1. What is your date of birth? \[ \text{dd} \quad \text{MMM} \quad \text{yy} \] OR Age: \( \text{years} \) (estimate OK)

2. What is your sex? \( \text{male} \quad \text{female} \)

2a. Participant identifies as transgender? \( \text{yes} \quad \text{no} \)

3. What is your ethnicity? \textit{Mark all that apply.}

\textbf{Thailand}

- 3a. Thai
- 3c. Karen
- 3e. Tai Yai
- 3g. Akha
- 3i. Hmong
- 3k. Yao
- 3m. Lisu
- 3n. Lahu
- 3o. Lua
- 3p. other, specify: 

\textbf{China}

- 3b. Uighur
- 3d. Han
- 3f. Zhuang
- 3h. Hui
- 3j. Kazakh
- 3l. other, specify: 

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? \( \text{years} \)
Demographics (DM-1)

Description and Purpose

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

Form-specific Instructions

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.
## Pre-existing Conditions (PRE-1)

<table>
<thead>
<tr>
<th>Description</th>
<th>Date of Diagnosis/Surgery</th>
<th>Comments</th>
<th>Is condition ongoing?</th>
<th>Staff Initials / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

No pre-existing conditions reported or observed.

---

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

---

**Form Completion Date**

<table>
<thead>
<tr>
<th>dd</th>
<th>MMM</th>
<th>yy</th>
</tr>
</thead>
</table>

---

**Language**

| 01 |

---

**DON TX A X**

TO DATAFAXSAMPLE: HPTN 058 (123)
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).
1. Have you ever injected drugs? .................................................................
   1a. Have you ever injected opiates?...........................................................
   1b. When was the last time you injected opiates? ......................................
   1c. In the last 28 days, how many times have you injected opiates? .......

2. When was the last time you injected any drugs other than opiates? ...........
   2a. In the last 28 days, how many times did you inject any drug other than opiates? .................................................................

3. Have you ever used buprenorphine or naloxone?.................................

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.................................................................

5. Are you currently in treatment with methadone, morphine, LAAM, naltrexone, or nalmefene? ...........................................................................

6. Are you currently enrolled in any other HIV prevention or drug use intervention study?........................................................................................

7. Will you be available to participate in this study for the next two years? .......
Screening Assessment (SA-1)
1. Date of initial HIV specimen collection: ........................................
   
   1a. Was specimen processed for storage? .................................
   
   2. Participant's HIV status: ....................................................
   
   yes  no
   
   negative  positive
Screening HIV Status (SS-1)

Description and Purpose

This form documents a potential participant’s HIV status at screening visits. This form is to be used only at screening visits.

Form-specific Instructions

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

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

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? ..................................................

   5c. spouse, family, or friends? ............................................................

   5d. illegal sources or activities? ............................................................

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 housing, alcohol use, drug use, and sexual behavior. This form is administered at the screening visit to those participants found to be eligible based on the Eligibility Checklist.

Enrolled participants are also administered the Risk Assessment at week 26, 52, 78, 104, 130, and 156 visits.

Form-specific Instructions
**INCARCERATION**

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

<table>
<thead>
<tr>
<th># of times</th>
<th>If &gt; 0, how many days total?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7a. jail? ...........................................................................................................................................

7b. prison? ...........................................................................................................................................

7c. detention? ........................................................................................................................................

**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

   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

10. In the last 6 months, did you ever drink alcohol to reduce drug withdrawal symptoms? ........................................................................................................................................
Risk Assessment (RA-2)

Read out loud to the participant the section marked “Read to participant” before asking Item 8.

**Item 8:** Use response card # 1 to help the participant identify his or her weekly drinking frequency. Non-drinkers go to Item 11.

**Item 9:** Use response card # 2 to help the participant identify the frequency of his or her drinking to get or stay drunk.
**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 month, did you…

<table>
<thead>
<tr>
<th>11a. smoke marijuana?</th>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>11b. smoke amphetamines or methamphetamines?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11c. snort or swallow amphetamines or methamphetamines?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11d. snort or sniff cocaine?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11e. smoke heroin?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11f. snort or swallow heroin?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11g. smoke opium?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11h. swallow opium?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11i. take buprenorphine?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11j. take methadone?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11k. take downers or benzodiazepenes?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11l. take ecstasy or MDMA?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11m. snort or swallow ketamine?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11n. sniff glue?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>11o. chew or swallow kat leaf?</td>
<td></td>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>
Risk Assessment (RA-3)

Read out loud to the participant the section marked “Read to participant” before asking Item 4.
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 month, did you use a needle to inject any drugs under your skin or into a vein?.................................................................................................................................

13. In the last month, did you inject any of these drugs alone (that is, not mixed with another drug)?
   
   13a. amphetamines ........................................................................................................
   
   13b. cocaine ..................................................................................................................
   
   13c. heroin ..................................................................................................................
   
   13d. opium ....................................................................................................................
   
   13e. buprenorphine ..................................................................................................
   
   13f. methadone ........................................................................................................
   
   13g. benzodiazepenes? ..............................................................................................
   
   13h. ketamine ...........................................................................................................
   
   13i. other, specify: __________________________________________________________

14. In the last month, did you mix two drugs together and inject them? .................

14a. What drugs did you mix? Refer to Drug Code List on back of form.

   drug #1  drug #2

   14a1. N/A

   14a2. ___________________________ ___________________________

   14a3. ___________________________ ___________________________
Risk Assessment (RA-4)

Read out loud to the participant the section marked “Read to participant” before asking Item 5.

**Item 12:** Note that the time frame is “in the last month.” Observe the skip patterns for non-injection or infrequent injection drug users.

**Item 13:** Note that the time frame is “in the last month.” For each item, mark yes or no.

**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.

**Drug Code List**

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>heroin</td>
</tr>
<tr>
<td>02</td>
<td>cocaine</td>
</tr>
<tr>
<td>03</td>
<td>amphetamines</td>
</tr>
<tr>
<td>04</td>
<td>buprenorphine</td>
</tr>
<tr>
<td>05</td>
<td>opium</td>
</tr>
<tr>
<td>06</td>
<td>ketamine</td>
</tr>
<tr>
<td>07</td>
<td>benzodiazepenes</td>
</tr>
</tbody>
</table>
15. In the last month, on how many days did you inject? ........................................... # of days

16. On days that you inject, how many times a day do you usually inject? ........... # of times

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

17a. use rinse water that others had used? ....................................................... # of times

17b. use a cooker that others had used? ............................................................... # of times

17c. use cotton that others had used? ................................................................. # of times

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

17e. use a needle that others had discarded? ...................................................... # of times

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? ................................................................. 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? ................................................................. 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 # 4 and 5 to assist the participant by presenting a picture of frontloading and backloading practices.

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 month.

Item 20: Needle or syringe use is after someone else. Record how many times and with how many different people in the last month.
21. In the last 6 months, did you ever use a needle or syringe after someone that you know is HIV-positive used it? ...........................................................

22. In the last 6 months, how often did you inject drugs... Show Card #2. 

22a. with people you know well? .................
22b. with people you don’t know well? ...........

23. In the last 6 months, how often did you get your needles new from a... Show Card #2.

23a. drugstore/pharmacy? .........................
23b. hospital or health center? .................
23c. needle seller? .................................
23d. needle exchange? ............................

24. In the last 6 months, did you always use a brand-new needle every time you injected? ...........................................................

25. In the last 6 months, did you ever clean your needle either before or after injecting? ...........................................................

25a. How often do you clean your needle before injecting? Show Card #2..............
25b. How often do you clean your needle after injecting? Show Card #2 ..............
Risk Assessment (RA-6)

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

Item 22: Use response card # 2 to identify the response categories. For each item, mark the response time that best mirrors the participant’s frequency of that behavior.

Item 23: Use response card # 2 to identify the response categories. For each item, mark the response time that best mirrors the participant’s frequency of that behavior.

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 18a and after injecting in Item 18b. Participants who did not clean their needles go to Item 20.
26. The last time you injected, did you...
   26a. clean the needle before you injected? .......................................................
   26b. use a new needle? ....................................................................................
   26c. clean the needle after you injected? ........................................................
   26d. inject with other people at the same time?.............................................
   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. ........................................................

27. How many days ago did you last inject? ..........................................................

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? ........................................................
   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? ........
      28a4. detoxification
      28a5. Narcotics Anonymous, Cocaine Anonymous, Meth Anonymous, or Alcoholics Anonymous
      28a6. other, specify:  

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.
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? ..........................................

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? ............................................................................................................

32a. Is your primary sex partner male or female? ............................................

33. In the last month, how many times did you have vaginal or anal sex with your primary sex partner?...........................................................................................

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?.....................................................

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 23.

**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 28.

**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 1 partner for three different sexual encounters, count this as 1 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 1 partner for three different sexual encounters, count this as 1 partner.
### HIV Test Results

<table>
<thead>
<tr>
<th>Sample</th>
<th>Alternate Collection Date</th>
<th>HIV EIA</th>
<th>HIV Western Blot</th>
<th>HIV IFA</th>
<th>HIV Western Blot</th>
<th>HIV IFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not done/Not collected</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>dd MMM yy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not done/Not collected</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>dd MMM yy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not done/Not collected</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>dd MMM yy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments:** 

---

**Participant ID**

Site Number | Participant Number | Chk

---

**Participant ID**

Site Number | Participant Number | Chk

---

**Initial Specimen Collection Date**

dd | MMM | yy

---

**HIV Test Results**

1. HIV EIA
2. HIV Western Blot
3. HIV IFA
4. HIV Western Blot
5. HIV IFA
6. HIV Western Blot
7. HIV IFA

**Comments:**

---
**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.

- 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.

**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.

**HIV Test Results:**

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

- Refer to protocol appendix for the HIV seroconversion testing algorithm.

- **Item 1:** Record result of non-rapid HIV EIA.
### Local Laboratory Results (LL-1)

**Participant ID**
- Site Number
- Participant Number
- Chk

**Alternate Collection Date**
- dd
- MMM
- yy

**Initial Specimen Collection Date**
- dd
- MMM
- yy

**Visitor Code**
- 1

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

#### HEMOGRAM

1a. CBC ....................  

1b. Hemoglobin............  

1c. Platelets  

**BLOOD CHEMISTRIES**

#### LIVER FUNCTION TESTS

2a. ALT (SGPT) .............  

2b. Total bilirubin ..........  

#### RENAL FUNCTION TESTS

3a. Creatinine ...............  

**Comments:**

---

07-APR-06

07-APR-06

Sample

Language

01

Staff Initials / Date
Local Lab Results (LL-1)

Description and Purpose

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

Form-specific Instructions

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.
Urine Test Results

1. PREGNANCY TEST
   1a. Test result .......................................

2. URINE DRUG SCREEN
   2a. Was drug detected? ..................

Comments:

Language
Staff Initials / Date

Urine Test Results (UTR-1)
Urine Test Results (UTR-1)

Description and Purpose

TEXT TO BE PROVIDED.

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 (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.
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 in the last 6 months? .............................................................. yes no If no, go to item 3.

2. Because of your participation in this study, have you…

2a. been arrested or had trouble with the police or other legal problems?............................................................................................................

2b. had trouble getting or keeping housing?............................................

2c. had trouble getting or keeping a job or trouble with income or economic support?................................................................................

2d. had trouble getting health care or with health insurance?.................

2e. had personal trouble with friends, family, or acquaintances?...............

2f. had any other type of problem?.......................................................... Specify: ____________________________________________________________

Complete a separate Social Impact Log (SIL) for each impact.  

If yes, how many times?  

yes no if no, go to item 3.

If no or don’t know, end of form.

3. In the last 6 months, has your participation in this study had a positive or beneficial impact on your life? .................................................. yes no don’t know

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

__________________________________________________________________________
Social Impact Assessment (SIA-1)

Description and Purpose

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

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

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

Form-specific Instructions

Item 1: Record if the participant has been affected negatively by his or her involvement in the 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.
# Induction Record (IR-1)

**HPTN 058 (123)**

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

**Induction Record**

<table>
<thead>
<tr>
<th>Induction #</th>
<th>Substitution</th>
<th>Detox</th>
</tr>
</thead>
</table>

**Language**

01

**Staff Initials / Date**

07-APR-06

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>COWS Score</th>
<th>Dose</th>
<th>Associated AE Log Page</th>
<th>Staff Initials / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>dd</td>
<td>MMM</td>
<td>mm</td>
<td>hr</td>
<td>min</td>
<td>mg</td>
</tr>
</tbody>
</table>

**Comments:**

__________________________________________________________________________

__________________________________________________________________________

**Sample**

01

/hivnet/forms/PTN_058/forms/p058_induction_record.fm
Induction Record (IR-1)
TEXT TO BE PROVIDED.
### Dosing Log (DL-1)

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

**Dosing Log**

#### Date

**Date**

<table>
<thead>
<tr>
<th>dd</th>
<th>MMM</th>
<th>yy</th>
</tr>
</thead>
</table>

**Time 24-hr clock**

<table>
<thead>
<tr>
<th>hr</th>
<th>min</th>
</tr>
</thead>
</table>

#### SUPERVISED DOSES

**Dose (mg)**

**Days Covered by Dose**

**TAKE-HOME DOSES**

**Staff Initials/Date**

#### Comments:

________________________________________________________________________________

---

**07-APR-06**

**SAMPLE**

---

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

Substitution

Detox
TEXT TO BE PROVIDED.
1. What is the reason for this interim visit? *Mark all that apply.*

- [ ] 1a. participant missed or will miss all or part of a regularly scheduled study visit, and is outside of any visit window

- [ ] 1b. report a social impact

- [ ] 1c. update a social impact

- [ ] 1d. HIV testing

- [ ] 1e. other, specify: ________________________________

1a1. Which regularly scheduled visit does this interim visit complete or replace?
Interim Visit (IV-1)

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

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

English (if above is in Local Language):

2. Onset Date


dd  MMM  yy

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
Report as new AE.
☐ 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)
Report on Concomitant Medications Log.
☐ New/Prolonged hospitalization
Comment below.
☐ Procedure/Surgery
Comment below.
☐ Other
Comment below.

8. Is this AE serious according to ICH guidelines?

yes  no

9. Has this AE been reported to the DAIDS Safety Office?

10. This AE was first reported at visit:

Visit code required (regular or interim).

Comments:

English (if Comments above are in Local Language):

Note: Number pages sequentially (001, 002, 003) for each participant.
Adverse Experience Log (AE-1)

Any Adverse Experience (AE) reported by the participant or clinically observed after initiation of study product, regardless of whether or not it is related to study product, must be documented any time during study participation.

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).
### Concomitant Medications Log

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

**Concomitant Medications Log**

<table>
<thead>
<tr>
<th>Medication (generic name)</th>
<th>Staff Initials/Log Entry Date</th>
<th>Taken for a reported AE?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indication</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Continuing at end of study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dd MMM yy</td>
<td>dd MMM yy</td>
<td></td>
</tr>
</tbody>
</table>

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

End of form. Fax to SCHARP DataFax.

No medications taken throughout study.

Staff Initials/Date

**Language**

<table>
<thead>
<tr>
<th>Language</th>
<th>01</th>
</tr>
</thead>
</table>

**Sample:** Do not fax to DataFax
Concomitant Medications Log (CM-1)

All medication(s) that are used by the participant during the study, 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.
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:________________________________________________________

07-APR-06
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.
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.
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).
Comments (COM-1)

Instructions: Use this form to record additional information about a specific participant or to clarify data recorded on another form. For Visit Code, enter the visit code of the form or visit on which you are commenting. Please print information legibly.

Record the acronym(s) of the form(s) to which the comments apply: ____________________________ or □ not applicable
See upper right hand corner of form for acronym. For example, this form’s acronym is COM-1.

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Comments (COM-1)

Description and Purpose

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

Form-specific Instructions

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

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

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

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

Print legibly on the Comments form; do not use cursive handwriting.
**Missed Visit (MV-1)**

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
<th>Missed Visit</th>
</tr>
</thead>
</table>

**Form Completion Date**

<table>
<thead>
<tr>
<th>dd</th>
<th>MMM</th>
<th>yy</th>
</tr>
</thead>
</table>

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

**Comments:**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
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.
Participant Incident Log (PIL-1)

Participant ID

Site Number | Participant Number | Chk

dd MMM yy

Form Completion Date:

SC Staff Name: ________________________________

Source of Information: ________________________________

If applicable:

Plate #: ____________________________

Visit: ____________________________

Event and resolution details:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Subject: Mark all that apply.

☐ forms

☐ protocol

☐ data

☐ lab

☐ enrollment

☐ randomization

☐ other, specify: ________________________________

Page 1 of 1

Sample: Do not fax to DataFax

HPTN 058 (123) PIL-1 (487)

07-APR-06

SAMPLE

Language 0

Staff Initials / Date

/hivnet/forms/PTN_058/forms/p058_std_ppt_incident_log_23jun03.fm
Termination (TM-1)

Participant ID

Site Number Participant Number Chk

1. Termination Date:  
   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.
   - □ 2b. Death. *Indicate date and cause if known.*
     - 2b1. Date of death  
     - 2b2. Cause of death ____________________________
   - □ 2c. Participant refused further participation, specify: ____________________________
   - □ 2d. Participant unable to adhere to visit schedule.
   - □ 2e. Participant relocated, no follow-up planned.
   - □ 2f. Investigator decision, specify: ____________________________
   - □ 2g. Unable to contact participant.
   - □ 2h. HIV infection.
   - □ 2i. Inappropriate enrollment.
   - □ 2j. Invalid ID due to duplicate screening/enrollment.
   - □ 2k. Other, specify: ____________________________
   - □ 2l. Early study closure.

3. Was termination associated with…
   - □ 3a. Adverse Experience?  
     - yes  
     - no  
     - don’t know  
     - Record Adverse Experience Log page: page #

Comments: ____________________________
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.
Interview Cards

HPTN 058
How often?

• every day
• 5–6 days per week
• 3–4 days per week
• 1–2 days per week
• less than once per week
• never

How often?

• always
• more than half the time
• about half the time
• less than half the time
• never
Interview Cards

HPTN 058

Interview Cards

HPTN 058
Frontloading

1. Remove the plunger from the syringe. Using a steady hand, draw up the fluid and empty half into each of the syringes.

2. Carefully replace both plungers.

Backloading

1. Remove the plunger from the syringe. Using a steady hand, draw up the fluid and empty half into each of the syringes.

2. Carefully replace both plungers.