9	People sometimes look to others for companionship, assistance, or other types of support. Please tell me how often each of the following kinds of support are available to you if you need them.			
	9a. Someone to have a good time with:			
	<input type="checkbox"/> <i>None of the time</i>	<input type="checkbox"/> <i>A little of the time</i>	<input type="checkbox"/> <i>Some of the time</i>	<input type="checkbox"/> <i>Most of the time</i>
	9b. Someone to get together with for relaxation:			
	<input type="checkbox"/> <i>None of the time</i>	<input type="checkbox"/> <i>A little of the time</i>	<input type="checkbox"/> <i>Some of the time</i>	<input type="checkbox"/> <i>Most of the time</i>
	9c. Someone to do something enjoyable with:			
	<input type="checkbox"/> <i>None of the time</i>	<input type="checkbox"/> <i>A little of the time</i>	<input type="checkbox"/> <i>Some of the time</i>	<input type="checkbox"/> <i>Most of the time</i>

No instructions necessary.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Contact Date:

dd MMM yy

Index Treatment Belief Questionnaire

		<i>Agree strongly</i>	<i>Agree</i>	<i>Disagree</i>	<i>Disagree strongly</i>	
1	If you have side effects, you should continue to take your HIV treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	HIV treatment is safe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	HIV treatment is effective (by effective we mean, does it work).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	If you miss your medication one day, what should you do? <input type="checkbox"/> <i>Take double dose</i> <input type="checkbox"/> <i>Take regular dose</i> <input type="checkbox"/> <i>Take one and half doses</i>					
5	In the past 3 months, have you set personal goals for your HIV treatment?	<input type="checkbox"/> <i>Yes</i>	<input type="checkbox"/> <i>No</i>			
6	In the past 3 months, have you asked questions to your medical provider about your HIV?	<input type="checkbox"/> <i>Yes</i>	<input type="checkbox"/> <i>No</i>			
		<i>Agree strongly</i>	<i>Agree</i>	<i>Disagree</i>	<i>Disagree strongly</i>	
7	If you have side effects, you should continue to take your substance use treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8	Substitution therapy (site specific, only ask if available) therapy is safe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>N/A</i>
9	Substance use treatment is effective (by effective we mean, does it work).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10	If you miss your substance use treatment medication one day, what should you do? <input type="checkbox"/> <i>Take double dose</i> <input type="checkbox"/> <i>Take regular dose</i> <input type="checkbox"/> <i>Take one and half doses</i>					

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English

Completed by: _____ *(initials/date)*

Item-specific Instructions:

Item 8	If substitution therapy is not available at the site, mark N/A.
---------------	---



Visit Code: .

Participant ID:

- - -

Site Number Participant Number Chk Cohort

Specimen Collection Date:

dd MMM yy

Urine Drug Screen

Not done/Not collected → *End of form.*

1	Was drug detected?	<i>Yes</i>	<i>No</i>	<i>Not done/ Not collected</i>
1a.	Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1b.	Methamphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1c.	Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1d.	Opiates/morphine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1e.	Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1f.	Buprenorphine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1g.	Cannabinoids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1h.	Cocaine metabolite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1i.	Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>(Local language)</i> _____			
	<i>(English)</i> _____			

Comments *(Local language)*: _____

Comments *(English)*: _____

Results from tests performed on urine samples (drug screening) are recorded on this form.

Item-specific Instructions:

Specimen Collection Date	Record the date that the specimen was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Not done/Not collected	If the urine sample was not collected (e.g. the participant refused or forgot), mark "Not done/Not collected", then end of form.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Assessment Date:

dd MMM yy

Follow-up Behavior Assessment

A broad range of participants are taking part in this study. So some questions may not apply to you. We ask the same questions of all participants.

In this interview, you will be asked about your sexual behaviors and possible alcohol and drug use. Some of the questions may seem very personal. Please remember that all of your answers will be kept private. Your responses are linked only to your study number, not to your name.

We need you to answer these questions honestly. We do not judge about alcohol or drug use. We make no judgments about how you have sex or the number of times or with whom.

These questions help us understand the type of behaviors our participants are doing while on study. Your honesty will help us understand these differences in behaviors.

FOLLOW-UP DEMOGRAPHICS

1 How would you describe your current living situation? *Mark all that apply.*

- 1a. Live in a house that I own or rent
- 1b. Live in parent's home
- 1c. Live in other relative's home (e.g. sibling, cousin, aunt and/or uncle)
- 1d. Rent a room or space in someone else's house or apartment
- 1e. Stay with someone else for free (don't pay regular room and board)
- 1f. Live on the street, in a park, alley or abandoned building
- 1g. Live in a homeless shelter
- 1h. Stay at more than two different places a week
- 1i. Live in a drug recovery or any transitional house
- 1j. Other place, specify:

Local language: _____

English: _____

- 1k. Refuse to answer

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.



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(FBA-2) 172

Visit Code: .

Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Site Number			Network Number				Chk	Cohort		

Follow-up Behavior Assessment

2 Who lives with you? *Mark all that apply.*

- 2a. Spouse/partner/girl-boyfriend
- 2b. Own children
- 2c. Parents
- 2d. Other family members
- 2e. Friends
- 2f. Others (e.g., roommates, tenants)
- 2g. Live alone
- 2h. Refuse to answer

3 What is your relationship status? Are you:

- Married
- Living with a sexual partner but not married
- Separated
- Divorced
- Widowed
- Single
- Refuse to answer

4 At any time during the last 3 months, that is from today, have you been unemployed?

- Yes
- No
- Refuse to answer

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential. Answer these questions to reflect your behavior for the past 3 months.

This is an interviewer-administered form.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

5 Which of the following best describes your current employment status? Are you:

- Employed full-time*
- Employed part-time*
- Unemployed but seeking work*
- Unemployed—not seeking work*
- Retired*
- Refuse to answer*

6 In the past month, how many days have you been working for pay? # days

7 (*Index: Intervention ONLY*) Do you have a designated support person? Yes No → *If no, go to item 8.*

7a. What is the relationship of the support person to you?

- Spouse/partner/girl-boyfriend*
- Father/mother*
- Sibling*
- Other family member*
- Friend*
- Other, specify:*

Local language: _____

English: _____

INCARCERATION

8 In the last 3 months, how many different times were you in...

8a. Jail/prison? # of times

8b. Involuntary detoxification/detention? # of times

8c. Other incarceration, specify: # of times

Local language: _____ *English:* _____

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential. Answer these questions to reflect your behavior for the past 3 months.

This is an interviewer-administered form.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

ALCOHOL USE (Audit C) *Answer questions to reflect your behavior over the past 3 months.*

9 How often do you have a drink containing alcohol?

Never **→** *If never, go to item 12.* *2-3 times a week*

Monthly or less *4 or more times a week*

2-4 times a month

10 How many standard drinks containing alcohol do you have on a typical day?

1 or 2 *7 to 9*

3 or 4 *10 or more*

5 or 6

11 How often do you have six or more drinks on one occasion?

Never *Weekly*

Less than monthly *Daily or almost daily*

Monthly

NON-INJECTION DRUG USE

12 In the last 3 months, did you... *Yes* *No*

12a. Use marijuana?

12b. Use stimulants (cocaine, methamphetamines)?

12c. Use opiates (heroin, opium)?

12d. Use other drugs (*as indicated by sites*), specify:

Local language: _____

English: _____

13 When was the last time you used marijuana, amphetamines, methadone, opiates or benzodiazepines that you did not inject? OR *Never*

dd MMM yy

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 12	If appropriate, use local or street name of the drug.
Item 12d	Record any non-injected use of the drugs indicated (smoke, ingest, sniff, etc.).
Item 13	When possible record the complete date (day, month, and year). If the exact date is unknown, record month and year. If the participant has never used these drugs in a non-injected method, mark "never."



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

INJECTION DRUG USE

14 In the last 3 months, did you use a needle to inject any drugs under your skin or into a vein? Yes No → *If no, go to item 33 on page 8.*

15 In the last 3 months, which of the following did you inject?

	<i>Yes</i>	<i>No</i>		<i>Yes</i>	<i>No</i>
15a. Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	15i. Ketamine	<input type="checkbox"/>	<input type="checkbox"/>
15b. Methamphetamines	<input type="checkbox"/>	<input type="checkbox"/>	15j. Homemade opioids	<input type="checkbox"/>	<input type="checkbox"/>
15c. Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	15k. Short and long action stimulants	<input type="checkbox"/>	<input type="checkbox"/>
15d. Heroin	<input type="checkbox"/>	<input type="checkbox"/>	15l. Dezomorphine	<input type="checkbox"/>	<input type="checkbox"/>
15e. Opium	<input type="checkbox"/>	<input type="checkbox"/>	15m. Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>
15f. Buprenorphine	<input type="checkbox"/>	<input type="checkbox"/>	<i>Local language:</i> _____		
15g. Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<i>English:</i> _____		
15h. Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>			

16 In the last month, on how many days did you inject drugs? *# of days*

17 In the last month, on days that you injected, how many times a day did you usually inject drugs? *# of times a day*

18 When was the last day you injected (including today)? *dd* *MMM* *yy* OR *# of months ago*

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 15m	If appropriate, use local or street name of the drug. Only record the names of drugs not already marked in 15a–15l.
Item 18	When possible record the complete date (day, month, and year). If the exact date is unknown, record month and year.



Visit Code:

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Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

SHARING

Often people share syringes and other equipment because they are in a rush, they are concerned about the police, feeling sick or for a variety of other reasons.

		Yes	No	Don't know
19	Have you shared rinse water in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	19a. The last time you injected, did you share rinse water?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Have you shared a cooker/container in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	20a. The last time you injected, did you share a cooker/container?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	Have you shared filter cotton in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	21a. The last time you injected, did you share filter cotton?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If no, go to item 20. *If no, go to item 21.* *If no, go to item 22.*

CLEANING

22	How often do you clean your needle before injecting?	<input type="checkbox"/> <i>Always</i> <input type="checkbox"/> <i>More than half the time</i> <input type="checkbox"/> <i>Less than half the time</i> <input type="checkbox"/> <i>Never</i>			
	22a. The last time you injected, did you clean the needle before you injected?	Yes	No	Don't know	
	22b. The last time you injected, did you use a new needle?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	22c. How often do you clean your needle after injecting?	<input type="checkbox"/> <i>Always</i> <input type="checkbox"/> <i>More than half the time</i> <input type="checkbox"/> <i>Less than half the time</i> <input type="checkbox"/> <i>Never</i>			
	22d. The last time you injected, did you clean the needle after you injected?	Yes	No	Don't know	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(FBA-7) 177

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Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

PRE-FILLING AND BACKLOADING SYRINGES

23	The last time you injected, did you use a pre-filled syringe?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't know
24	The last time you injected, did you inject drugs that were frontloaded or backloaded into the syringe or needle that you used?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't know
25	In the last 3 months, how many different people did you use injection drugs with?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of people</i>	→ <i>If 000, go to item 31.</i>
26	In the last 3 months, how many times did you even once pass on a needle or syringe to someone else after you used it?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of times</i>	→ <i>If 000, go to item 28.</i>
27	In the last 3 months, with how many different people did you pass on a needle or syringe after you had used it?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of people</i>	
28	In the last 3 months, how many times did you ever, even once, use a needle or syringe after someone else used it?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of times</i>	→ <i>If 000, go to item 30.</i>
29	In the last 3 months, with how many different people did you use a needle or syringe after someone else used it?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of people</i>	
30	In the past 3 months, when you shared syringes, how often did you inject last?	<input type="checkbox"/> Always	<input type="checkbox"/> Most times	<input type="checkbox"/> Sometimes
		<input type="checkbox"/> Rarely	<input type="checkbox"/> Never	<input type="checkbox"/> I have not shared in the past 3 months
31	In the last 3 months, did you get your new needles/syringes from a...			
	31a. <input type="checkbox"/> I did not get new needles in the last 3 months	→ <i>Go to item 33 on page 8.</i>		
		<i>Yes</i>	<i>No</i>	
	31b. Pharmacy or health center?	<input type="checkbox"/>	<input type="checkbox"/>	
	31c. Needle seller?	<input type="checkbox"/>	<input type="checkbox"/>	
	31d. Needle exchange?	<input type="checkbox"/>	<input type="checkbox"/>	
	31e. Other drug injectors?	<input type="checkbox"/>	<input type="checkbox"/>	
	31f. Other, specify?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>Local language:</i> _____	<i>English:</i> _____		
32	In the last 3 months, when you obtained new needles, typically, how many did you buy at one time?	<input type="text"/> <input type="text"/> <input type="text"/>	<i># of needles</i>	

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
Item 32	If the participant has not obtained his/her own needles or cannot remember, enter "000."



(HPTN 074) DF/Net 074

(FBA-8) 178

Visit Code: .

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Site Number Network Number Chk Cohort

Follow-up Behavior Assessment

SEXUAL BEHAVIOR QUESTIONS

The next few questions are about sexual behavior. These are very personal questions. Please remember that all the information you give us is confidential. We ask that you answer the questions as honestly as you can.

33 In the last month, did you have vaginal or anal sex? Yes No → *If no, go to item 39.*

34 In the last month, how many different female sex partners have you had? # of female sex partners

35 In the last month, how many different male sex partners have you had? # of male sex partners

36 Do you have a main partner such as a husband/wife or boyfriend/girlfriend? Yes No → *If no, go to item 38.*

36a. Is your main partner male or female?

Male Female Other, specify: (Local language) _____
(English) _____

37 In the last month, how many times did you have vaginal or anal sex with your main partner? # of times → *If 000, go to item 38.*

37a. How many of these times did you (or your partner) use a condom? # of times

38 In the last month, how many times did you have vaginal or anal sex with someone other than a main partner? # of times → *If 000, go to item 39.*

38a. How many of these times did you (or your partner) use a condom? # of times

Next I am going to ask about your sex trade (paid or paying) partners. By sex trade partners, I mean people that you had oral, vaginal or anal sex with in exchange for money, drugs, food or a place to stay.

39 In the last month, how many times did you give sex partners money or drugs in exchange for sex? # of times

40 In the last month, how many times did a sex partner give you money or drugs in exchange for sex? # of times

This assessment documents information on a participant's behaviors. These questions ask the participant to provide sensitive information. To increase honest and accurate responses it is important to demonstrate that all information will be kept private and confidential.

This is an interviewer-administered form.

Item-specific Instructions:

Item 36	"Main partner" is someone you consider your wife/husband/boyfriend/girlfriend, have oral, vaginal or anal sex with, have been in a relationship with for at least 3 weeks. Do not include anyone you have had sex with casually or in exchange for money, drugs, food or a place to stay.
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Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Partner HIV Test Results

HIV TEST RESULTS

1	Specimen #1 Collection Date:	<input type="text"/> <input type="text"/> <i>dd</i>	<input type="text"/> <input type="text"/> <input type="text"/> <i>MMM</i>	<input type="text"/> <input type="text"/> <i>yy</i>	<i>OR</i>	<input type="checkbox"/> →	<i>Not done/ Not collected</i>	<i>If not done/not collected at a visit where HIV testing is required by the protocol, provide reason in Comments.</i>
	1a. Were any of the HIV test results positive or Reactive?	<input type="checkbox"/> <i>Yes</i>		<input type="checkbox"/> <i>No</i>				
2	Specimen #2 Collection Date:	<input type="text"/> <input type="text"/> <i>dd</i>	<input type="text"/> <input type="text"/> <input type="text"/> <i>MMM</i>	<input type="text"/> <input type="text"/> <i>yy</i>	<i>OR</i>	<input type="checkbox"/> →	<i>Not done/ Not collected</i>	<i>If not done/not collected at a visit where HIV testing is required by the protocol, provide reason in Comments.</i>
	2a. Were any of the HIV test results positive or Reactive?	<input type="checkbox"/> <i>Yes</i>		<input type="checkbox"/> <i>No</i>		2b. Specimen #2 Visit Code: <input type="text"/> <input type="text"/> . <input type="text"/>		
3	Final HIV Status:	<input type="checkbox"/> <i>Negative</i>		<input type="checkbox"/> <i>Positive</i>		<input type="checkbox"/> <i>Indeterminate</i>		

Comments (*Local language*): _____

Comments (*English*): _____

The **Partner HIV Test Results** CRF documents the results of HIV testing performed at the site at scheduled and interim visits. Record test results on this form as they become available from the local lab. Fax this form to DataFax when the final test results are available and recorded.

Item-specific Instructions:

Specimen Collection Date	Record the date that the specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit.
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Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Assessment Date:

dd MMM yy

Index Follow-up HIV Care and ART

The next few questions are about anti-HIV medicines called antiretroviral therapy that you may be taking. These questions are not about drugs you may be taking to treat substance use. We need to know what is really happening, not what you think we "want to hear." Many people find it hard to take their medications all of the time.

1 Since your last visit, have you seen an HIV clinician? Yes No → **If no, go to item 2.**

1a. If yes, on what date?

dd MMM yy

1b. How many total clinical visits have you had since your last study visit? # of clinical visits

2 Since your last study visit, with whom have you shared that you are living with HIV? *Mark all that apply.*

2a. Spouse/Partner/Girl-Boyfriend 2e. Friends

2b. Own children 2f. Others

2c. Parents 2g. No one

2d. Other family members 2h. Refuse to answer

3 How many of your drug partners (the people you inject drugs with) know that you have HIV?

All of my partners Less than half of my partners

More than half of my partners None of my partners

This is an interviewer-administered form.

Item-specific Instructions:

Item 1a	When possible record the complete date (day, month, year). If the exact date is unknown, record month and year.
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(HPTN 074) DF/Net 074

(IFH-2) 186

Visit Code: .

Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number		Network Number		Chk	Cohort		

Index Follow-up HIV Care and ART

4 Who is the most supportive in helping you with your HIV care and treatment?

- Health care providers (such as doctors or nurses)
- Your spouse/live-in partner/long-term partner
- Injecting partners
- Commercial sex workers
- Your mother or father
- Your in-laws
- Other family members
- Priests/religious leaders
- Your neighbors or community members
- Friends
- Your employers
- Other, specify:

Local language: _____ English: _____

5 How often have you talked to your family or support person about your HIV medications?

- | | |
|--|---------------------------------------|
| <input type="checkbox"/> More than once per week | <input type="checkbox"/> Once a month |
| <input type="checkbox"/> Once a week | <input type="checkbox"/> One time |
| <input type="checkbox"/> 2-3 times a month | <input type="checkbox"/> Never |

6 Since your last visit, has any HIV clinician told you that you should initiate ART treatment for your own health?

- Yes
- No
- Not applicable

7 Since your last visit, have you visited an HIV clinic or pharmacy with the intention of starting ART?

- Yes No

This is an interviewer-administered form.

Item-specific Instructions:

Item 6	If the participant has not seen an HIV clinician since their last visit, mark “Not applicable.”
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This is an interviewer-administered form.



Visit Code: .

No data recorded on this page

Participant ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number		Network Number			Chk	Cohort	

Index Follow-up HIV Care and ART

15 The last time you missed at least one tablet, which of these best describes the reason why? *Mark only one. End of form.*

- I forgot
- I did not have the medication with me at the time I needed to take it
- I did not want person(s) nearby to see me taking the medication
- I was trying to avoid side effects
- I felt healthy
- I was drunk
- I am not engaging in any behaviors that can transmit HIV to others
- I do not believe the medicines are beneficial
- not applicable—no missed tablets
- Other, specify:

Local language: _____ English: _____

16 If you were on ART since your last visit, have you stopped? By stopped we mean that you have not taken any of your medication for the last 2 weeks. Yes No → **If no, go to item 18.**

17 What date did you stop taking ART?
dd MMM yy

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(IFH-5) 189

Visit Code: .

No data recorded on this page

Participant ID:

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Site Number Network Number Chk Cohort

Index Follow-up HIV Care and ART

18	Sometimes people have trouble taking HIV medications (ART) because of personal situations or circumstances. What are the reasons you have stopped taking ART or have not yet started to take ART?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not Applicable</i>
	18a. You don't think that you need it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18b. You don't have time to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18c. You don't have the energy or motivation to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18d. You missed an appointment, so it is difficult to go back.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18e. You have been too sick to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18f. Your drug use got in the way of going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18g. You had unwanted side effects or complications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18h. You don't understand when you are supposed to take each pill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18i. You sold or lost your medicine or your medicine was stolen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	18j. Your drinking (alcohol) got in the way of going back to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18k. You had to wait too long, so you left without being seen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19	Sometimes people find it difficult to take HIV medications (ART) because of their family or friends. What are the reasons you have stopped taking ART or have not yet started to take ART?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not Applicable</i>
	19a. You don't have enough support from family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	19b. You don't want others to know you have HIV (e.g., see me take medication).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This is an interviewer-administered form.

Item-specific Instructions:

<p>No data recorded on this page</p>	<p>Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.</p>
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Visit Code: .

No data recorded on this page

Participant ID:

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Site Number *Network Number* *Chk* *Cohort*

Index Follow-up HIV Care and ART

	Many people find it difficult to take HIV medications (ART), even if they have previously taken ART, because of challenges in the health systems/health care process. What were the reasons you have stopped taking ART or have not yet started to take ART?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not applicable</i>
20a.	You do not have the necessary materials (e.g. paperwork, identification, test results) needed by the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20b.	ART is too expensive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20c.	ART was not available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20d.	HIV care provider would not continue your medicine or prescription.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20e.	You do not know how or where to get ART.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20f.	You find transport/travel to the clinic is difficult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20g.	You have been traveling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20h.	You have been in jail or incarcerated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20i.	You are scared of being arrested for your drug use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20j.	You will need to register with the government as being a drug user.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

21 Are there any other reasons you find it difficult to continue taking ART or why you have not yet started to take ART?

Local language: _____

English: _____

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
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Visit Code: .

Participant ID:

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Site Number Network Number Chk Cohort

Assessment Date:

dd MMM yy

Follow-up Substance Use Treatment

1 Since your last visit, have you tried to start MAT (methadone or buprenorphine) to treat your substance use? Yes No → *If no, go to item 2.*

1a. When was your last visit?

dd MMM yy

2 Are you currently taking methadone or buprenorphine? Yes No → *If no, go to item 3.*
 If yes, and this is the participant's first time in MAT during the study, complete the Substance Use Treatment Initiation CRF.

2a. How long have you currently been on MAT (methadone or buprenorphine)? months

3 If you were on substance use treatment since your last visit, have you stopped taking MAT or buprenorphine? By stopped, we mean that you have not been taking it for at least 2 weeks. Yes No → *If no, end of form.*

3a. What date did you stop taking MMT or buprenorphine?

dd MMM yy

This CRF monitors the participant's status in substance use treatment throughout the study.

This is an interviewer-administered form.



Visit Code: .

No data recorded on this page

Participant ID:

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Site Number Network Number Chk Cohort

Follow-up Substance Use Treatment

4	Sometimes people find it difficult to continue MMT or buprenorphine because of personal situations or circumstances. What are the reasons you have stopped MMT or buprenorphine?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not applicable</i>
4a.	You want to keep injecting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b.	You want to handle your drug problem or stop injecting on your own.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4c.	You had side effects or withdrawal symptoms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4d.	Your injecting got in the way of going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4e.	Your drug use got in the way of going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4f.	You have been too sick to go to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4g.	You missed an appointment, so it is difficult to go back.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4h.	You can handle your drug problem yourself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4i.	Your drinking (alcohol) got in the way of going to the clinic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Sometimes people find it difficult to continue MMT or buprenorphine because of their family or friends. What are the reasons you have stopped MMT or buprenorphine?	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not applicable</i>
5a.	You don't have enough support from family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5b.	You don't want to stop seeing the friends you inject with.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5c.	Your family objects to drug treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5d.	You don't feel you have enough support from friends and family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This CRF monitors the participant's status in substance use treatment throughout the study.

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
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Visit Code: .

No data recorded on this page

Participant ID:

- - -

Site Number *Network Number* *Chk* *Cohort*

Follow-up Substance Use Treatment

6 Many people find it difficult to continue MMT or buprenorphine, even if they have previously tried, because of challenges in the health systems/health care process. What were the reasons you have not continued MMT or buprenorphine?

	<i>Agree</i>	<i>Disagree</i>	<i>Not relevant/ Not applicable</i>
6a. The waiting list is too long.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6b. You don't have the necessary materials (ID card, paperwork).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6c. You find getting on drug treatment is too much of a hassle.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6d. You do not know how or where to get drug treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6e. You find transport/travel to the clinic is difficult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6f. You have been traveling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6g. You have been in jail or incarcerated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6h. You are scared of being arrested for your drug use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6i. You are scared of losing your job.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6j. You were asked to leave MAT.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7 Are there any other reasons you find it difficult to continue MAT or buprenorphine?

Local language: _____

English: _____

This CRF monitors the participant's status in substance use treatment throughout the study.

This is an interviewer-administered form.

Item-specific Instructions:

No data recorded on this page	Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
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(HPTN 074) DF/Net 074

(SNE-1) 210

Encounter #:

Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

- - -

Site Number Network Number Chk Cohort

Assessment Date:

dd MMM yy

Systems Navigator Encounter

1 Staff ID: _____

2 Activity type: *Initial* *Weekly/Monthly* *Interim*

3 Contact initiated/requested by:

- Systems navigator* *Participant*
- Psychosocial counselor* *Other, specify:*
- Agency/clinic* *Local language: _____ English: _____*
- Participant's designated support person*

4 Type of encounter:

- In person (not at home)* *E-mail/Internet*
- Home contact* *Text/SMS*
- Telephone* *Other, specify:*
- Social media* *Local language: _____ English: _____*

5 Is the participant currently taking antiretroviral therapy (ART)? *Yes* *No*

6 Is the participant currently receiving methadone or buprenorphine? *Yes* *No*

7 Does the participant have a designated support person? *Yes* *No* → *If no, go to item 8 on page 2.*

7a. Did the support person participate in this contact activity? *Yes* *No*

7b. What is the relationship of the support person to the participant?

- Spouse/partner/girl- boyfriend* *Friend*
- Father/Mother* *Other, specify:*
- Sibling* *Local language: _____ English: _____*
- Other family member*

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the system navigator. Complete this CRF any time the participant has contact with a systems navigator.

Item-specific Instructions:

Encounter Number	Number encounters sequentially throughout the study starting with 001. Do not repeat encounter numbers. Do not re-number any encounters after faxing, unless instructed by the SDMC.
Staff ID	Identify the staff member conducting the encounter. Do not use full names, document only the staff member's initials (last, first). If more than one staff members share initials utilize a middle initial as well.
Activity Type	Indicate whether this communication is the initial, weekly or monthly contact as outlined in the protocol. If the contact is not a scheduled encounter, or due to an ongoing crisis period, indicate "interim."



(HPTN 074) DF/Net 074

(SNE-2) 211

Encounter #:

Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

Site Number Network Number Chk Cohort

Systems Navigator Encounter

8	Total number of minutes of activity:	0-5 minutes	6-10 minutes	11-15 minutes
		16-30 minutes	31-60 minutes	60+ minutes

9 Primary focus of contact:

<input type="checkbox"/> Substance use treatment	<input type="checkbox"/> Legal/Judicial
<input type="checkbox"/> HIV care	<input type="checkbox"/> Sexual health services
<input type="checkbox"/> Needle and syringe exchange programs	<input type="checkbox"/> Social services
<input type="checkbox"/> ART initiation/Management	<input type="checkbox"/> Priests/religious leaders
<input type="checkbox"/> Assistance with primary designated support person	<input type="checkbox"/> Your neighbors or community members
<input type="checkbox"/> Social network management	<input type="checkbox"/> Clinical/medical management
<input type="checkbox"/> Additional counseling	<input type="checkbox"/> Other, specify:

Local language: _____
 English: _____

10 Additional areas addressed: *Mark all that apply.*

<input type="checkbox"/> 10a. Substance use treatment	<input type="checkbox"/> 10h. Legal/Judicial
<input type="checkbox"/> 10b. HIV care	<input type="checkbox"/> 10i. Sexual health services
<input type="checkbox"/> 10c. Needle and syringe exchange programs	<input type="checkbox"/> 10j. Social services
<input type="checkbox"/> 10d. ART initiation/Management	<input type="checkbox"/> 10k. Priests/religious leaders
<input type="checkbox"/> 10e. Assistance with primary designated support person	<input type="checkbox"/> 10l. Your neighbors or community members
<input type="checkbox"/> 10f. Social network management	<input type="checkbox"/> 10m. Clinical/medical management
<input type="checkbox"/> 10g. Additional counseling	<input type="checkbox"/> 10n. Other, specify:

Local language: _____
 English: _____

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the system navigator. Complete this CRF any time the participant has contact with a systems navigator.

Item-specific Instructions:

Encounter Number	Number encounters sequentially throughout the study starting with 001. Do not repeat encounter numbers. Do not re-number any encounters after faxing, unless instructed by the SDMC.
-------------------------	--



(HPTN 074) DF/Net 074

(SNE-3) 212

Encounter #:

Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

- - -

Site Number Network Number Chk Cohort

Systems Navigator Encounter

11	Assessment of client status: <input type="checkbox"/> Client has no immediate complicating psychosocial issues <input type="checkbox"/> Client has complicating psychosocial issues that post minimal risk to ART or substance use adherence <input type="checkbox"/> Client has complicating psychosocial issues that pose moderate risk to ART or substance use adherence <input type="checkbox"/> Client has complicating psychosocial issues that pose severe risk to ART or substance use adherence
12	Was a referral made at this encounter? <input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, go to item 13.</i> 12a. What was the referral made for? Mark all that apply. <input type="checkbox"/> HIV care (ART) <input type="checkbox"/> Needle/syringe exchange program <input type="checkbox"/> Initial substance use treatment <input type="checkbox"/> Mental health counseling <input type="checkbox"/> Reentry into substance use treatment
13	Was a social impact reported at this encounter? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, complete Social Impact Log for each impact. If this is an interim visit, also complete a Follow-up Visit form.</i>
14	Was a Serious Adverse Experience reported at this encounter? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, complete AE Log for each reported AE. If this is an interim visit, also complete a Follow-up Visit form.</i>
15	Did the participant report initiating any antiretroviral medications for treatment at this encounter? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, complete Index ART Initiation CRF. If this is an interim visit, also complete a Follow-up Visit form.</i>
16	Did the participant report initiating substance use treatment (MAT) at this encounter? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, complete Substance Use Treatment Initiation CRF. If this is an interim visit, also complete a Follow-up Visit form.</i>

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the system navigator. Complete this CRF any time the participant has contact with a systems navigator.

Item-specific Instructions:

Encounter Number	Number encounters sequentially throughout the study starting with 001. Do not repeat encounter numbers. Do not re-number any encounters after faxing, unless instructed by the SDMC.
-------------------------	--



Encounter #:

Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

- - -

Site Number Network Number Chk Cohort

Assessment Date:

dd MMM yy

Psychosocial Encounter

1 Counselor ID: _____

2 Contact type:

Study site visit

Telephone contact

Off-site contact, specify: _____ *Local language:* _____

English: _____

3 Activity type:

Introductory session

First session

Second session

Booster session

Index and supporter session

4 Does the participant have a designated support person? *Yes* *No* → *If no, go to item 5 on page 2.*

4a. Did the support person participate in this contact activity? *Yes* *No*

4b. What is the relationship of the support person to the participant?

Spouse/partner/girl- boyfriend *Friend*

Father/Mother *Other, specify:* _____

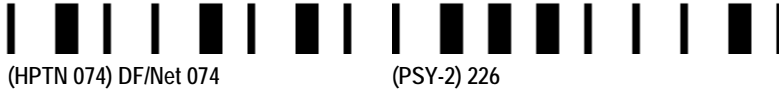
Sibling *Local language:* _____ *English:* _____

Other family member

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the psychosocial counselor. Complete this CRF any time the participant has contact with a psychosocial counselor.

Item-specific Instructions:

Counselor ID	Identify the staff member conducting the encounter. Do not use full names, document only the staff member's initials.
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Encounter #:
Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

- - -
 Site Number Network Number Chk Cohort

Psychosocial Encounter

5 Indicate focus of session. *Mark all that apply.*

- 5a. *Dealing with HIV infection*
- 5b. *HIV disclosure*
- 5c. *Risk reduction*
- 5d. *ART adherence and/or development of medication adherence plan*
- 5e. *Engagement into care*
- 5f. *Adherence communication skills*
- 5g. *Sexual risk communication skills*
- 5h. *Injection risk communication skills*
- 5i. *Relationships/Social support*
- 5j. *HIV literacy*
- 5k. *Other, specify:*

Local language: _____

English: _____

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the psychosocial counselor. Complete this CRF any time the participant has contact with a psychosocial counselor.

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the psychosocial counselor. Complete this CRF any time the participant has contact with a psychosocial counselor.



(HPTN 074) DF/Net 074

(PSY-4) 228

Encounter #:

Note: Number encounters sequentially (001, 002, 003) for each participant.

Participant ID:

- - -

Site Number Network Number Chk Cohort

Psychosocial Encounter

7 Barriers to MMT/buprenorphine addressed. Mark all that apply.

- 7a. Need for MMT/buprenorphine
- 7b. Hassle of taking medication
- 7c. Time to go to the clinic
- 7d. Going to the clinic is a hassle
- 7e. Previously missed appointments
- 7f. Too sick
- 7g. Alcohol use interference
- 7h. Drug use interference
- 7i. Don't have food/water to take medicine
- 7j. Don't understand when/how to take medicine
- 7k. Side effects/complications
- 7l. Family or friend support
- 7m. Navigating structural issues--referral to systems navigator
- 7n. Other, specify: _____

Local language: _____

English: _____

7o. No barriers addressed

8 Total number of minutes of activity:

0-5 minutes	6-10 minutes	11-15 minutes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16-30 minutes	31-60 minutes	60+ minutes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9 As a result of this counseling, were systems navigator services provided?

Yes No

Use this CRF in conjunction with the Intervention Manual to document participant encounters with the psychosocial counselor. Complete this CRF any time the participant has contact with a psychosocial counselor.

This form is used to document the storage of specimens that will be tested at a lab other than the site local laboratory.

Item-specific Instructions:

Items 1-4	<ul style="list-style-type: none">• Mark “not stored” if the specimen was collected as required at this visit but was not stored.• Mark “not collected” if the specimen is required to be collected and stored at this visit but was not collected.• Mark “not required” if a specimen is not required and was not collected and stored at this visit.
------------------	--



(HPTN 074) DF/Net 074

(ACL) 232

Participant ID:

- - -

Site Number Network Number Chk Cohort

Date of Contact:

dd MMM yy

Agency Contact

1 Contact initiated by:

Systems navigator
 Counselor
 Agency/clinic
 Other, specify: (Local Language) _____ (English) _____

2 Type of facility contacted:

HIV clinic
 Substance use treatment facility
 Needle and syringe exchange program
 Mental health counselor/facility
 Sexual health services
 Social services
 Clinical/medical services
 Legal/judicial
 Other, specify: (Local Language) _____ (English) _____

3 Type of contact:

In person
 Telephone
 Email/internet
 Text message/SMS
 Other, specify: (Local Language) _____ (English) _____

This form documents each contact between HPTN 074 study staff and any referral sites/agencies that are made on the behalf of an index participant. One **Agency Contact** CRF should be submitted for each contact that is made.



(HPTN 074) DF/Net 074

(EXT) 315

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>	<i>Cohort</i>			

Form Completion Date:

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

Study Extension

1 Did the participant continue in HPTN 074? Yes No → *If no, go to item 2.*

1a. If yes, date participant consented:

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

<i>MMM</i>			

 → *End of form.*

2 What was the primary reason for not joining the HPTN 074 Study Extension? *Mark only one.*

- Participant Death → *Date of Death:*

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

<i>MMM</i>			
- Investigator determination/decision, specify: _____
- Participant refused further participation, specify: _____
- Participant relocated
- Incarceration
- Compulsory rehab
- Unable to contact participant
- Other, specify: _____

Purpose: This form is required for all HPTN 074 participants regardless of enrollment into study extension.



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Initial Specimen Collection Date:

dd MMM yy

CD4+ Count and Viral Load

1 CD4 + Count: *Not done/ Not collected*

Alternate Collection Date:

dd MMM yy

1a. Absolute CD4+: *Unable to analyze* *cells/mm3*

2 HIV-1 RNA PCR: *Not done/ Not collected*

Alternate Collection Date:

dd MMM yy

2a. HIV RNA PCR (plasma): *<* *=* *>* *viral copies/mL* OR *Undetectable*

2b. RNA PCR kit code: *kit code*

Comments (*Local language*): _____

Comments (*English*): _____

This form is to document a participant's CD4+ and Viral Load results as collected per protocol.

Item-specific Instructions:

Initial Specimen Collection Date	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.								
Not done/Not collected	Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.								
Alternate Collection Date	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.								
Results Reporting	<ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. <p>If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.</p>								
Item 2a	Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record "0003100" as the value. If the value reported is < 400 copies, mark the less than (<) box and record "0000400" as the value.								
Item 2b	<p>Record the four-digit RNA PCR kit code from the table below.</p> <table border="1" data-bbox="376 1290 1246 1503"> <thead> <tr> <th data-bbox="376 1290 1011 1346">RNA PCR Kit</th> <th data-bbox="1011 1290 1246 1346">Code</th> </tr> </thead> <tbody> <tr> <td data-bbox="376 1346 1011 1402">Abbott m2000 Real-time</td> <td data-bbox="1011 1346 1246 1402">0406</td> </tr> <tr> <td data-bbox="376 1402 1011 1458">Roche Cobas AmpliPrep/Cobas Tagman Ver. 1.0</td> <td data-bbox="1011 1402 1246 1458">0108</td> </tr> <tr> <td data-bbox="376 1458 1011 1503">Roche Cobas AmpliPrep/Cobas Tagman Ver. 2.0</td> <td data-bbox="1011 1458 1246 1503">0110</td> </tr> </tbody> </table>	RNA PCR Kit	Code	Abbott m2000 Real-time	0406	Roche Cobas AmpliPrep/Cobas Tagman Ver. 1.0	0108	Roche Cobas AmpliPrep/Cobas Tagman Ver. 2.0	0110
RNA PCR Kit	Code								
Abbott m2000 Real-time	0406								
Roche Cobas AmpliPrep/Cobas Tagman Ver. 1.0	0108								
Roche Cobas AmpliPrep/Cobas Tagman Ver. 2.0	0110								



Participant ID:

- - -

Site Number Network Number Chk Cohort

Date Reported to Site:

dd MMM yy

Adverse Experience Log

1	Adverse Experience (AE): <i>Record diagnosis if available. Include anatomical location, if applicable.</i>		
2	Onset date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<i>dd MMM yy</i>
3	Severity Grade:	<input type="checkbox"/> <i>Grade 1—mild</i> <input type="checkbox"/> <i>Grade 3—severe</i> <input type="checkbox"/> <i>Grade 5—death</i> <input type="checkbox"/> <i>Grade 2—moderate</i> <input type="checkbox"/> <i>Grade 4—potentially life-threatening</i>	
4	Relationship to study product:	<input type="checkbox"/> <i>Related</i> <input type="checkbox"/> <i>Not related</i> <i>If not related, record rationale or alternative etiology in Comments.</i>	
5	Study product administration:	<input type="checkbox"/> <i>No change</i> <input type="checkbox"/> <i>Held</i> <input type="checkbox"/> <i>Permanently discontinued</i> <input type="checkbox"/> <i>N/A</i>	
6	Status or Outcome of AE:	<input type="checkbox"/> <i>Continuing</i> <input type="checkbox"/> <i>Resolved</i> <input type="checkbox"/> <i>Death</i> <input type="checkbox"/> <i>Severity/frequency increased (Report as new AE)</i> <input type="checkbox"/> <i>Continuing at end of study participation</i>	6a. Status/Outcome Date <i>(Leave blank if Status/Outcome is "continuing".)</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>
7	Treatment: <i>Mark "none" or all that apply.</i>	<input type="checkbox"/> <i>None</i> <input type="checkbox"/> <i>Medication(s)</i> <input type="checkbox"/> <i>Procedure/surgery</i> <i>Comment below.</i> <input type="checkbox"/> <i>New/prolonged hospitalization</i> <input type="checkbox"/> <i>Other, specify: _____</i> <i>Comment below.</i>	
8	Is this an SAE according to ICH guidelines?	<input checked="" type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	
9	Has or will this AE be reported as an EAE? (if a SUSAR)?	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	
10	At which visit was this AE first reported? <i>Visit code required (regular or interim).</i>	<input type="text"/> <input type="text"/> . <input type="text"/> <i>visit code</i>	

Comments (*Local language*): _____

Comments (*English*): _____

To document Grade 3 or higher Adverse Experience (AE) and only SAEs.

If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).

Item-specific Instructions:

Page	Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
Item 1	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality.
Item 2	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
Item 3	Report only Grade 3 or higher AEs and only SAEs. To grade the severity of an AE, consult the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences</i> .
Item 4	Study agent is defined as the participant's current or last known ART and/or opiate substitution therapy. Mark the assessment of the relationship between the AE and the study agent. Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. If "not related," record an alternative etiology, diagnosis, or explanation in Comments. For more information, refer to the <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> .
Item 5	<ul style="list-style-type: none"> • No change: Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation. • Held: Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "held" for the AE(s) that contributed to the product hold. • Permanently discontinued: Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, only mark "permanently discontinued" for the AE that contributed to the permanent discontinuation. • N/A (not applicable): Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is grade 5-death.
Item 6	<ul style="list-style-type: none"> • Continuing: AE is continuing at the time it is reported. • Resolved: Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. • Death: Mark only if the severity of this AE is grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." • Severity/frequency increased: If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "continuing" box previously marked and mark "severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs. • Continuing at end of study participation: Mark this box whenever an AE is continuing at the time of participant study termination.
Item 6a	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
Item 7	Indicate all treatments administered for this AE, including treatment provided by a health care professional and participant self-treatment. Do not indicate treatments that were clinically indicated or prescribed but not administered.
Items 8 and 9	For questions about ICH guidelines and EAE reporting, refer to the <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> .



Visit Code: .

Participant ID:

- - -

Site Number Network Number Chk Cohort

Form Completion Date:

dd MMM yy

Missed Visit

1 Target Visit Date:

dd MMM yy

2 Reason visit was missed. *Mark only one.*

- 2a. Unable to contact participant
- 2b. Unable to schedule appointment(s) within window
- 2c. Participant refused visit
- 2d. Participant incarcerated
- 2e. Participant admitted to a health care facility
- 2f. Participant withdrew from the study → *Complete Termination form.*
- 2g. Participant deceased → *Complete Termination form. Complete Adverse Event Log.*
- 2h. Participant travelled outside the province for work
- 2i. Other, specify: *(Local language)* _____
(English) _____

Comments (*Local language*): _____

Comments (*English*): _____

Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).

If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit.

Item-specific Instructions:

Item 1	Record the target date of the visit. A complete date is required.
Item 2	Record the reason the participant missed the visit.



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(TM) 490

Participant ID:

<i>Site Number</i>			<i>Network Number</i>				<i>Chk</i>		<i>Cohort</i>		

Termination

1 Termination Date:

--	--

--	--	--

--	--

Date the site determined that the participant was no longer in the study.

dd *MMM* *yy*

2 Reason for termination. *Mark only one.*

2a. Scheduled exit visit/end of study —————→ **End of form.**

2b. Death (Indicate date and cause if known.)

dd *MMM* *yy*

2b1. Date of death:

--	--

--	--	--

--	--

OR date unknown

2b2. Cause of death: _____ **OR** cause unknown

Complete or update Adverse Experience Log.

2c. Participant refused further participation, specify: _____

2d. NOT APPLICABLE FOR THIS PROTOCOL

2e. Participant relocated, no follow-up planned

2f. Investigator decision, specify _____

2g. Unable to contact participant

2h. NOT APPLICABLE FOR THIS PROTOCOL

2i. Inappropriate enrollment —————→ **End of form.**

2j. Invalid ID due to duplicate screening/enrollment —————→ **End of form.**

2k. Other, specify _____

2l. Early study closure —————→ **End of form.**

2m. Index Termination (Network Partners only) —————→ **End of form.**

3 Was termination associated with an adverse experience? *yes* *no* *don't know*

 —————→ *If no or don't know, end of form.*

3a. Record AE Log page number:

--	--	--

page # **OR** Specify: *(Local language)* _____

(English) _____

Comments *(Local language)*: _____

Comments *(English)*: _____

This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

Item 1	Document the date that the participant declares that he/she does not want to continue in the study. If the termination is due to death, indicate the date that the site is notified that the participant is deceased. A complete date is required.
Item 2	Mark only the primary reason for termination.
Item 2a	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1	If date is recorded, at a minimum, the month and year are required.
Item 2l	Early study closure: Only mark 2l when instructed by SCHARP.
Item 2m	Only mark item 2m for Network Partners.
Item 3a	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line.

Purpose: This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study extension.

Item-specific Instructions:

Item 1	Document the date that the participant declares that he/she does not want to continue in the study extension. If the termination is due to death, indicate the date that the site is notified that the participant is deceased. A complete date is required.
Item 3	Mark only the primary reason for termination from the study extension.
Item 3a	Scheduled exit visit/end of study: Only mark 3a if the participant completes the protocol-defined final visit for the study extension.
Item 3b1	If date is recorded, at a minimum, the month and year are required.
Item 3l	Early study closure: Only mark 3l when instructed by SCHARP.
Item 4a	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line.



Participant ID:

- - -

Site Number Network Number Chk Cohort

Form Completion Date:

dd MMM yy

Protocol Deviation Log

1	Site awareness date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	2	Deviation date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	<i>dd MMM yy</i>		<i>dd MMM yy</i>
3	Has or will this deviation be reported to local IRB/EC? <input type="checkbox"/> Yes <input type="checkbox"/> No		
4	Has or will this deviation be reported to DAIDS as a critical event? <input type="checkbox"/> Yes <input type="checkbox"/> No		
5	Type of deviation: <input type="text"/> <input type="text"/> <i>deviation code</i> <i>(See back of form for code listing.)</i>		
6	Description of deviation <i>(Local language)</i> : _____ _____		
	Description of deviation <i>(English)</i> : _____ _____		
7	Plans and/or action taken to address the deviation <i>(Local language)</i> : _____ _____		
	Plans and/or action taken to address the deviation <i>(English)</i> : _____ _____		
8	Plans and/or action taken to prevent future occurrences of the deviation <i>(Local language)</i> : _____ _____		
	Plans and/or action taken to prevent future occurrences of the deviation <i>(English)</i> : _____ _____		
9	Deviation reported by (staff name): _____		

Item-specific Instructions:

Purpose	This form documents and reports protocol deviations identified for study participants.
General Information/Instructions	<ul style="list-style-type: none"> • Consult HPTN 074 Management Group (074mgmt@hptn.org) to confirm whether the event qualifies as reportable deviation. • After confirmed, complete this form each time a protocol deviation is identified. • Reportable protocol deviations are defined by the HPTN as individual incidents, trends or omissions that result in: <ul style="list-style-type: none"> - Significant added risk to the participant - Non-adherence to significant protocol requirements - Significant non-adherence to GCP • If a deviation needs to be reported but is not associated with a participant (for example, necessary test kits are not available on site), use a PTID that follows the format below on the PDL CRF: <ul style="list-style-type: none"> - XXX-00000-0 - Enter your site DataFax ID number in the first 3 digits followed by zeros. Assign page numbers sequentially when completely new PDLs using this PTID.
Page	Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.
Item 2	Record the date the event occurred (start date).
Item 5	Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.
Item 6	Briefly describe the specific details of the deviation.
Item 9	Record name of site staff person who completed the form.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	Study product management deviation: Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form.
05	Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
06	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
07	Physical assessment deviation: Examples include a protocol-specified exam or assessment consistently not being performed (a single missed exam during one participant visit would not be considered a reportable protocol deviation).
08	Lab assessment deviation: Examples include a protocol-specified laboratory assay consistently not being performed (a single missed assay during one participant visit would not be considered a reportable protocol deviation).
09	Use of non-IRB/EC-approved materials: Examples include use of ANY study-related material that has not received IRB or EC approval for use per site requirements.
10	Informed assent/consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
99	Other