

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

DEM-1 (001)

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			Participant Number				Chk

Demographics

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

1. What is your date of birth? **OR** Age: years (estimate OK)

dd MMM yy

male female

2. What is your gender?

3. What is your ethnicity? *Mark all that apply.*

Thailand

China

- 3a. Thai
- 3b. Karen
- 3c. Tai Yai
- 3d. Akha
- 3e. Hmong
- 3f. Yao
- 3g. Lisu
- 3h. Lahu
- 3i. Lua
- 3j. Burmese
- 3k. Chinese
- 3l. other, specify: *Local Language* _____ *English* _____

- 3m. Uighur
- 3n. Han
- 3o. Zhuang
- 3p. Hui
- 3q. Kazakh
- 3r. other, specify: *Local Language* _____ *English* _____

4. What is your current marital status?

- single
- married
- living with partner/not married
- divorced
- widowed

5. How many years of education/ schooling have you completed? years

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Demographics (DEM-1)

Description and Purpose

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

Form-specific Instructions

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

Item 3: If participant's response is not in the list, check "other" and write response on the line. Response must be translated into English before the form is sent to DataFax.

Item 4: If participant's marital status does not exactly fit the categories, ask the participant to choose the category that best describes his or her marital status.

SAMPLE. DO NOT FAX TO DATAFAX



Note: Number pages sequentially (01, 02, 03) for each participant.

HPTN 058 (123)

PRE-1 (012)

Participant ID

- -

Site Number Participant Number Chk

Form Completion Date

dd MMM yy

Pre-existing Conditions

No pre-existing conditions reported or observed. _____ → **End of form. Fax to SCHARP DataFax.**
Staff Initials / Date

1.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	
2.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	
3.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	
4.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	
5.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	
6.	Description	<i>MMM</i>	<i>yy</i>	Date of Diagnosis/ Surgery	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Is condition ongoing?	yes <input type="checkbox"/> no <input type="checkbox"/>
Comments Local Language/English				<small>Staff Initials / Date</small>	

Pre-existing Conditions (PRE-1)

This form is used to document the participant's pre-existing medical conditions. Only medical conditions experienced up to study product initiation should be recorded unless otherwise specified in the protocol or Study Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, and chronic conditions (controlled or not controlled by medication).

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.

Description: Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."

Date of Diagnosis/Surgery: If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.

Comments: This field is optional. Use it to record any additional relevant information about the condition.

Is condition ongoing?: Mark "yes" for any current or chronic conditions.

Pre-existing Conditions Revisions and Updates:

- If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).

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Visit Code

1

HPTN 058 (123)

DSM-1 (045)

Participant ID

- -

Site Number Participant Number Chk

DSM-IV Diagnostic Worksheet

Form Completion Date

dd MMM yy

Instructions: Read each question aloud to the participant and record a response for each drug(s) the participant has used more than once in the past 6 months (past 12 months from the Enrollment Visit). Ask all questions for each drug class used before asking questions about other drugs or alcohol. Do not read questions for drug(s) not used more than once in the past 12 months.

Introductory Question (<i>Read only one aloud to the participant</i>)	Opiates/ Heroin	Benzodi-azepines	Alcohol
<p><input type="checkbox"/> At Enrollment Visit: In the past 12 months, did you take any of the following drugs more than once to get high, to feel better, or to change your mood?</p> <p><input type="checkbox"/> At 6-Month Follow-up Visit: In the past 6 months, did you take any of the following drugs more than once to get high, to feel better, or to change your mood?</p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>

Criteria	Questions	Opiates/ Heroin	Benzodi-azepines	Alcohol
<p>1. Tolerance: A need for markedly increased amounts of the substance to achieve intoxication of desired effect. The drug effect is markedly decreased when the same amount is used.</p>	<p>1. Have you found that you need to use more (<i>insert "opiates or heroin"/ "benzodiazepines"/ "alcohol"</i>) to get the same effect that you did when you first started taking it?</p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>2. Withdrawal: Withdrawal is manifested by either the characteristic withdrawal syndrome; or, when the same or a closely related substance is taken to relieve or avoid withdrawal symptoms.</p>	<p>2. When you reduced or stopped using (<i>insert "opiates or heroin"/ "benzodiazepines"/ "alcohol"</i>) did you have any of the following withdrawal symptoms? <i>Show Card #8.</i></p> <p>Did you use any drug(s) to keep yourself from getting sick or to relieve or avoid withdrawal symptoms?</p> <p><i>If yes to either question, mark "yes.".....</i></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>
<p>3. Amount/duration: Substance is often taken in larger amounts or over a longer period of time than intended.</p>	<p>3. Have you often found that when you used (<i>insert "opiates or heroin"/ "benzodiazepines"/ "alcohol"</i>) you end up taking more than you thought you would? ...</p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>	<p>yes no</p> <p><input type="checkbox"/> <input type="checkbox"/></p>

DSM-IV Diagnostic Worksheet (DSM-1)

Introductory Question: Based on which visit (Enrollment Visit or 6-Month Follow-up Visit) the participant is receiving at the site, mark the appropriate introductory question and read aloud to the participant.

Three or more criteria must be met for a diagnosis of dependency. For example, if the interviewer marks “yes” for questions 1, 2, and 4 for any one drug, the participant meets the criteria for dependency for that drug because three criteria are met (criteria 1, 2, and 4). However, if the interviewer marks “yes” for only questions 1 and 2, the participant does not meet the definition of dependency for that drug because only two criteria are met (criteria 1 and 2).

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HPTN 058 (123)



DSM-2 (046)

Visit Code

1

Participant ID

- -

Site Number Participant Number Chk

DSM-IV Diagnostic Worksheet

Criteria	Questions	Opiates/ Heroin	Benzodi- azepines	Alcohol
4. Reduce/control: Persistent desire or unsuccessful efforts to reduce or control substance use.	4. Have you tried to reduce or stop taking (insert "opiates or heroin"/ "benzodiazepines"/ "alcohol") but failed?	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>
5. Time: A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.	5. On the days you have used (insert "opiates or heroin"/ "benzodiazepines"/ "alcohol"), did you spend substantial time (> 2 hours) obtaining, using, or recovering from the drug, or thinking about using the drug?	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>
6. Effects on activities: Important social, occupational, or recreational activities are given up or reduced because of substance use.	6. Did you spend less time working, enjoying hobbies, or being with others because of your use of (insert "opiates or heroin"/ "benzodiazepines"/ "alcohol")?	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>
7. Problems: Substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.	7. Have you continued to use (insert "opiates or heroin"/ "benzodiazepines"/ "alcohol") even though you knew that it caused you health or mental problems?	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>	yes no <input type="checkbox"/> <input type="checkbox"/>

Total Score	Opiates/ Heroin	Benzodi- azepines	Alcohol
Of the seven criteria, how many were met?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Total score ≥ 3 for any drug class = dependence.

Interviewer Signature _____

MD Signature _____

01-DEC-08

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0 1

Language

Staff Initials / Date

DSM-IV Diagnostic Worksheet (DSM-2)

Three or more criteria must be met for a diagnosis of dependency. For example, if the interviewer marks “yes” for questions 1, 2, and 4 for any one drug, the participant meets the criteria for dependency for that drug because three criteria are met (criteria 1, 2, and 4). However, if the interviewer marks “yes” for only questions 1 and 2, the participant does not meet the definition of dependency for that drug because only two criteria are met (criteria 1 and 2).

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

LLS-1 (051)

Participant ID

[] [] []	-	[] [] [] [] [] []	-	[]
Site Number		Participant Number		Chk

Initial Specimen Collection Date

[] []	[] [] [] []	[] []
dd	MMM	yy

Screening Local Laboratory Results

Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

[] []	[] [] [] []	[] []
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Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

[] []	[] [] [] []	[] []
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Alternate Collection Date

dd	MMM	yy
[] []	[] [] [] []	[] []

1. HIV SPECIMEN

1a. Participant's HIV status..... *negative* *positive* *indeterminate*

2. HEMOGRAM

2a. WBC [] [] [] [] . [] $\times 10^3/mm^3$

2b. Hemoglobin..... [] [] . [] g/dL

2c. Platelets [] [] [] [] [] [] [] $cells/mm^3$

3. LIVER FUNCTION TESTS

3a. ALT (SGPT) [] [] [] [] U/L

3b. Total bilirubin [] [] . [] mg/dL

4. RENAL FUNCTION TESTS

4a. Creatinine [] [] . [] mg/dL

5. HEPATITIS

5a. Hepatitis B surface antigen..... *non-reactive* *reactive* *indeterminate*

5b. Hepatitis C antibody.....

6. SPECIMEN STORAGE

6a. Was blood specimen processed for storage?..... *yes* *no*

Comments: *Local Language* _____

Comments: *English* _____

[] [] [] [x] 26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Screening Local Laboratory Results (LLS-1)

Description and Purpose

This form documents a potential participant's eligibility-related laboratory results at screening visits. This form is to be used only at screening visits.

Form-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. Complete date required.

Alternate Collection Date: This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. Complete date required.

Results Reporting

- 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.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
- 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.

Item 1a: Record final HIV status, as determined by local lab and study staff.

Item 6: Storage refers to the specimen aliquots for QA testing, as detailed in SSP. This variable allows SCHARP to determine for which PTIDs and visits specimens are stored and available for QA testing.

- If aliquots were completed successfully, check "yes." If the aliquots were not completed for any reason, check "no."

SAMPLE. DO NOT FAX TO DATAFAX

HPTN 058 (123)



ICS-1 (055)

Participant ID

- -
 Site Number Participant Number Chk

Informed Consent for Enrollment Evaluation Survey

Survey Completion Date

/ /
 dd MMM yy

Staff administering survey: _____

Instructions: I would like to ask you questions about how you felt when you took the comprehension quiz earlier today. Unlike before, there are no correct or incorrect answers to the questions I am going to ask you. Please know that your answers to this survey do not affect your participation in the trial. We are asking you these questions only because we want to know how it felt to be asked questions about the trial after the informed consent process.

1. Would that be OK? *yes* *no* → **If no, end of form.**

To begin, I am going to ask you six questions about how you felt when taking the comprehension quiz. After each question, please tell me if you felt that way or not. You can respond by saying that you strongly disagree, disagree, neither disagree or agree, agree, or strongly agree with the statement.

2. When taking the comprehension quiz:

	<i>strongly disagree</i>	<i>disagree</i>	<i>neither disagree or agree</i>	<i>agree</i>	<i>strongly agree</i>
2a. you were anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2b. you did not mind	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2c. you were bored	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2d. you were irritated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2e. you found the questions easy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2f. you felt pressured	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instructions: I am now going to ask you two more questions. The responses are the same as before.

	<i>strongly disagree</i>	<i>disagree</i>	<i>neither disagree or agree</i>	<i>agree</i>	<i>strongly agree</i>
3. Taking the comprehension quiz made you feel like the researchers really wanted you to understand the clinical trial:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Testing is a good way to find out if a person really understands the clinical trial:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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SAMPLE

Language

Staff Initials / Date

Informed Consent for Enrollment Evaluation Survey (ICS-1)

Purpose: Following Enrollment, all participants must be asked if they are willing to participate in this evaluation survey and the form should be completed accordingly.

**SAMPLE. DO NOT FAX
TO DATAFAX**



HPTN 058 (123)

ICQ-1 (057)

Participant ID

- -

Site Number Participant Number Chk

**Enrollment Informed Consent
Comprehension Quiz**

Quiz Completion Date

dd MMM yy

Instructions: Read all questions aloud one-by-one and mark the "true" or "false" box based on the participant's response to the statement. When all questions have been responded to, then follow the instructions listed on the back of page 3.

Read aloud to participant: Please answer True or False to the following statements.

Question	1st Attempt		2nd Attempt		3rd Attempt	
	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect
1. The purpose of this study is to compare how well two different treatment methods help prevent the spread of HIV and death in injection drug users by reducing drug use and other risky behaviors.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
2. Suboxone has been approved by the US FDA as a treatment for opiate dependence. Suboxone is not currently approved by the [country name] FDA, but investigators have received permission to conduct this study with Suboxone in [country name].	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
3. Suboxone alone prevents HIV infection.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
4. You should not use opiates for at least 12 hours before receiving the first dose of Suboxone to avoid opiate withdrawal symptoms.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
5. If you decide to participate in this study, you will be asked to come to the clinic every day for up to approximately 3 weeks.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	

01-DEC-08

SAMPLE

Language

Staff Initials / Date

Enrollment Informed Consent Comprehension Quiz (ICQ-1)

Purpose: This quiz is to assess that the participant demonstrates sufficient comprehension of the study. Each statement can be asked over 3 attempts. See the back of page 3 for instructions on completing this form.

SAMPLE. DO NOT FAX
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HPTN 058 (123)

ICQ-2 (058)

Participant ID

- -
 Site Number Participant Number Chk

Enrollment Informed Consent Comprehension Quiz

Question	1st Attempt		2nd Attempt		3rd Attempt	
	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect
6. If you are in the Substitution treatment group, your dose of Suboxone will be determined at your first clinic visit.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
7. There are no direct benefits to you if you participate in this study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
8. If you are jailed during your participation in the study, we will conduct all study visits at the facility where you are incarcerated.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
9. If you become HIV infected after you have enrolled in the research study, you will have to leave the research study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
10. One reason that we may end your participation in the study early without your permission is that you are not able to follow the procedures required by the study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
11. You might encounter problems if others find out that you have enrolled in this study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
12. When you are enrolled into the study, you cannot withdraw from the study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	

01-DEC-08

SAMPLE

Language

Staff Initials / Date

Enrollment Informed Consent Comprehension Quiz (ICQ-2)

See the back of page 3 for instructions on completing this form.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)



ICQ-3 (059)

Participant ID

- -
 Site Number Participant Number Chk

Enrollment Informed Consent Comprehension Quiz

NOTE TO INTERVIEWER:	1st Attempt	2nd Attempt	3rd Attempt
In the space provided, list the item numbers that were answered incorrectly, if any:			

	1st Attempt	2nd Attempt	3rd Attempt
13. Record the total number of questions answered correctly :	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

14. Outcome:

- 14a. participant enrolled
- 14b. participant declined to consent
- 14c. participant did not pass enrollment quiz

If participant declined to consent or did not pass the enrollment quiz, do not fax this form to SCHARP DataFax.

Enrollment Informed Consent Comprehension Quiz (ICQ-3)

General Information/Instructions:

- Review all responses with participant, both correct and incorrect.
- If participant answered 9 or more questions correctly, participant can sign/mark the consent form.
- If participant answered 4 or more questions incorrectly:
 - Re-ask only those questions answered incorrectly and record the participant's new answers in the "2nd Attempt" column.
 - Follow the same process for questions answered incorrectly during the 2nd attempt and record the new answers in the "3rd Attempt" column.
 - After the 3rd attempt, the participant cannot enroll if at least 9 of the questions have not been answered correctly during the 3 attempts.

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

ENR-1 (061)

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"/>	
Site Number				Participant Number							Chk

Enrollment/Randomization

1. Date of study consent:

dd *MMM* *yy*

Item 2 is for China sites only. Thailand site go to item 3.

2. Did participant consent to specimen storage? *yes* *no* → **If no, go to item 3.**

2a. Date of specimen consent:

dd *MMM* *yy*

3. Randomization date:

dd *MMM* *yy*

4. Randomization time: : *24-hr clock*

hr *min*

5. Envelope number:

6. Treatment arm: *substitution* *detox*

7. Is this participant part of the safety phase? *yes* *no*

Enrollment/Randomization (ENR-1)

Description and Purpose

This form documents randomization and enrollment of eligible participants. Randomization is the effective time point of enrollment in HPTN 058, and the procedures for randomization are detailed in SSP section 4.6.

Form-specific Instructions

Items 1, 2a (if applicable), and 3: Complete dates are required.

Item 1: “Date of study consent” refers to consent for study enrollment, not consent for study screening.

Item 2: This item is only completed by sites where participants are asked to provide consent for long-term specimen storage. Other sites skip to item 3.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)

RA-1 (121) Visit Code

□□□□.□□

1

Participant ID

□□□□-□□□□□□-□
Site Number Participant Number Chk

Risk Assessment

Visit Date

□□ □□□□ □□
dd MMM yy

INJECTION AND HIV TESTING HISTORY

Items 1-4 are administered at screening only. At follow-up visits, go to item 5.

- 1. How old were you when you first injected drugs? □□ years
- 2. Have you ever had an HIV test? yes no **→ If no, go to item 5.**
- 3. When was your most recent HIV test? □□ □□□□ □□
dd MMM yy
- 4. What was the result of that test? negative positive don't know

ECONOMIC SUPPORT

- 5. In the last month, have you earned money or received financial support through...
 - 5a. regular employment? yes no **→ If yes, how much did you receive?** □□□□□□
 - 5b. government or public assistance? yes no **→** □□□□□□
 - 5c. spouse, family, or friends? yes no **→** □□□□□□
 - 5d. other sources or activities? yes no **→** □□□□□□
- 6. In the last month, how many days did you work? □□ # of days

Risk Assessment (RA-1)

Description and Purpose

The Risk Assessment questionnaire collects information on incarceration, economic support, alcohol use, drug use, and sexual behavior. This form is administered at the screening visit to those participants found to be eligible based on the Screening Assessment form. All enrolled participants are also administered the Risk Assessment at week 26, 52, 78, 104, 130, and 156 visits.

Form-specific Instructions

Items 1-4: Items 1–4 are only administered at the screening visit, and are skipped at all follow-up visits.

Item 4: A self-report of a previous positive HIV test result does not determine ineligibility. HIV testing must still be completed to determine eligibility.

Item 5: For each category of economic support, if the participant reports earning money or receiving support, record the amount in the local currency.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)



RA-2 (122)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Risk Assessment

INCARCERATION

7. In the last 6 months, how many different times were you in...

	# of times	If > 0, how many days total?
7a. jail?.....	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
7b. prison?	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
7c. detention?	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
7d. a detoxification center?	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
7e. other incarceration, specify:	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Local Language _____

English _____

ALCOHOL USE

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

8. In the last 6 months, how often did you drink alcohol? *Show Card #1.*

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

If never, go to item 11 on page 3. ←

9. In the last 6 months, when you drank alcohol, how often did you drink enough to get drunk or stay drunk? *Show Card #2.*

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

10. In the last 6 months, did you ever drink alcohol to reduce drug withdrawal symptoms?

yes no

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Risk Assessment (RA-2)

Item 7: Item 7c. “Detention” includes juvenile detention. Sites should determine prior to study activation how site-specific categories of incarceration will be recorded on this form.

Item 8: Read out loud to the participant the section marked “Read to participant” before asking item 8. Use response card # 1 to help the participant identify his or her weekly drinking frequency. Non-drinkers (those who choose the “never” category) go to item 11 on page 3.

Item 9: Use response card # 2 to help the participant identify the frequency of his or her drinking to get or stay drunk.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)



RA-3 (123)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Risk Assessment

NON-INJECTION DRUG USE

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

11. In the last 6 months, did you...	yes	no	If yes, how many times in the last month?
11a. smoke marijuana?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11b. smoke amphetamines or methamphetamines?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11c. snort or swallow amphetamines or methamphetamines?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11d. snort or sniff cocaine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11e. smoke heroin?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11f. snort or swallow heroin?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11g. smoke opium?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11h. swallow opium?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11i. take buprenorphine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11j. take methadone?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11k. take downers or benzodiazepines?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11l. take ecstasy or MDMA?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11m. snort or swallow ketamine?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11n. sniff glue?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11o. chew or swallow kat leaf?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11p. drink cough syrup?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
11q. use other non-injection drugs? Specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Local Language _____

English _____

Risk Assessment (RA-3)

Item 11: Read out loud to the participant the section marked “Read to participant” before asking item 11.

Note that the time frame changes within each sub-item. The participant is first asked if they used the each non-injection drug **in the last 6 months**. If the participant responds “yes,” they are then asked, “**how many times in the last month?**” If “no,” skip to the next sub-item.

Item 11p: Note that this item refers to using cough syrup to get high, not to treat a cough.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

HPTN 058 (123)

RA-4 (124)

Participant ID

- -
Site Number Participant Number Chk

Risk Assessment

INJECTION DRUG USE

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

12. In the last 6 months, did you use a needle to inject any drugs under your skin or into a vein? *yes* *no* **If no, go to item 28 on page 7.**

13. In the last 6 months, did you inject any of these drugs alone (that is, not mixed with another drug)? **If yes, how many times in the last month?**

	<i>yes</i>	<i>no</i>	
13a. amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13b. cocaine.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13c. heroin.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13d. opium.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13e. buprenorphine.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13f. methadone.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13g. benzodiazepines.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13h. ketamine.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13i. kat leaf.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
13j. other, specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Local Language _____

English _____

14. In the last 6 months, did you mix two or more drugs together and inject them? *yes* *no* **If no, go to item 15 on page 5.**

14a. What drugs did you mix? *Interviewer: Code participant's response using Drug Code List on back of form.*

	<i>drug #1</i>	<i>drug #2</i>	<i>drug #3</i>
N/A 14a1.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> 14a2.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> 14a3.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

10-AUG-07

SAMPLE

Language

Staff Initials / Date

Risk Assessment (RA-4)

Item 12: Read out loud to the participant the section marked “Read to participant” before asking item 12. If no injection drug use is reported in the last 6 months, skip to item 28 on page 7.

Item 13: Note that the time frame changes within each sub-item. The participant is first asked if they used the each injection drug **in the last 6 months**. If the participant responds “yes,” they are then asked, “**how many times in the last month?**” If “no,” skip to the next sub-item.

Items 14a1–14a3: Refer to the list below and record the codes of the drugs mixed and injected. If only one or two pairs were injected, mark “N/A” for item 14a2 and/or item 14a3. NOTE: When fewer than three drugs are mixed, record the two drugs mixed and draw a line through the remaining boxes under “drug 3.”

Drug Code List

01	amphetamines	06	methadone
02	cocaine	07	benzodiazepenes
03	heroin	08	ketamine
04	opium	09	kat leaf
05	buprenorphine		

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)

RA-5 (125) Visit Code

□□□□.□□

1

Participant ID

□□□□-□□□□□□-□
Site Number Participant Number Chk

Risk Assessment

15. In the last month, on how many days did you inject drugs?..... □□ # of days

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

17. In the last 6 months, how many times did you... # of times

17a. use rinse water that others had used?..... □□□

17b. use a cooker that others had used?..... □□□

17c. use filter cotton that others had used?..... □□□

17d. inject drugs that were frontloaded or backloaded into the syringe or needle that you used? *Show Cards #3 and #4.*..... □□□

17e. use a needle that others had discarded?..... □□□

18. In the last 6 months, how many different people did you use drugs with?..... □□□ # of people

19. In the last 6 months, did you ever even once pass on a needle or syringe to someone else after you used it? yes no **If no, go to item 20.**

19a. How many times did you do this in the last 6 months?..... □□□ # of times

19b. With how many different people did you do this in the last 6 months? □□□ # of people

20. In the last 6 months, did you ever even once use a needle or syringe after someone else used it? yes no **If no, go to item 22 on page 6.**

20a. How many times did you do this during the last 6 months?..... □□□ # of times

20b. With how many different people did you do this in the last 6 months? □□□ # of people

Risk Assessment (RA-5)

Item 15: Record the number of days.

Item 16: Record the number of times.

Item 17: For each item, record the number of times. Display response cards # 3 and 4 to assist the participant by presenting a picture of frontloading and backloading practices.

Item 18: Record the number of different people.

Item 19: Needle or syringes are passed to someone else. If “yes,” also record how many times and with how many different people in the last 6 months.

Item 20: Needle or syringe use is after someone else. If “yes,” also record how many times and with how many different people in the last 6 months.

**SAMPLE. DO NOT FAX
TO DATAFAX**

HPTN 058 (123)



RA-6 (126)

Visit Code

□□□□.□□

1

Participant ID

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Site Number Participant Number Chk

Risk Assessment

21. In the last 6 months, did you ever use a needle or syringe after someone that you know is HIV-positive used it? yes no don't know

22. In the last 6 months, did you get your new needles from a... yes no
22a. drugstore/pharmacy?
22b. hospital or health center?.....
22c. needle seller?.....
22d. needle exchange?.....
22e. other drug injectors?

23. In the last 6 months, where did you most often get your new needles? *Show Card #5.*

- drugstore/pharmacy
- hospital or health center
- needle seller
- needle exchange
- other drug injectors
- other, specify: *Local Language* _____ *English* _____
- didn't get new needles in last 6 months

24. In the last 6 months, did you always use a new needle every time you injected?..... yes no **If yes, go to item 27 on page 7.**

25. In the last 6 months, did you ever clean your needle either before or after injecting? **If no, go to item 26 on page 7.**

	<i>always</i>	<i>more than half the time</i>	<i>about half the time</i>	<i>less than half the time</i>	<i>never</i>
25a. How often do you clean your needle before injecting? <i>Show Card #2.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25b. How often do you clean your needle after injecting? <i>Show Card #2.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

□□□□ 26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Risk Assessment (RA-6)

Item 21: Needle or syringe use is after someone else known to be HIV-positive.

Item 22: Note the item refers to where participants got their NEW needles.

Item 23: Note the item refers to the one category where participants got their NEW needles most often. Mark only one response. Use response card #5.

Item 25: Needle cleaning is before or after injecting. Using the categories on response card # 2 to assist the participant, indicate frequency of cleaning before injecting in item 25a and after injecting in item 25b. Participants who did not clean their needles go to item 26.

**SAMPLE. DO NOT FAX
TO DATAFAX**

HPTN 058 (123)

RA-7 (127) Visit Code

□□□□.□□

1

Participant ID

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Site Number Participant Number Chk

Risk Assessment

26. The last time you injected, did you...

- 26a. clean the needle before you injected? *yes* *no*
- 26b. use a new needle? *yes* *no*
- 26c. clean the needle after you injected? *yes* *no*
- 26d. inject with other people at the same time?..... *yes* *no*
- 26e. share the needle? By share I mean you used the needle after someone **or** you passed on the needle to someone else after you used it. *yes* *no*

27. How many days ago did you last inject? □□□ # of days

28. In the last 6 months, did you participate in any type of drug treatment program, drug counseling, or drug detoxification other than treatment received as part of this study? *yes* *no*

→ If no, go to item 29 on page 8.

28a. What types of treatment did you receive? *Mark all that apply.*

- 28a1. inpatient or residential treatment/therapeutic community
- 28a2. outpatient treatment
- 28a3. methadone maintenance → 28a3a. How many weeks were you on methadone maintenance? # of weeks □□
- 28a4. detoxification
- 28a5. religious or faith-based program
- 28a6. Narcotics Anonymous, Cocaine Anonymous, Meth Anonymous, or Alcoholics Anonymous
- 28a7. other, specify: *Local Language* _____

English _____

Risk Assessment (RA-7)

Item 26: Mark “yes” or “no” for each item describing the participant’s injection practice the last time that they injected.

Item 27: Record the number of days since the participant last injected. If he or she injected today, record zero.

Item 28: If no drug treatment reported in the last 6 months, skip to item 29 on page 8.

Item 28a: Record the number of weeks on methadone maintenance. Note: Methadone detoxification does not count as methadone maintenance treatment.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)



RA-8 (128)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Risk Assessment

SEXUAL BEHAVIOR QUESTIONS

Read to participant: 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.

- 29. In the last month, did you have vaginal or anal sex? *yes* *no* → **If no, end of form.**
- 30. In the last month, how many different female sex partners did you have?
- 31. In the last month, how many different male sex partners did you have?
- 32. Do you have a primary sex partner such as a husband/wife or boyfriend/girlfriend? *yes* *no* → **If no, go to item 34.**
- 32a. Is your primary sex partner male or female? *male* *female*
- 33. In the last month, how many times did you have vaginal or anal sex with your primary sex partner? → **If 0, go to item 34.**
- 33a. How many of these times did you (or your partner) use a condom?
- 34. In the last month, how many times did you have vaginal or anal sex with someone other than a primary sex partner? → **If 0, go to item 35.**
- 34a. How many of these times did you (or your partner) use a condom?
- 35. In the last month, how many sex partners did you give money or drugs to in exchange for sex?
- 36. In the last month, how many sex partners gave you money or drugs in exchange for sex?

Risk Assessment (RA-8)

Read out loud to the participant the section marked “Read to participant” before asking item 29.

Item 29: If the participant reports no vaginal or anal sex in the last month, this is the end of the form.

Items 30 and 31: These items are asked of all participants and a response is expected for both items. Participants may report both male and female partners. “Zero” is also an acceptable response.

Item 32: If the participant has more than one relationship considered to be primary, ask about the partner to whom the participant is most committed. If the participant is equally committed, ask about the partner with whom the participant has been involved with the longest. If no primary sex partner is reported, go to item 34.

Items 33 and 34: Record the number of times that the participant had sex with his or her primary partner and then with a non-primary partner. For each, if > 0 , record the number of times while using a condom.

Item 35: Record the number of unique sex partners that the participant paid or gave drugs to in exchange for sex. If the participant paid one partner for three different sexual encounters, count this as one partner.

Item 36: Record the number of unique sex partners that paid or gave drugs to the participant in exchange for sex. If the participant was paid by one partner for three different sexual encounters, count this as one partner.

**SAMPLE. DO NOT FAX
TO DATAFAX**

Visit Code

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1

HPTN 058 (123)

HTR-1 (151)

Participant ID

□□□□-□□□□□□-□
Site Number Participant Number Chk

HIV Test Results

Initial Specimen Collection Date

□□ □□□□ □□
dd MMM yy

SAMPLE 1

Alternate Collection Date
Not done/ Not collected dd MMM yy
 □□ □□□□ □□
 □□ □□□□ □□

1. Rapid test 1 □□ negative positive
2. Rapid test 2 □□ negative positive
If negative for both, go to item 7.
3. HIV Western Blot/IFA negative positive indeterminate
If negative, go to item 7.

SAMPLE 2

Alternate Collection Date
Not done/ Not collected dd MMM yy
 □□ □□□□ □□

4. HIV Western Blot/IFA negative positive indeterminate
If negative or indeterminate, contact HPTN central lab for further instructions.
If positive, go to item 7.

SAMPLE 3

Alternate Collection Date
Not done/ Not collected dd MMM yy
 □□ □□□□ □□
 □□ □□□□ □□

5. HIV Western Blot/IFA negative positive indeterminate
6. RNA negative positive

7. HIV status negative positive other, specify: Local Language _____
English _____

Comments: Local Language _____

Comments: English _____

□□ □□ 26-JAN-07

SAMPLE

01
Language

Staff Initials / Date

HIV Test Results (HTR-1)

Description and Purpose

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

Form-specific Instructions

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. Complete date required.

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. 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. Complete date required.

Results Reporting: If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.

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

Items 1 and 2: Rapid Test Results. If negative for BOTH rapid tests, go to item 7. Otherwise, continue to item 3.

In the code boxes to the right of “Rapid test 1” and “Rapid test 2” (if applicable), record the assigned two-digit rapid test kit code. The rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03
Mirawell HIV Rapid	04
MedMira Reveal G2	05
BiolineHIV	06
Acon HIV	07

Item 4: If the result of the confirmatory test on the second sample is negative or indeterminate, contact the HPTN central lab for further testing instructions.

Items 5 and 6: These result boxes are provided to record the results of the tests likely to be conducted on a third sample, if needed. Complete according to Central Lab instructions.

Item 7: Record final HIV status as determined by study and laboratory staff.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit
Code

1

HPTN 058 (123)

LLF-1 (152)

Participant ID

--
Site Number Participant Number Chk

Initial Specimen Collection Date

dd MMM yy

Local Laboratory Results

Alternate Collection Date
Not done/ Not collected dd MMM yy
Not reported

1. HEMOGRAM

1a. WBC $\times 10^3/mm^3$
1b. Hemoglobin..... g/dL
1c. Platelets cells/mm³

AE Severity
Grade
If applicable
AE Log
Page #

Alternate Collection Date
Not done/ Not collected dd MMM yy

2. LIVER FUNCTION TESTS

2a. ALT (SGPT) U/L
2b. Total bilirubin mg/dL

AE Severity
Grade
If applicable
AE Log
Page #

Alternate Collection Date
Not done/ Not collected dd MMM yy

3. RENAL FUNCTION TESTS

3a. Creatinine mg/dL

AE Severity
Grade
If applicable
AE Log
Page #

Alternate Collection Date
Not done/ Not collected dd MMM yy

4. HEPATITIS

4a. Hepatitis B surface antigen..... *non-reactive reactive indeterminate*
4b. Hepatitis C antibody.....

Alternate Collection Date
Not done/ Not collected dd MMM yy

5. SPECIMEN STORAGE

5a. Was blood specimen processed for storage?..... *yes no*

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Local Laboratory Results (LLF-1)

Description and Purpose: Laboratory results other than HIV antibody test results at all post-enrollment study visits are recorded on this form.

Form-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. Complete date required.

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. 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. Complete date required.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
- 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. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
- 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.

AE Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate DAIDS Table for *Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
- Treat all missing digits in the lab value as zeros.
- If the lab value falls between two calculated severity grade ranges, assign it the higher grade.

AE Log Page #: Record the page number of the AE Log which is most closely associated with the abnormal lab value.

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

Item 5: Storage refers to the specimen aliquots for QA testing, as detailed in SSP section 11.6. This variable allows SCHARP to determine for which PTIDs and visits specimens are stored and available for QA testing.

SAMPLE. DO NOT FAX
TO DATAFAX

██████████ Visit
Code

□□□□.□□

1

HPTN 058 (123)

UTR-1 (161)

Participant ID

□□□□-□□□□□□-□
Site Number Participant Number Chk

Urine Test Results

Initial Specimen Collection Date

□□ □□□□ □□
dd MMM yy

Alternate Collection Date

Not done/
Not collected

dd MMM yy

□ □□□ □□□□ □□

Item 1 is for females only. If participant is male, go to item 2.

1. PREGNANCY TEST

negative positive

1a. Test result □ □

Alternate Collection Date

Not done/
Not collected

dd MMM yy

□ □□□ □□□□ □□

2. URINE DRUG SCREEN

**amphetamines
(AMP)**

**methadone
(MTD)**

**opiates
(MOP)**

**benzodiazepines
(BZO)**

yes no

yes no

yes no

yes no

2a. Was drug detected?

□ □

□ □

□ □

□ □

Comments: *Local Language* _____

Comments: *English* _____

□□□□ x 26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Urine Test Results (UTR-1)

Description and Purpose

Results from tests performed on urine samples (pregnancy and drug screening) are recorded on this form. This form is used for urine tests performed at screening and after enrollment.

Form-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. Complete date required.

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. 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. Complete date required.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
- 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.

Not done / Not collected: Mark the “Not done / Not collected” box only if a specimen was not obtained, or the lab test was not performed on the sample for some reason. Use the “Comments” area at the bottom of the form to explain why a sample was not collected or the test was not done.

**SAMPLE. DO NOT FAX
TO DATAFAX**

HPTN 058 (123)

SIA-1 (171) Visit Code

□□□□.□□

1

Participant ID

□□□-□□□□□□-□
Site Number Participant Number Chk

Social Impact Assessment

Contact Date

□□ □□□□ □□
dd MMM yy

Instruction: Before administering this assessment, update information about any unresolved previously reported social impacts on the corresponding Social Impact Log (SIL).

1. Because of your participation in this study, did anything negative or bad happen to you that you have not reported to us already?..... **yes** **no** → **If no, go to item 3.**

2. Because of your participation in this study, have you... **If yes, how many times?**

2a. been arrested or had trouble with the police or other legal problems?..... **yes** **no** → □□

2b. had trouble getting or keeping housing?..... **yes** **no** → □□

2c. had trouble getting or keeping a job or trouble with income or economic support?..... **yes** **no** → □□

2d. had trouble getting health care or with health insurance?..... **yes** **no** → □□

2e. had personal trouble with friends, family, or acquaintances?..... **yes** **no** → □□

2f. had any other type of problem? Specify:..... **yes** **no** → □□

Local Language _____

English _____

Complete a separate Social Impact Log (SIL) for each impact. ← total number of impacts □□

3. Has your participation in this study had a positive or beneficial impact on your life that you have not already reported to us?..... **yes** **no** **don't know** → **If no or don't know, end of form.**

3a. **If yes, please describe:** Summarize participant's response.

Local Language _____

English _____

Social Impact Assessment (SIA-1)

Description and Purpose

This form captures information on any social impacts—positive or negative—that the participant experiences as a result of study involvement. There is a wide range of “impacts,” including relationships, education, employment, housing, and health care. NOTE: Do not record previously reported social impacts. Use the original SIL-1 form to make updates to previously reported social impacts.

Form-specific Instructions

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

Item 2: Read all sub-items to the participant and mark a response for each. If the participant refuses to answer any item, write “refused” and line through the response box.

- Total the number of social impacts reported and enter the number in the boxes at the bottom of the column. Complete one Social Impact Log form for each impact reported.
- If two separate occurrences of the same type of social impact are reported, such as two separate episodes of relationship problems, mark the “yes” box and include both episodes in the total. Complete one Social Impact Log for each episode.

Item 3: A positive or beneficial impact means anything good or anything that has improved the participant’s quality of life. If “yes” is marked, provide a detailed explanation in item 3a.

**SAMPLE. DO NOT FAX
TO DATAFAX**



Note: Number pages sequentially (01, 02, 03) for each participant.

Page

HPTN 058 (123)

SIL-1 (181)

Participant ID

- -

Site Number Participant Number Chk

Social Impact Log

Instructions: Fax this form to SCHARP DataFax whenever a new Social Impact is recorded or information on this form is updated. Fax only pages with new entries or revisions.

1. Concisely describe social impact:

Local Language _____

English _____

dd MMM yy

2. Onset Date:

3. Reported at Visit:

.

4. Social Impact Code:

Social Impact Codes:

- 01 Police/Legal Problems 04 Health Care/Insurance
- 02 Housing 05 Friends/Family
- 03 Employment 06 Other

6. Describe what was done by staff and participant to address social impact:

6a. Participant: Local Language _____

English _____

6b. Staff: Local Language _____

English _____

Ask Participant:

5. What impact has this situation had on your quality of life?

- Minimal disturbance
- Moderate disturbance. No significant impact.
- Major disturbance with significant impact.

7. Record current status:

- Unresolved
- Unresolved at end of study
- Unable to resolve. No further action taken.
- Resolved

If either is marked, enter closure date: dd MMM yy

Reviewed by Investigator: _____
Principal Investigator (or designee) Signature Date

28-FEB-07

SAMPLE

Language

Staff Initials / Date

Social Impact Log (SIL-1)

Description and Purpose

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

Form-specific Instructions

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

Items 1 and 8: Provide a description of the social impact and then what was done by the staff and the participant to address the issue.

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

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

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

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

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

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

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

SAMPLE. DO NOT FAX
TO DATAFAX



Induction #

HPTN 058 (123)

IR-1 (185)

Participant ID

- -

Site Number Participant Number Chk

Induction Record

	Date			Time 24-hr clock		COWS Score	Dose mg	Associated AE Log Page # if applicable	Staff Initials/Date
	dd	MMM	yy	hr	min				
<input type="checkbox"/> 1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 7.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 8.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 9.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 10.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 11.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
<input type="checkbox"/> 12.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Induction Record (IR-1)

Description and Purpose

This form records the FIRST THREE DAYS of Suboxone dosing for ALL participants. After three days, all dosing is recorded on the Weekly Dosing Record (DR-1). Use as many lines as needed to record all dosing in the first three days. Check the “not given” box before unused lines before sending the completed form to SCHARP. NOTE: Use a new IR-1 for the first 3 days of dosing for each subsequent re-induction.

Form-specific Instructions

Induction #: Record the inductions in order using sequential numbers beginning with 01 (the first induction is 01; the second is 02 and so on).

Date: Date must be recorded for each dose, even if multiple doses are given on the same day. Complete date required.

Time: Record the time each dose is given, using the 24-clock.

COWS Score: Record the score from the Clinical Opiate Withdrawal Scale (COWS) that is administered prior to each dose.

Dose: Record each dose given in milligrams (mg). NOTE: Dosage is given in the Buprenorphine component of Suboxone.

Associated AE Log Page #: If a reportable adverse experience is associated with a specific Suboxone dose, record the log page from the associated Adverse Experience Log form (AE-1) in these boxes. This field is only completed when there is a reportable event and an AE-1 form is also completed. Do not complete this field for non-reportable adverse experiences.

SAMPLE. DO NOT FAX
TO DATAFAX



Week #

HPTN 058 (123)

DR-1 (187)

Participant ID

- -

Site Number Participant Number Chk

Weekly Dosing Record

No dosing given for week. Complete a Missed or Discontinuation of Weekly Dosing form. Staff Initials/Date _____

participant missed dosing visits _____

AE or SAE _____

dosing temporarily withheld _____

dosing permanently discontinued _____

investigator decision _____

other, specify: Local Language _____

English _____

Verified incarceration? _____

"REASON" IS NO LONGER CAPTURED ON THIS FORM

▶ End of form.

Participant began re-induction this week. Staff Initials/Date _____

	Date			Time 24-hr clock		SUPERVISED DOSES		TAKE-HOME DOSES		Staff Initials/Date
	dd	MMM	yy	hr	min	Dose mg	Days Covered by Dose	Dose mg	Days Covered by Dose	
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____
7.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	_____

Comments: Local Language _____

Comments: English _____

24-JUL-08

SAMPLE

Language

Staff Initials / Date

Weekly Dosing Record (DR-1)

Description and Purpose

This form records all Suboxone dosing AFTER the first three days of dosing. This form is designed to capture a calendar week of dosing (defined as Monday through Sunday). Partial weeks (e.g., dosing that begins on a Thursday or Friday) should be recorded on one page, and a new page should be used starting with the following Monday. One page is required for each participant for each week that Suboxone is given or scheduled to be given. Use one line for all dosing given to the participant on one day, including supervised doses and take-home doses.

Form-specific Instructions

Week #: Record the study week, starting with 01.

No Dosing box: This box is completed only when an entire week of scheduled dosing is missed. Complete a Missed or Discontinuation of Weekly Dosing form and check the reason why dosing was not given. Fax both forms to SCHARP DataFax.

Re-induction box: Check only when participant was re-induced on Suboxone for missing scheduled doses, or for the second detoxification in the detoxification arm.

Date: Date must be recorded for each day any dose—supervised or take-home—is given to the participant. Use one line for all dosing given in a single day. For take-home doses, record the date that the dose is given to the participant. Complete date required.

Time: Record the time each supervised dose is given, using the 24-clock.

Supervised Doses: Record each supervised dose given in milligrams (mg). Indicate the total days covered by that dose. NOTE: Dosage is given in the Buprenorphine component of Suboxone.

Take-home Doses: Record each take-home dose given in milligrams (mg). Indicate the total days covered by that dose. NOTE: Dosage is given in the Buprenorphine component of Suboxone.

SAMPLE. DO NOT FAX
TO DATAFAX



Week #

HPTN 058 (123)

MDD-1 (188)

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"/>	
Site Number				Participant Number							Chk

Missed or Discontinuation of Weekly Dosing

1. Did the participant come to the clinic during the dosing week? *yes* *no*

2. Primary reason no dosing was given for entire week:

<input type="checkbox"/> participant-based reason	}	Reason Code	<i>See code list on back of form.</i>
<input type="checkbox"/> protocol-specified reason			
<input type="checkbox"/> other, specify:			

<input type="text"/>	<input type="text"/>
----------------------	----------------------

If reason code is 06, 27, or 99, specify in Comments below.

Local Language: _____

English: _____

Comments: *Local Language* _____

Comments: *English* _____

Missed or Discontinuation of Weekly Dosing (MDD-1)

Purpose: Complete this form when documenting the primary reason that weekly dosing was missed or discontinued.

General Information/Instructions: Record the study week, starting with 01.

Item-specific Instructions

Item 2: Check the box that describes the primary reason why an entire week of scheduled dosing is missed or why dosing has been discontinued.

Reason Code: Use the following definitions to code the reason for missing or discontinuing weekly dosing:

Reason Codes

Dosing withheld per participant-based reasons:

- 01 reported incarceration
- 02 verified incarceration
- 03 participant refused
- 04 illness/hospitalization
- 05 relocation
- 06 personal obligation (e.g., travel, no transportation, etc.) Specify in Comments
- 19 unknown

Dosing withheld per protocol-specified reasons:

- 21 intoxication with any drug at the time of the dispensing visit
- 22 in need of temporary use of a medication that may interfere with BUP/NX
- 23 serious adverse event (SAE) not related to withdrawal that is potentially related to the study drug
- 24 pregnancy
- 25 enrollment in another study that, in the judgment of the investigator, will interfere with full participation in or interpretation of HPTN 058.
- 26 evidence of hypersensitivity to BUP/NX
- 27 continued dosing or dosing at the current level is contraindicated for any reason, as judged by the study clinician and/or PSRT (e.g., elevated ALT, high risk use of benzodiazepines or other CNS depressant drugs.) Specify in Comments

Reason not listed in the codes above

- 99 other. Specify in Comments

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

CAW-1 (191)

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"/>	
Site Number				Participant Number							Chk

Weekly Counseling Session Attendance

	Date			Duration	
	dd	MMM	yy	hr	min
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
9.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
11.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
12.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
13.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
14.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Weekly Counseling Session Attendance (CAW-1)

Description and Purpose

This form is used to record the date and duration of each weekly BDRC counseling session completed or partially completed during the first 12 weeks of the study. Use as many lines as needed to record all sessions completed or partially completed during the 12 week period. Send the completed form to SCHARP after the weekly counseling sessions are complete (approximately week 13).

Form-specific Instructions

Date: Record the date the counseling session occurred. Complete date required.

Duration: Record the length of each session, in hours and minutes.

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

CAM-1 (192)

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				Participant Number					Chk

Monthly Counseling Session Attendance

	Date			Duration	
	dd	MMM	yy	hr	min
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
9.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
11.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
12.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Monthly Counseling Session Attendance (CAM-1)

Description and Purpose

This form is used to record the date and duration of each monthly BDRC counseling session completed or partially completed AFTER the first 12 weeks of the study (weeks 13–52). Use as many lines as needed to record all monthly sessions completed or partially completed. Send the completed form to SCHARP after the monthly counseling sessions are complete (approximately week 53).

Form-specific Instructions

Date: Record the date the counseling session occurred. Complete date required.

Duration: Record the length of each session, in hours and minutes.

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)



IV-1 (350)

Visit Code

□□□□.□□

1

Participant ID

□□□□-□□□□□□-□

Site Number

Participant Number

Chk

Interim Visit

Visit Date

□□ □□□□ □□

dd

MMM

yy

1. What is the reason for this interim visit? *Mark all that apply.*

- 1a. report a new social impact
- 1b. report a new adverse experience
- 1c. HIV testing
- 1d. other, specify: *Local Language* _____
English _____

2. Besides this Interim Visit form, what other DataFax study forms were completed at this visit? *Mark all that apply.*

- 2a. HIV Test Results (HTR-1)
- 2b. Local Laboratory Results (LLF-1)
- 2c. Urine Test Results (UTR-1)
- 2d. Social Impact Log (SIL-1)
- 2e. Adverse Experience Log (AE-1)
- 2f. Pregnancy Report and History (PR-1)
- 2g. Concomitant Medications (CM-1)
- 2h. other, specify: *Local Language* _____
English _____

Interim Visit (IV-1)

The Interim Visit form is used to document interim visits that occur during study follow-up. Any any other forms completed for this visit must have the same Visit Code as the corresponding Interim Visit form.

SAMPLE. DO NOT FAX
TO DATAFAX

AA-1 (371) Visit Code

□□□□.□□

1

HPTN 058 (123)

AA-1 (371)

Participant ID

□□□□-□□□□□□-□

Site Number

Participant Number

Chk

Acceptability Assessment

Form Completion Date

□□ □□□□ □□

dd

MMM

yy

1. Looking at this card, choose the things that you like most about this study. *Show Card #6. Mark "none" or all that apply.*

- 1a. none
- 1b. staff treat me well
- 1c. talking with counselors is helpful
- 1d. Suboxone is helpful
- 1e. physical exam and lab tests give me information about my general health
- 1f. learned about ways to prevent HIV infection
- 1g. study helps family and community
- 1h. other, specify: *Local Language* _____
English _____

2. Looking at this card, choose the things that you dislike most about this study. *Show Card #7. Mark "none" or all that apply.*

- 2a. none
- 2b. staff do not treat me well
- 2c. talking with counselors is not helpful
- 2d. do not like the way Suboxone makes me feel
- 2e. did not receive Suboxone long enough
- 2f. did not like to receive physical exam and lab tests
- 2g. too many visits
- 2h. visits take too much time or there is a long wait
- 2i. do not like answering so many questions
- 2j. other, specify: *Local Language* _____
English _____

Acceptability Assessment (AA-1)

Description and Purpose: This form allows the participants to report their perception of the positive and negative qualities of the intervention.

Form-specific Instructions

Item 1: Use show card # 6. Mark all that apply or “none.”

Item 2: Use show card # 7. Mark all that apply or “none.”

SAMPLE. DO NOT FAX TO DATAFAX



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

Page [][] [][] [][]

HPTN 058 (123)

AE-1 (420)

Participant ID

[][][] - [][][][][] - []

Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

[][] [][][][] [][]

dd MMM yy

1. Adverse Experience (AE)

2. Onset Date

Record diagnosis if available. Include anatomical location, if applicable.

[][] [][][][] [][]

dd MMM yy

English (if above is in Local Language): _____

3. Severity

- Grade 1 - Mild
Grade 2 - Moderate
Grade 3 - Severe
Grade 4 - Life-threatening
Grade 5 - Death

4. Relationship to Study Product

- Definitely related
Probably related
Possibly related
Probably not related
Not related
Record reason why AE is "not related" in Comments below.

5. Study Product Administration

- No change
Held
Permanently discontinued
N/A
Change in administration
Comment below.

6. Status/Outcome

- Continuing
Resolved
Death
Severity/frequency increased
Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

[][] [][][][] [][]

dd MMM yy

7. Treatment Mark "None" or all that apply.

- None
Medication(s)
New/Prolonged hospitalization
Procedure/Surgery
Other

8. Is this AE serious according to ICH guidelines?

yes no [] []

9. Has/will this AE be reported as an EAE?

[] []

10. This AE was first reported at visit:

Visit code required (regular or interim).

[][][] []

Comments: _____

English (if Comments above are in Local Language): _____

Adverse Experience Log (AE-1)

In HPTN 058, complete an Adverse Experience Log (AE) any time during study participation to document only SAEs and EAEs reported by the participant or clinically observed after initiation of study product, regardless of whether or not it is related to study product.

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency.

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.

Adverse Experience (AE): 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. For example, “decreased hematocrit” or “increased ALT.”

Onset Date: 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.

Severity: To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences*.

Relationship to Study Product:

- **Definitely related:** The adverse event and administration of study agent are related in time, and a direct association can be demonstrated.
- **Probably related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event is more likely explained by study agent than other causes.
- **Possibly related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event can be explained equally well by causes other than study agent.
- **Probably not related:** A potential relationship between study agent and the adverse event could exist (i.e., the possibility cannot be excluded), but the adverse event is most likely explained by causes other than the study agent.
- **Not related:** The adverse event is clearly explained by another cause not related to the study agent.
- **NOTE: IN CASES OF DEATH,** when relationship of study product is under investigation, write “Pending” in the adjacent white space until relationship has been determined. Update accordingly.

Study Product Administration: N/A (not applicable) should be marked if the AE occurred after the participant had completed all administration of the study agent, or the study product is held for a different AE, or the AE is Grade 5 - Death.

Status/Outcome:

- **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 this box 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. 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.

Status/Outcome Date: 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.

AE Revisions and Updates:

- 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).

Items 8 and 9: For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS*.

SAMPLE. DO NOT FAX TO DATAFAX



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

Page

HPTN 058 (123)

CM-1 (423)

Participant ID

- -

Site Number Participant Number Chk

Concomitant Medications Log

No medications taken throughout reporting period. _____
 Staff Initials/Date
 ▶ **End of form. Fax to SCHARP DataFax.**

Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ▶ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Continuing at end of study <i>dd MMM yy</i>	

Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ▶ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Continuing at end of study <i>dd MMM yy</i>	

Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ▶ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Continuing at end of study <i>dd MMM yy</i>	

Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ▶ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Continuing at end of study <i>dd MMM yy</i>	

26-JAN-07

SAMPLE

Language

Concomitant Medications Log (CM-1)

All medication(s) that are used by the participant during the study (including the protocol-defined screening period), other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

When to fax this form:

- when the participant has completed study participation; and/or
- when instructed by SCHARP.

Page: Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.

No medications taken throughout study: Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”

Medication: Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.

Indication: For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”

Date Started: If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.

Date Stopped: At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year is required.

Taken for a reported AE?: If the medication was not taken for a reported AE, mark the “no” box and leave the AE Log page boxes blank.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

1

HPTN 058 (123)

PR-1 (440)

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Report and History

PREGNANCY REPORT

1. Date of last menstrual period: ^{dd} ^{MMM} ^{yy}

2. Estimated date of delivery: ^{dd} ^{MMM} ^{yy}

PREGNANCY HISTORY

3. Has the participant ever been pregnant before? ^{yes} ^{no} → **If no, end of form.**

3a. Is this the participant's first pregnancy since enrollment in this study? ^{yes} ^{no} → **If no, end of form.**

3b. Number of full term live births (≥ 37 weeks):

3c. Number of premature live births (< 37 weeks):

3d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks):

3e. Number of spontaneous abortions (< 20 weeks):

3f. Number of therapeutic/elective abortions:

3g. Number of ectopic pregnancies:

4. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment? ^{yes} ^{no} → **If yes, document in participant's records.**

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

01
Language

Staff Initials / Date

Pregnancy Report and History (PR-1)

This form is used to report the pregnancy of a study participant post enrollment through termination.

Item-specific Instructions:

Visit Code: Record the visit code of the visit at which the participant was determined to be pregnant.

Item 1: Record the first day or best estimate of the participant's last menstrual period. Complete date required.

Item 2: Complete date required.

**SAMPLE. DO NOT FAX
TO DATAFAX**

PO-1 (441) Visit Code

□□□□.□

1

HPTN 058 (123)

PO-1 (441)

Participant ID

□□□-□□□□□□-□
Site Number Participant Number Chk

Pregnancy Outcome

Outcome unknown at end of study. _____
Staff Initials/Date

➔ **End of form. Fax to SCHARP DataFax.**

1. How many pregnancy outcomes resulted from the reported pregnancy? □

2. OUTCOME #1

2a. Outcome Date dd MMM yy
□□ □□□□ □□

2b. Specify Outcome: Mark only one.

- full term live birth (≥ 37 weeks)
 - premature live birth (< 37 weeks)
 - spontaneous fetal death and/or still birth (≥ 20 weeks)
 - spontaneous abortion (< 20 weeks)
 - ectopic pregnancy
 - therapeutic/elective abortion
- ➔ 2b1. Method: C-section vaginal
- ➔ **Complete AE Log and EAE Reporting form.**

2c. Were any fetal/infant congenital anomalies identified?
yes no not assessed

If only one outcome, end of form.

➔ **If yes, complete EAE Reporting form.**

3. OUTCOME #2

3a. Outcome Date dd MMM yy
□□ □□□□ □□

3b. Specify Outcome: Mark only one.

- full term live birth (≥ 37 weeks)
 - premature live birth (< 37 weeks)
 - spontaneous fetal death and/or still birth (≥ 20 weeks)
 - spontaneous abortion (< 20 weeks)
 - ectopic pregnancy
 - therapeutic/elective abortion
- ➔ 3b1. Method: C-section vaginal
- ➔ **Complete AE Log and EAE Reporting form.**

3c. Were any fetal/infant congenital anomalies identified?
yes no not assessed

➔ **If yes, complete EAE Reporting form.**

Comments: Local Language/English _____

□□□ [X] 26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Pregnancy Outcome (PO-1)

This form is used to report the pregnancy outcome(s) of a pregnancy reported post enrollment through termination. A Pregnancy Outcome form is required for each Pregnancy Report and History form completed for a participant. This form is completed when information about a pregnancy outcome becomes available to study staff. If an outcome is unknown at study end, mark the “Outcome unknown at end of study” box at the top of the page and fax to DataFax. When the outcome is known, draw a line through this box, record the outcome, and refax. A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SCHARP for guidance on how to complete this form.

Item-specific Instructions:

Visit Code: Record the visit code of the participant’s corresponding Pregnancy Report and History form.

Specify Outcome: If the outcome is therapeutic/elective abortion, note that while the abortion itself is not an adverse experience, if the abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, with “procedure/surgery” marked under “Treatment.”

Congenital anomalies: This item should be updated if information becomes available during the mother’s (the study participant’s) study follow-up period regarding a congenital anomaly. If a congenital anomaly is identified, complete an Expedited Adverse Event Reporting form (EAE), but do not complete an AE Log. A congenital anomaly is not considered an adverse experience of the mother (the study participant).

SAMPLE. DO NOT FAX
TO DATAFAX

HPTN 058 (123)

 Visit Code
MV-1 (463)

.

Participant ID

--
Site Number Participant Number Chk

Missed Visit

Form Completion Date

dd MMM yy

Instructions: Record the Visit Code of the scheduled visit that was missed.

Comments: *Local Language* _____

English _____

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Missed Visit (MV-1)

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.

Visit Code: Record the visit code of the visit that was missed.

Form Completion Date: Record the date that the form is completed. This will not necessarily be the date of the missed visit.

Comments: The comments field may be used to record the reason a visit is missed, or it may be left blank.

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 058 (123)

ESI-1 (489)

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"/>	
Site Number				Participant Number						Chk	

End of Study Inventory

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?.....

visit code

<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
----------------------	----------------------	----------------------	---	----------------------

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?.....

of interim visits

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

3a. Adverse Experience Log (AE-1) *page #*

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

OR *no pages submitted*

3b. Concomitant Medications Log (CM-1) *page #*

<input type="text"/>	<input type="text"/>
----------------------	----------------------

3c. Pre-existing Conditions (PRE-1)..... *page #*

<input type="text"/>	<input type="text"/>
----------------------	----------------------

3d. Social Impact Log (SIL-1) *page #*

<input type="text"/>	<input type="text"/>
----------------------	----------------------

OR *no pages submitted*

4. Indicate the **highest** week number submitted for this participant for each of the following forms:

4a. Weekly Dosing Record (DR-1)..... *week #*

<input type="text"/>	<input type="text"/>
----------------------	----------------------

Comments: _____

End of Study Inventory (ESI-1)

This form is used to confirm that SCHARP has received all study data for a given participant. Complete this form once for each enrolled participant after participant has terminated from the study (as documented by a Termination form).

- **Form Completion Date:** Complete date required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3b:** Record the highest page number of the Concomitant Medications Log submitted for this participant.
- **Item 3c:** Record the highest page number of the Pre-existing Conditions forms submitted for this participant.
- **Item 3d:** Record the highest page number of the Social Impact Log submitted for this participant.
- **Item 4a:** Record the highest week number of the Weekly Dosing Record submitted for this participant.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 058 (123)

TM-1 (490)

Participant ID

Site Number			Participant Number						Chk	

Termination

1. Termination Date: dd MMM yy Date the site determined that the participant was no longer in the study.

--	--	--	--	--	--	--	--

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.*

2b1. Date of death dd MMM yy

--	--	--	--	--	--	--	--

OR Date unknown

2b2. Cause of death _____

Local Language/English

OR Cause unknown

Complete or update Adverse Experience Log.

2c. Participant refused further participation, specify: *Local Language* _____

2d. ~~Participant unable to adhere to visit schedule.~~ *English* _____

2e. Participant relocated, no follow-up planned.

2f. Investigator decision, specify: *Local Language* _____ *English* _____

2g. Unable to contact participant.

~~2h. HIV infection inappropriate enrollment.~~

2j. Invalid ID due to duplicate screening/enrollment.

2k. Other, specify: *Local Language* _____ *English* _____

2l. Early study closure.

3. Was termination associated with...

3a. Adverse Experience? yes no don't know

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------

—————> **Record Adverse Experience Log page:** page #

--	--	--

Comments: *Local Language* _____

Comments: *English* _____

26-JAN-07

SAMPLE

01

Language

Staff Initials / Date

Termination (TM-1)

The Termination form is 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. A complete date is required, unless termination is due to death.

Item 2: Although more than one of the listed reasons may describe why a participant left the study early, 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:** At a minimum, the month and year are required.
- **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.

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.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

Participant ID

- -
 Site Number Participant Number Chk

Screening Informed Consent Comprehension Quiz

Form Completion Date

dd MMM yy

Instructions: Read all questions aloud one-by-one and mark the “true” or “false” box based on the participant’s response to the statement. When all questions have been responded to, then follow the instructions listed on the back of page 2.

Read aloud to participant: Please answer True or False to the following statements.

Question	1st Attempt		2nd Attempt		3rd Attempt	
	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect
1. The purpose of screening is to see if you are eligible to participate in the research study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
2. After you learn all screening information, you may or may not choose to complete the screening assessments.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
3. Only those who are eligible to join the research study will receive HIV testing.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
4. You don’t need to sign or make your mark on the consent form if you decide to complete the screening assessments.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
5. Female participants who are pregnant cannot join the research study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
6. Suboxone is the medicine that treats AIDS.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
7. If your first HIV test is positive, you will have a confirmation test.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	

Screening Informed Consent Comprehension Quiz (non-DF, Page 1 of 3)

Purpose: This quiz is to assess that the participant demonstrates sufficient comprehension of the study process. Each statement can be asked over 3 attempts. See the back of page 2 for instructions on completing this form.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

Participant ID

Site Number			Participant Number				Chk	

Screening Informed Consent Comprehension Quiz

Question	1st Attempt		2nd Attempt		3rd Attempt	
	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect	Answer	✓ = Correct X = Incorrect
8. The screening process will take about 1 hour.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
9. Your name will never be used in any publication or presentation about this research study.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
10. You will not be compensated for your time or transportation costs when you are given an appointment to complete the screening assessments.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
11. If you are injured from the screening, you will receive immediate treatment.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	
12. Neither you nor the study staff can choose which study arm you will be assigned into.	<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false		<input type="checkbox"/> true <input type="checkbox"/> false	

NOTE TO INTERVIEWER: In the space provided, list the item numbers that were answered incorrectly, if any:	1st Attempt	2nd Attempt	3rd Attempt

	1st Attempt	2nd Attempt	3rd Attempt
13. Record the total number of questions answered correctly :	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>

01-DEC-08

SAMPLE

Language

Staff Initials / Date

Screening Informed Consent Comprehension Quiz (non-DF, Page 2 of 3)

General Information/Instructions:

- Review all responses with participant, both correct and incorrect.
- If participant answered 9 or more questions correctly, participant can sign/mark the consent form.
- If participant answered 4 or more questions incorrectly:
 - Re-ask only those questions answered incorrectly and record the participant's new answers in the "2nd Attempt" column.
 - Follow the same process for questions answered incorrectly during the 2nd attempt and record the new answers in the "3rd Attempt" column.
 - After the 3rd attempt, the participant cannot enroll if at least 9 of the questions have not been answered correctly during the 3 attempts.

SAMPLE. DO NOT FAX TO DATAFAX Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

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"/>
Site Number				Participant Number						Chk

Screening Informed Consent Comprehension Quiz

14. Outcome:

- 14a. participant proceeded to screening
- 14b. participant declined to consent
- 14c. participant did not pass screening quiz

Screening Informed Consent Comprehension Quiz (non-DF, Page 3 of 3)

No additional instructions necessary.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Answer Key—Screening Informed Consent Comprehension Quiz

Question	
1. Page ____ : Introduction.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
2. Page ____ : Introduction and What are your rights when you screen to be a research participant?	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
3. Page ____ : What will happen if you agree to the study screening? You will be offered HIV counseling and testing whether or not you are eligible to join the study.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
4. Page ____ : Introduction. If you decide to participate in the screening, you will be asked to sign a consent form.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
5. Page ____ : Are there risks related to pregnancy? You must have a pregnancy test before you enter this study. You are not eligible for this study if you are pregnant or breastfeeding. If you are found to be currently pregnant, there are no risks to having had the screening procedures.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
6. Page ____ : Why is this research being done? Suboxone itself does not directly prevent HIV, nor is it a treatment for AIDS.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
7. Page ____ : What will happen if you agree to the study screening? If your first HIV test shows you may be infected with HIV, you will receive a confirmatory test.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
8. Page ____ : What will happen if you agree to the study screening? The screening will take 2–4 hours.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
9. Page ____ : What about confidentiality?	<input checked="" type="checkbox"/> true <input type="checkbox"/> false

Answer Key—Screening Informed Consent Comprehension Quiz (non-DF, Page 1 of 2)

Item-specific instructions:

- **Items 1–9:** For “Page ____”, record the page number that the item appears in your site-specific Informed Consent.

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HPTN 058 (123)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Answer Key—Screening Informed Consent Comprehension Quiz

Question	
10. Page ____ : What are the costs or payments to you? You will be compensated [site-specific amount in local currency] for your time and will also be reimbursed for your actual transportation expenses.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
11. Page ____ : What happens if you are injured during the screening? If you are injured as a result of being in this screening, you will be given immediate treatment for your injuries. You may have to pay for this care. If we find any illness or injury during the screening that is not related to the screening, we will tell you about medical care and other services available in the community. If there is a research-related complication or injury, we will not give you money.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
12. Page ____ : Why is this research being done?	<input checked="" type="checkbox"/> true <input type="checkbox"/> false

Answer Key—Screening Informed Consent Comprehension Quiz (non-DF, Page 2 of 2)

Item-specific instructions:

Items 10–12: For “Page ____”, record the page number that the item appears in your site-specific Informed Consent.

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HPTN 058 (123)

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				Participant Number					Chk

Screening Assessment

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

1. Have you ever injected drugs? *yes* *no* → **If no, go to item 3.**
 - 1a. Have you ever injected opiates? *yes* *no* → **If no, go to item 2.**
 - 1b. When was the last time you injected opiates?

<input type="text"/>	<input type="text"/>
----------------------	----------------------

dd

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------

MMM

<input type="text"/>	<input type="text"/>
----------------------	----------------------

yy
→ **If more than 28 days ago, go to item 2.**
 - 1c. In the last 28 days, how many times have you injected opiates?

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

 # of times
2. When was the last time you injected any drugs other than opiates? *never* **OR**

<input type="text"/>	<input type="text"/>
----------------------	----------------------

dd

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------

MMM

<input type="text"/>	<input type="text"/>
----------------------	----------------------

yy
→ **If never or if more than 28 days ago, go to item 3.**
- 2a. In the last 28 days, how many times did you inject any drug other than opiates?

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

 # of times
3. Have you ever used buprenorphine or naloxone? *yes* *no* → **If no, go to item 5.**
4. Did you ever have an allergic reaction to buprenorphine or naloxone? By allergic reaction I mean you had difficulty breathing, wheezing, hives, swelling of your face, or loss of consciousness soon after taking the drug. *yes* *no*
5. Currently, or within the last 12 weeks, have you been in treatment with methadone, LAAM, buprenorphine, naltrexone, or nalmefene? *yes* *no*
6. Are you currently enrolled in any other HIV prevention or drug use intervention study? *yes* *no*
7. Will you be available to participate in this study for the next 2 years? *yes* *no*

Screening Assessment

Description and Purpose

This form is used to determine initial eligibility. Note that the items are designed and structured to mask the eligibility criteria, so that the participant will not be able to determine exactly why he or she is ineligible. This is done so that potential participants cannot easily make up answers to qualify for enrollment.

NOTE: This form should be completely administered to each potential participant. Ask ALL items on the page even when an answer indicates that the participant is not eligible. Be careful not to indicate ineligibility to the participant until after all the items have been asked.

Sites should develop a list of local words or common language (street names or slang) to use for the following terms: **opiates, buprenorphine, naloxone, methadone, morphine, LAAM, naltrexone, and nalmefene.**

When administering the items containing these words to the participant, first read the item as written and then explain using the common name. For example, for item 1a, the interviewer would say, "Have you ever injected opiates? *By opiates, I mean (use common name for opiates).*" All interviewers should use the SAME common names so that the questions are being administered in the same way for all participants.

After completing the entire form, use the following table to determine if the participant is eligible to continue the screening process. If the participant is ineligible, based on the screening assessment responses discontinue screening process. Otherwise continue with the screening process.

Screening Assessment Item	Related Eligibility Criterion and Interpretation
1. Have you ever injected drugs?	Inclusion: Must have injected opiates at least 12 times in the past 28 days. If NO, participant is NOT eligible
1a. Have you ever injected opiates?	Inclusion: Must have injected opiates at least 12 times in the past 28 days. If NO, participant is NOT eligible
1b. When was the last time you injected opiates?	Inclusion: Must have injected opiates at least 12 times in the past 28 days. If the date entered is MORE than 28 prior to the interview date, participant is NOT eligible
1c. In the last 28 days, how many times have you injected opiates?	Inclusion: Must have injected opiates at least 12 times in the past 28 days. If the number entered is LESS than 12, participant is NOT eligible.
2a. In the last 28 days, how many times did you inject any drug other than opiates?	Exclusion: Injecting substances other than opiates more than twice per month. If number entered is MORE than 2, participant is NOT eligible
4. Did you ever have an allergic reaction to buprenorphine or naloxone?	Exclusion: Known hypersensitivity to buprenorphine or naloxone. If YES, participant is NOT eligible
5. Currently, or within the last 12 weeks, have you been in treatment with methadone, LAAM, buprenorphine, naltrexone, or nalmefene?	Exclusion: Current treatment with methadone, LAAM, buprenorphine, naltrexone, or nalmefene. If YES, participant is NOT eligible
6. Are you currently enrolled in any other HIV prevention or drug use intervention study?	Exclusion: Current enrollment in another HIV prevention or drug use intervention study. If YES, participant is NOT eligible
7. Will you be available to participate in this study for the next two years?	Inclusion: Plans to be available for study visits for at least two years. If NO, participant is NOT eligible

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HPTN 058 (123)

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				Participant Number					Chk

Eligibility Checklist

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

INCLUSION CRITERIA: ALL MUST BE MET

- 1. At least 18 years old (DM-1)
- 2. Willing and able to provide written consent for study participation (Consent and study notes)
- 3. HIV-uninfected on specimen obtained within 28 days of enrollment (LLS-1)
- 4. Meets DSM-IV criteria for opiate dependence, as determined by study clinician (DSM-IV Diagnostic Worksheet)
- 5. Injected opiates at least twelve times in the last 28 days, according to self-report (Screening Assessment)
- 6. Positive urine test for opiates (UTR-1)
- 7. If female, medically unable to become pregnant or willing to use an effective method of contraception for the first 12 months of the study (Medical History)
- 8. Willing to provide contact information and be contacted by study staff as needed (Locator)
- 9. Plans to be available for study visits for at least 2 years (Screening Assessment)

EXCLUSION CRITERIA: NONE MUST BE MET

- 10. Current or recent (within the last 12 weeks) treatment for opioid dependence with methadone, LAAM, buprenorphine, naltrexone, or nalmefene, according to self-report (Screening Assessment)
- 11. Current enrollment in another HIV prevention or drug use intervention study (Screening Assessment)
- 12. Known allergy to buprenorphine or naloxone, according to self-report (Screening Assessment)
- 13. Meets DSM-IV criteria for dependence on alcohol or benzodiazepines; requiring immediate medical attention for dependence on or other substances (except tobacco) as judged by the study clinician (Study notes and Physical Exam)
- 14. Injecting substances other than opiates more than twice in the last 28 days, according to self-report (Screening Assessment)
- 15. Psychological disturbance or cognitive impairment interfering with the participant's ability to comply with the study visit schedule and procedures, as judged by the local study clinician (Study notes and Physical Exam)
- 16. Pregnant or lactating (Medical History)
- 17. Acute or chronic renal failure, as judged by the study clinician (LLS-1 and Medical History)
- 18. ALT greater than 3 times the upper limit of normal value (LLS-1)
- 19. Hemoglobin less than 8 g/dL for men, less than 7 g/dL for women (LLS-1)
- 20. Platelet count less than 50,000/mm³ (LLS-1)
- 21. Total bilirubin greater than 2.5 times the upper limit of normal (LLS-1)
- 22. Other medical or psychiatric condition that, in the opinion of the investigator, would make participation in the study unsafe or otherwise interfere with the study objectives or interpretation (Study notes and Physical Exam)

23. Is participant eligible for enrollment?..... yes no

Investigator or Designee Signature

22-FEB-08

Date

Language

Staff Initials / Date

SAMPLE

Eligibility Checklist

Items 1–22: The source document for each criterion is listed in parentheses.

Second Detox Eligibility Checklist (non-DataFax)

Items 1–16: The source document for each criterion is listed in parentheses.

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HPTN 058 (123)

Participant ID

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Site Number				Participant Number					Chk

Answer Key—Enrollment Informed Consent Comprehension Quiz

Question	
1. Page ____ : Introduction: The purpose of this study is to compare how well two different treatment methods help prevent the spread of HIV in injection drug users by reducing drug use and other risky behaviors.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
2. Page ____ : Why is this research being done? Suboxone has been approved by the US FDA as a treatment for opiate dependence. Suboxone is not currently approved by the [country name] FDA, but investigators have received permission to conduct this study with Suboxone in [country name].	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
3. Page ____ : Why is this research being done? Suboxone itself does not directly prevent HIV or treat AIDS.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
4. Page ____ : What will happen if you agree to take part in this study? To avoid opiate withdrawal after receiving the first dose of Suboxone, it is important that you do not use opiates for at least 12 hours before the visit to receive Suboxone for the first time.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
5. Page ____ : What will happen if you agree to take part in this study? If you decide to participate in this research study, you will be asked to come to the clinic every day for up to approximately 3 weeks.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
6. Page ____ : What will happen if you are in the Substituion Treatment group? If you are in the Substitution Treatment group, during the first one to three weeks that you are taking Suboxone, you will have to come to the clinic every day and we will adjust your dose to make sure it is the best one for you.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
7. Page ____ : Are there potential benefits to taking part in this study? There are no direct benefits to you if you participate in this study.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false

Answer Key—Enrollment Informed Consent Comprehension Quiz (non-DF, Page 1 of 2)

Item-specific instructions:

- **Items 1–7:** For “Page ____”, record the page number that the item appears in your site-specific Informed Consent.

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HPTN 058 (123)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Answer Key—Enrollment Informed Consent Comprehension Quiz

Question	
8. Page ____ : What happens if you miss study visits? If you are jailed during your participation in the study, you cannot participate during your period of imprisonment. However, you can continue your study visits after you are released.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
9. Page ____ : What happens if you become infected with HIV? If your HIV test result is positive after you have enrolled in the study, you will continue your participation in the study. We will provide you with some tests to assess your health and measure the stage of your HIV infection. We will also provide you with any appropriate referrals so that you can get additional care as needed.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
10. Page ____ : Some of the reasons that we may end your participation in the study early without your permission is that you are not able to attend the visits or follow the procedures required by the study.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false
11. Page ____ : What are the risks/discomforts of this study? We will make every effort to protect your privacy and confidentiality while you are in this study. However, it is possible that you could have problems if people learn that you are here for this study. People may think that you are infected with HIV or at risk of HIV because of sexual behavior or drug use. It is also possible that others may find out that you have been screened for this study and assume that you are an injection drug user. You might encounter problems if others find out that you have enrolled in this study.	<input checked="" type="checkbox"/> true <input type="checkbox"/> false
12. Page ____ : What are your rights as a research participant? You may decide not to take part in the study or to leave at any time.	<input type="checkbox"/> true <input checked="" type="checkbox"/> false

Answer Key—Enrollment Informed Consent Comprehension Quiz (non-DF, Page 2 of 2)

Item-specific instructions:

Items 8–12: For “Page ____”, record the page number that the item appears in your site-specific Informed Consent.

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HPTN 058 (123)

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"/>
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Site Number

Participant Number

Chk

**DSM-IV Diagnostic Worksheet
Comments**

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

dd

MMM

yy

Comments: Use this page to record notes and/or supporting information.

Local Language _____

English _____

DSM-IV Diagnostic Worksheet (Page 1)

No instructions necessary.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

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				Participant Number					Chk

Medical History

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Allergies

1. Have you ever had an allergic or anaphylactic reaction (tightening in your chest, difficulty breathing, face swelling, hives, or losing consciousness) to...
- | | | | |
|-------------------------------------|--------------------------|--------------------------|--|
| | yes | no | Month/year, cause, and description of reaction:
Local Language/English |
| 1a. any medicines? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 1b. food or other substances? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
- **If yes to any, complete Pre-existing Conditions form.**

Medications

2. Are you currently taking/receiving...
- | | | | |
|--|--------------------------|--------------------------|--------------------------------------|
| 2a. medications prescribed by a doctor, such as medicine for tuberculosis, depression, hypertension, or other condition? | yes | no | Notes: Local Language/English |
| | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 2b. other medicines used to treat drug or alcohol problems (including methadone, naltrexone)? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 2c. non-prescription medicines? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 2d. vitamins or herbs? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 2e. other medicines (not including recreational drugs)? | <input type="checkbox"/> | <input type="checkbox"/> | _____ |

Note: Participant is NOT INELIGIBLE if s/he is currently taking anti-TB prophylaxis or therapy, but dosing may need to be adjusted. Document all medications here and on the Concomitant Medications Log, including vitamins and herbal products if the participant is enrolled.

Immunizations

3. Have you had a hepatitis B vaccine?
- | | | | | |
|--|--------------------------|--------------------------|--------------------------|---|
| | yes | no | don't know | |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → If no or don't know, go to item 4 on page 2. |
- 3a. How many doses received?
- | | |
|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> |
| MMM | yy |
- N/A 3a1. Dose 1 month/year
- | | | | |
|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|----------------------|
- 3a2. Dose 2 month/year
- | | | | |
|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|----------------------|
- 3a3. Dose 3 month/year
- | | | | |
|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
|----------------------|----------------------|----------------------|----------------------|

Medical History (Page 1)

Items 1a and 1b: If yes to any, record the month/year, cause, and description of the reaction in the space provided. Also, complete a Pre-existing Conditions form.

Item 2e: If yes, record medication names in the Notes section.

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HPTN 058 (123)

Participant ID

Site Number			Participant Number					Chk	

Medical History

Medical History

4. Have you ever had any of the following...

	yes	no	don't know
4a. hospitalizations for reasons other than surgery (excluding normal vaginal deliveries)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b. any surgeries?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4c. anemia (low blood count)?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4d. blood transfusion / blood products?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4e. tuberculosis?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4f. lung problems, asthma or wheezing, or shortness of breath?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4g. diabetes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4h. heart problems (e.g., chest pain, heart murmur, palpitations)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4i. endocarditis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4j. stomach or colon problem (e.g., ulcer, blood in stool)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4k. hepatitis or liver disease (jaundice)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4l. pancreatitis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4m. kidney problems?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4n. malignancy/cancer?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4o. bruising or bleeding problems?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4p. skin problems (rashes, ulcers)?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4q. seizures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4r. mental illness/depression?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4s. suicidal ideation/attempt?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4t. psychosis (e.g., hearing voices)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4u. drug overdose?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If yes to any, record type of condition, date of diagnosis/surgery, and description on Pre-existing Conditions form if participant will be enrolled.

Note: Participant is **INELIGIBLE** if s/he has a psychiatric or cognitive condition that precludes compliance with the visit schedules and procedures.

Note: Participant is **INELIGIBLE** if s/he has any medical or psychiatric condition that would make participation in the study unsafe or otherwise interfere with the study objectives or interpretation.

			X	26-JAN-07
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SAMPLE

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Language	

Staff Initials / Date

Medical History (Page 2)

No additional instructions.

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HPTN 058 (123)

Participant ID

- -

Site Number Participant Number Chk

Medical History

Medical History—Women Only

Items 5–12 are for women only. If participant is male, go to item 13 on page 4.

- | | | | | |
|----|---|--------------------------|--------------------------|--------------------------|
| | | yes | no | don't know |
| 5. | Are you currently pregnant or do you think you might be pregnant? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | Are you currently breastfeeding? | <input type="checkbox"/> | <input type="checkbox"/> | |

If yes to any, participant is ineligible.

- | | | | | | | |
|----|--|----------------------|----------------------|----------------------|-----------|--------------------------|
| | | dd | MMM | yy | | don't know |
| 7. | When did your last period start? | <input type="text"/> | <input type="text"/> | <input type="text"/> | OR | <input type="checkbox"/> |

- | | | | | |
|----|---|--------------------------|--------------------------|------------------------------|
| | | yes | no | |
| 8. | Do you have regularly spaced periods? | <input type="checkbox"/> | <input type="checkbox"/> | If yes, go to item 9. |

- | | | | | |
|------|------------------------------|--------------------------|--------------------------|--------------------------|
| 8a. | What is the reason? Is it... | yes | no | don't know |
| 8a1. | hysterectomy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8a2. | menopause? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8a3. | other reason, specify: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Local Language: _____

English: _____

Note: Record date of any surgeries and description on Pre-existing Conditions form.

- | | | | |
|-----|--|--------------------------|--------------------------|
| | | yes | no |
| 9. | Have you had a bilateral tubal ligation? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. | Are you planning to become pregnant in the next 12 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. | Do you use a birth control method? | <input type="checkbox"/> | <input type="checkbox"/> |

11a. Type and frequency of use:

Local Language: _____

English: _____

If no, discuss plans for birth control use. See description below. If participant identifies as lesbian, discuss plan to use birth control should she have sex with men any time during trial. Go to item 12 on page 4.

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Medical History (Page 3)

No additional instructions.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

Participant ID

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Site Number

Participant Number

Chk

Medical History

12. If you decide to join the study, would you be willing to use birth control from now through the first year of the study?

yes

no

If no, go to item 13.

12a. Record method and discussion, if any:

Local Language: _____

English: _____

Note: Women who report no sexual activity with a man must articulate a plan to begin "adequate" birth control if they become sexually active with a man during the course of the study.

Occupational/Social

13. Are there any occupational or social reasons that may prevent the participant from participating in and completing this study (e.g., moving for work, frequent travel out of town, pending legal problems/incarceration)?

yes

no

13a. Describe:

Local Language: _____

English: _____

If no, complete signature fields at bottom of page, then end of form.

Signature of staff collecting history

Date

Signature of clinician reviewing history

Date

26-JAN-07

SAMPLE

0	1
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Language

Staff Initials / Date

Medical History (Page 4)

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

Page 1 of 2

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number			Chk

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy

Clinical Opiate Withdrawal Scale

LAST DRUG USE

<p>Date</p> <table border="1"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td colspan="2">dd</td> <td colspan="2">MMM</td> <td colspan="2">yy</td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	dd		MMM		yy		<p>Time 24-hour clock</p> <table border="1"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td>:</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td colspan="2">hr</td> <td></td> <td colspan="2">min</td> </tr> </table>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	hr			min		<p>Drug used</p> <p>How taken?</p>
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	Time 24-hour clock <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> hr min	Time 24-hour clock <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> hr min	Time 24-hour clock <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> hr min
<p>Resting pulse rate (beats per minute): Measured after participant is sitting/lying for one minute. 0 = pulse rate 80 or below, 1 = pulse rate 81–100, 2 = pulse rate 101–120, 4 = pulse rate > 120</p>			
<p>Sweating: Over last half-hour, not accounted for by room temperature or participant activity. 0 = no report of chills or flushing, 1 = subjective report of chills or flushing, 2 = flushed or observable moistness on face, 3 = beads of sweat on brow or face, 4 = sweat streaming off face</p>			
<p>Restlessness: Observation during assessment. 0 = able to sit still, 1 = reports difficulty sitting still, but is able to do so, 3 = frequent shifting or extraneous movements of legs/arms, 5 = unable to sit still for more than a few seconds</p>			
<p>Pupil size: 0 = pupils pinned or normal size for room light, 1 = pupils possible larger than normal for room light, 2 = pupils moderately dilated, 5 = pupils so dilated that only rim of the iris is visible</p>			
<p>Bone or joint aches: If participant was having pains previously, only the additional component attributed to opiate withdrawal is scored. 0 = not present, 1 = mild diffuse discomfort, 2 = participant reports severe diffuse aching of joints/ muscles, 4 = participant is rubbing joints or muscles and is unable to sit still because of discomfort</p>			
<p>Runny nose or tearing: Not accounted for by cold symptoms or allergies. 0 = not present, 1 = nasal stuffiness or unusually moist eyes, 2 = nose running or tearing, 4 = nose constantly running or tears streaming down cheeks</p>			
Page 1 subtotal:			

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Clinical Opiate Withdrawal Scale (Page 1)

The Clinical Opiate Withdrawal Scale (COWS) provides a quantitative measure of opiate withdrawal. The COWS contains 11 domains that are scored and summed by the clinician for a total score. The higher the score is, the greater the withdrawal. In HPTN 058, the score must be ≥ 8 to randomize and begin BUP/NX dosing on day 1.

On the day of induction, clinician will:

1. Complete PTID and form completion date (complete date required).
2. Assess last use of drugs and record in space provided. Regardless of reported last dose use, clinicians will use the COWS to objectively measure withdrawal.
3. Record time of first COWS assessment in the first column. Assess each item on the COWS scale.
4. Total the score at end of column.
5. If score is less than 8, wait one hour and repeat assessment, completing second column.
6. Randomization occurs when COWS score is 8 or higher. Do NOT open randomization envelope until ready to begin induction.
7. Follow induction guidelines in SSP and BUP/NX Manual.

If participant shows no signs of withdrawal or reports very recent opiate use, clinician may reschedule the randomization and induction for next day if possible.

Use a new COWS form for each subsequent day of induction.

SAMPLE. DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

HPTN 058 (123)

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				Participant Number					Chk

Clinical Opiate Withdrawal Scale

<p>GI Upset: Over last half-hour. 0 = no GI symptoms, 1 = stomach cramps, 2 = nausea or loose stools, 3 = vomiting or diarrhea, 5 = multiple episodes of diarrhea or vomiting</p>			
<p>Tremor: Observation of outstretched hands. 0 = no tremor, 1 = tremor can be felt but not observed, 2 = slight tremor observable, 4 = gross tremor or muscle twitching</p>			
<p>Yawning: Observation during assessment. 0 = no yawning, 1 = yawning once or twice during assessment, 2 = yawning three or more times during assessment, 4 = yawning several times/minutes</p>			
<p>Anxiety or irritability: 0 = none, 1 = participant reports increasing irritability or anxiousness, 2 = participant obviously irritable/anxious, 4 = participant so irritable or anxious that participation in the assessment is difficult</p>			
<p>Gooseflesh skin: 0 = skin is smooth, 3 = piloerection of skin can be felt or hairs standing up on arms, 5 = prominent piloerection</p>			
Page 2 subtotal:			
Page 1 subtotal:			
Total score:			
Observer's initials:			

Score:

- 5-12 = mild
- 13-24 = moderate
- 25-36 = moderately severe
- > 36 = severe withdrawal

Clinical Opiate Withdrawal Scale (Page 2)

No additional instructions.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

HPTN 058 (123)

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				Participant Number					Chk

Physical Exam

Exam Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

VITAL SIGNS

Staff Initials / Date

- | | | | | | | | | | | | |
|--------------|--------------------------|----------------------|--------------------------|----------------------|----------|----------------------|----------------------|----------------------|----------------------|----------------------|------------|
| 1. Weight | <input type="text"/> | <input type="text"/> | <input type="text"/> | kg | 4. BP | <input type="text"/> | <input type="text"/> | / | <input type="text"/> | <input type="text"/> | mmHg |
| 2. Height | <input type="text"/> | <input type="text"/> | <input type="text"/> | cm | 5. Pulse | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | per minute |
| 3. Body Temp | <input type="text"/> | <input type="text"/> | . | <input type="text"/> | °C | 6. Respirations | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | per minute |
| 3a. | <input type="checkbox"/> | oral | <input type="checkbox"/> | ear thermometry | | | | | | | |

FINDINGS

Staff Initials / Date

- | | | | | |
|--------------------------|--------------------------|--------------------------|---|--|
| <i>not evaluated</i> | <i>normal</i> | <i>abnormal</i> | → | If items 7–13 not evaluated or abnormal, please specify (Local Language/English). |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 7. HEENT _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 8. Mouth/oral hygiene _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 9. Lymph nodes _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 10. Heart _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 11. Lungs _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 12. Abdomen _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 13. Skin (note jaundice, track marks, lesions)
_____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 14. Other, specify: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 15. Other, specify: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 16. Other, specify: _____ |

If abnormal and ongoing for any at Enrollment, record on Pre-existing Conditions form.

Comments: _____

26-JAN-07

SAMPLE

Language

Staff Initials / Date

Physical Exam

Description and Purpose

This form is used to document the participant's vital signs and physical exam findings. Because this form is a non-DataFax form, this form should not be faxed to SCHARP DataFax.

Note: If a participant is being re-screened, a new Physical Exam form must be completed as part of the subsequent Screening Attempt.

Form-specific Instructions

- **Vital Signs:** When recording weight, height, oral temp, blood pressure (BP), pulse, and respirations, remember to use leading zeros when needed. The staff member who completes these items should initial and date in the space provided next to "Vital Signs."
- **Findings:** The staff member who completes these items should initial and date in the space provided next to "Findings."
- **Items 7–13:** For each item marked "not evaluated" or "abnormal," specify the reason the organ system was not evaluated (since evaluation of all listed organ systems is required) or was abnormal in the space provided. Record any abnormalities ongoing at Enrollment onto the participant's Pre-existing Conditions form.
- **Items 14–16:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 7–13 were evaluated, mark items 14–16 as "not evaluated." Record any abnormalities ongoing at Enrollment onto the participant's Pre-existing Conditions form.



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

HPTN 058 (123)

IL-1 (429)

Participant ID

- -
Site Number Participant Number Chk

Date Reported to Site

dd MMM yy

Incarceration Log

1. Incarceration Date:

dd MMM yy

2. Expected date of release:

OR

3. Type of incarceration:

Incarceration Code (see code list on back of form.)

4. Primary reason for incarceration:

Reason Code (see code list on back of form.)

5. Was the incarceration verified?

yes no

6. Status/Outcome

- Continuing
- Released
- Transferred to other type of incarceration (detoxification center, labor camp, other) Report on new Incarceration Log.
- Death (Complete Termination)
- Incarceration continuing at end of study

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing"

dd MMM yy

7. Did this incarceration result in missed dosing weeks?

yes no
 → If no, go to item 8.

7a. Record the MDD-1 Week # of the first missed dosing week resulting from this incarceration:

MDD-1 Week #

8. Did this incarceration result in missed scheduled visits?

yes no
 → If no, end of form.

8a. Record the MV-1 Visit Code of the first missed scheduled visit resulting from this incarceration:

MV-1 Visit Code

Comments: Local Language _____

Comments: English _____

Incarceration Log (IL-1)

Purpose: This form should be completed for each new incarceration event.

Item-specific instructions:

- **Item 1:** If the actual date of incarceration is unknown, record an estimate of the date.
Note: If the participant was transferred from another type of incarceration that was already reported on an Incarceration Log, the incarceration date should be the same as the date recorded on item 6a of that previous Incarceration Log.
- **Item 2:** At a minimum, month and year are required. If no date is available, mark the “unknown” box.
- **Item 3:** Use the following definitions to code the type of incarceration:

Incarceration Codes:	
01	jail
02	prison
03	house of detention
04	labor camp
05	detoxification center
06	lockup
07	military camp
08	probation office
99	other (specify on Comments line)

- **Item 4:** Use the following definitions to code the primary reason for incarceration:

Reason for incarceration Codes:	
01	drug-related (e.g., positive urine test, possession of drugs or drug equipment)
02	other criminal activities (e.g., theft, act of violence)
19	unknown

- **Item 5:** If this item was initially marked “no” but the incarceration is later verified, update this item.
- **Item 6:** Update the “Status/Outcome” as available.
 - “Transferred to other type of incarceration” means the participant is still incarcerated, but has moved from one type of incarceration to another type (i.e., the Incarceration Codes are different). For example, the participant moved from a detoxification center (Code 04) to a labor camp (Code 01).
- **Item 6a:** If the actual date of the “Status/Outcome” is unknown, record an estimate of the date.
- **Items 7 and 8:** Update this information as needed.