The following questions are about your personal background and living situation.

1. What is your date of birth? .................................................................

2. What is your sex? ...........................................................................
   male female

Item 3 for China and Chennai sites only, Russia site go to item 4.

3. What is your ethnic origin, or primary language spoken (Chennai only)?

   Xinjiang
   ☐ Uighur
   ☐ Han
   ☐ Hui
   ☐ Kazakh
   ☐ Other, specify: ____________________________

   Guangxi
   ☐ Han
   ☐ Zhuang
   ☐ Yao
   ☐ Miao
   ☐ Deng
   ☐ Other, specify: ____________________________

   Chennai
   ☐ Tamil
   ☐ Telugu
   ☐ Kannada
   ☐ Malayalam
   ☐ Hindi
   ☐ Other, specify: ____________________________

4. What is your current marital status?
   ☐ single
   ☐ married
   ☐ living with partner/not married
   ☐ separated/married but living separately
   ☐ divorced
   ☐ widowed
5. What is your highest level of education?

- no schooling
- primary schooling
- some secondary schooling (middle school or high school)
- completed secondary schooling (high school)
- vocational or trade schooling
- some university or community college
- completed university
- graduate/professional schooling

6. Are you currently a student? ............................................................... yes  

6a. Full-time, part-time, or correspondence? ...........................................

- full-time
- part-time
- correspondence

7. Are you employed... Read categories.

- full time (≥ 30 hours per week)
- part-time
- occasional or time-to-time
- unemployed  

- other; please specify: Local Language ..................................................  

- English .................................................................

7a. Are you self-employed? ................................................................. yes  

- no  

/language  

/Staff Initials / Date  

SAMPLE—English  

16-APR-02
8. What kind of housing do you live in?

- □ homeless, no fixed address
- □ rent house
- □ rent room or apartment alone
- □ rent room or apartment with others
- □ own their own house or apartment
- □ stay with parents
- □ stay with other relatives
- □ stay with others, do not pay rent
- □ dormitory/group housing
- □ staff quarters
- □ other, specify: Local Language ____________________________ English ____________________________
1. Are you available to take part in this study for the next 12 months? □ yes □ no → If no, participant is ineligible. End of form.

Items 2–4 for Russia and China sites only. Chennai site go to item 5 on page 2.

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.

2. Have you ever injected drugs? ........................................................ □ yes □ no → If no, participant is ineligible. End of form.

3. During the last month (that is, since ________), on average, how often did you inject per week? Show Card #1.

□ never

□ less than once per week

□ 1–2 times per week

□ 3–4 times per week

□ 5–6 times per week

□ once per day or more

4. During the last 3 months (that is, since ________), how many times did you inject drugs using a needle or works that someone else had already used? ........................................................... □ □ □

End of form for Russia and China sites.
Items 5–15 for Chennai site only.

Instruction: Items 5–10 for males only. If participant is female, go to item 11 on page 3.

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.

5. During the last 6 months (that is, since_________), have you had vaginal or anal sex with any female partners? By vaginal or anal sex I mean when your penis was in your partner’s vagina or in her anus.................................................................

   yes no If no, go to item 10.

6. During the last 6 months, how many different female sex partners have you had? ..................................................................................

7. During the last 6 months, have you had vaginal or anal sex with an HIV-positive female partner? ..........................................................................

   yes no don’t know If no or don’t know, go to item 9.

8. During the last 6 months, how often have you had vaginal or anal sex with an HIV-positive female partner?
   
   Show Card #2.

   □ less than once per month
   □ once per month
   □ less than once per week
   □ once per week or more

9. During the last 6 months, how many times have you had vaginal or anal sex with a female partner in exchange for money or drugs?...

10. During the last 6 months, have you been told by a health care provider that you had, or have you been treated for a sexually transmitted disease (such as syphilis, gonorrhea, or chlamydia)?

   yes no
**Instruction:** Items 11–15 for females only. If participant is male, end of form.

**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.

11. During the last 6 months (that is, since _________), have you had vaginal or anal sex with any male partners? By vaginal or anal sex I mean when your partner’s penis was in your vagina or in your anus.................................................

   - [ ] yes
   - [ ] no

   **If no, go to item 15.**

12. During the last 6 months, how many different male sex partners have you had?.................................................

   - [ ]

13. During the last 6 months, have you had vaginal or anal sex with an HIV-positive male partner?.................................................

   - [ ] yes
   - [ ] no
   - [ ] don’t know

   **If no or don’t know, go to item 15.**

14. During the last 6 months, how often have you had vaginal or anal sex with an HIV-positive male partner? 

   - [ ] less than once per month
   - [ ] once per month
   - [ ] less than once per week
   - [ ] once per week or more

15. During the last 6 months, have you been told by a health care provider that you had, or have you been treated for a sexually transmitted disease (such as syphilis, gonorrhea, or chlamydia)?

   - [ ] yes
   - [ ] no
Sample: Do not Fax to Data Fax

HPTN 033 PPS (011) EC-1 (031)

Page 1 of 2

Eligibility Checklist

000-

Participant ID

Site Number Participant Number Chk

Eligibility Checklist

Form Completion Date

dd MMM yy

Language

01

Staff Initials / Date

07-FEB-02

Sample

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

Eligibility Checklist (EC-1)

Items 1–2 for Russia and China sites only. Chennai site go to item 3.

1. Has the participant injected drugs at least 3 times per week in the last month? See item 3, EL-1.
   - [ ]

2. Has the participant injected drugs on at least 3 occasions in the last 3 months using injection equipment after another person? See item 4, EL-1.
   - [ ]

   If no to both items 1 and 2, participant is ineligible. Go to item 9 on page 2.

Items 3–8 for Chennai site only. Russia and China sites go to item 9 on page 2.

Instruction: Items 3–5 for males only. If participant is female, go to item 6.

3. Has the participant had vaginal or anal sex with an HIV-infected female partner at least once per week during the last 6 months? See item 8, EL-2.
   - [ ]

4. Has the participant exchanged money or drugs for sex with a female partner at least 5 times during the last 6 months? See item 9, EL-2.
   - [ ]

5. Has the participant been diagnosed with or been treated for a sexually transmitted disease in the last 6 months? See item 10, EL-2.
   - [ ]

   If no to all of items 3–5, participant is ineligible. Go to item 9 on page 2.

Instruction: Items 6–8 for females only. If participant is male, go to item 9 on page 2.

6. Has the participant had 5 or more male sex partners in the last 6 months? See item 12, EL-3.
   - [ ]

7. Has the participant had vaginal or anal sex with an HIV-infected male partner at least once per week during the last 6 months? See item 14, EL-3.
   - [ ]

8. Has the participant been diagnosed with, or been treated for a sexually transmitted disease in the last 6 months? See item 15, EL-3.
   - [ ]

   If no to all of items 6–8, participant is ineligible. Go to item 9 on page 2.
Items 9–13 for all sites.

9. Is the participant at least 16 years of age (Russia) or at least 18 years of age (China and India)?
   See item 1, DM-1.
   
10. Is the participant available for 12 months of study participation?

11. Is the participant able and willing to provide adequate locator information?

   If no to one of items 9–11, participant is ineligible. Go to item 12.

12. Does the participant have an obvious psychological or psychiatric disorder that would preclude provision of informed consent or otherwise contraindicate study participation?

   12a. Specify: Local Language
   English

13. Does the participant have any other condition that would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?

   13a. Specify: Local Language
   English

14. Insert date 28 days from Screening date: 
   dd MMM yy

   If yes to either items 12 or 13, participant is ineligible.
1. Did participant provide informed consent for study participation?...

1a. What are the reasons why the participant did not provide informed consent? Mark all that apply.

- [ ] time commitment too great
- [ ] unwilling to commit to visit schedule
- [ ] wants more time to consider
- [ ] not interested in participating in research
- [ ] unwilling to have HIV test or receive HIV test results
- [ ] is afraid of disclosure/loss of confidentiality
- [ ] is afraid of difficulty with job or insurance coverage
- [ ] is afraid of difficulty with government officials
- [ ] is afraid of spouse/partner’s reaction or domestic violence
- [ ] other: Local Language ___________________________ English ___________________________

End of form if participant did not provide informed consent.

1b. Date of informed consent: [ ] dd [ ] MMM [ ] yy

2. Did participant provide informed consent for blood storage for possible future research? ............................................................

2a. Date of informed consent: [ ] dd [ ] MMM [ ] yy

If no, go to item 3 on page 2.
HPTN 033 PPS (011)

Participant ID: 000

Enrollment

3. Is participant eligible based on the Eligibility Checklist? ..................
   - [ ] yes  - [ ] no

4. Did participant return for enrollment on or before date indicated in item 14, EC-2? .................................................................
   - [ ] yes  - [ ] no

5. Is the participant HIV-negative according to study algorithm? .......
   - [ ] yes  - [ ] no

6. Was participant enrolled?
   - [ ] yes  - [ ] no

   Enrolment Date: dd MMM yy

   End of form.

   Go to item 6a.

6a. What are the reasons why the participant was not enrolled? Mark all that apply.
   - [ ] time commitment too great
   - [ ] unwilling to commit to visit schedule
   - [ ] wants more time to consider
   - [ ] not interested in participating in research
   - [ ] unwilling to have HIV test or receive HIV test results
   - [ ] is afraid of disclosure/loss of confidentiality
   - [ ] is afraid of difficulty with job or insurance coverage
   - [ ] is afraid of difficulty with government officials
   - [ ] is afraid of spouse/partner’s reaction or domestic violence
   - [ ] participant did not return for enrollment visit, reason unknown
   - [ ] other: Local Language ____________________________ English ____________________________

Comments: Local Language __________________________________________

Comments: English __________________________________________________

[ ] [ ] [X] 07-FEB-02

Sample
**INJECTION DRUG USE QUESTIONS**

*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.

1. Using the choices on this card, please tell me how often in the last **3 months** (that is, since ________) you have injected each of the following: *Show Card #3.*

<table>
<thead>
<tr>
<th>Injection Drug</th>
<th>0 (never)</th>
<th>less than once per week</th>
<th>1–2 times per week</th>
<th>3–4 times per week</th>
<th>5–6 times per week</th>
<th>once per day or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. heroin by itself</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b. cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1c. speedball (heroin and cocaine together)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1d. heroin mixed with another drug, specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Local Language</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>English</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1e. opium/opiates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1f. buprenorphine (morphine)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1g. amphetamines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1h. morphine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1i. tranquilizers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1j. other, specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Local Language*    |           |                         |                    |                    |                    |                      |

*English*           |           |                         |                    |                    |                    |                      |
2. Using the same choices, please tell me how often in the last 3 months you have done each of the following: Show Card #3.

<table>
<thead>
<tr>
<th></th>
<th>0 (never)</th>
<th>less than once per week</th>
<th>1–2 times per week</th>
<th>3–4 times per week</th>
<th>5–6 times per week</th>
<th>once per day or more</th>
<th>don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a. used a needle or works after someone else</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2b. used a needle after someone who is HIV positive used it</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2c. shared rinse water</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2d. shared a cooker</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2e. shared cotton</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2f. used drugs that were frontloaded or backloaded into your syringe</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
SEXUAL BEHAVIOR QUESTIONS—MALE

Instruction: Items 3–21 for males only. If participant is female, go to item 22 on page 7.

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.

3. During the last 6 months (that is, since ________), have you had vaginal or anal sex with any female partners? By vaginal or anal sex I mean when your penis was in her vagina or in her anus. ............................

4. During the last 6 months, with how many different female partners have you had vaginal or anal sex? ..............................................................

5. Do you have a primary female sex partner? By primary I mean a wife, girlfriend, or steady partner. ..............................................................

6. What is this partner’s HIV status? ..............................................................

7. Does this partner inject drugs? ..............................................................
Primary Partner

*Read to participant:* The following questions ask about your sexual practices with your primary female partner.

8. During the last 6 months, on average, how often have you had vaginal sex with your primary female partner? By vaginal sex I mean your penis was in her vagina. *Show Card #4.*

- [ ] less than once every 3 months
- [ ] less than once per month
- [ ] about once per month
- [ ] about 2 or 3 times per month
- [ ] about once per week
- [ ] 2–3 times per week
- [ ] more than 3 times per week

9. During the last month (that is, since________), how many times have you had vaginal sex with your primary female partner? 

9a. How many of those times did you use a condom from start to finish? 

10. During the last 6 months (that is, since________), how many times have you had anal sex with your primary female partner? By anal sex I mean your penis was in her anus. 

10a. How many of those times did you use a condom from start to finish? 

If 0, go to item 10 on page 11.
Risk Assessment

Other Partners
Read to participant: The following questions ask about your sexual practices with females other than a primary female partner, including females you have dated, non-steady girlfriends, casual encounters, and sex workers.

11. During the last 6 months (that is, since_________), have you had vaginal or anal sex with a female who was not a primary partner? By vaginal or anal sex I mean when your penis was in her vagina or in her anus. ................................................................. yes no □ □ If no, go to item 15 on page 6.

12. During the last 6 months, on average, how often have you had vaginal sex with a female who was not your primary partner? By vaginal sex I mean your penis was in her/their vagina. Show Card #4.

☐ less than once every 3 months
☐ less than once per month
☐ about once per month
☐ about two or three times per month
☐ about once per week
☐ 2–3 times per week
☐ more than 3 times per week

13. During the last month (that is, since_________), how many times did you have vaginal sex with a female who was not your primary partner?... If 0, go to item 14.

13a. How many of these times did you use a condom from start to finish? .................................................................

14. During the last 6 months (that is, since_________), how many times have you had anal sex with a female who was not your primary partner? If 0, go to item 15 on page 6.

14a. How many of these times did you use a condom from start to finish? .................................................................
Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Risk Assessment (RA-6)

Sample: Do not Fax to DataFax

Visit Code

HPTN 033 PPS (011)

RA-6 (126)

Participant ID

Site Number 0 0 0 0

Participant Number

Risk Assessment

Staff Initials / Date

End of form for males.

Read to participant: The following questions ask about your sexual practices with males.

15. Have you ever had anal sex with another male? By anal sex I mean when your penis was in his anus, or his penis was in your anus.................

16. During the last 6 months (that is, since_________), with how many different males have you had anal sex? ......................................................

17. During the last month (that is, since_________), how many times have you had insertive anal sex with a male partner? By insertive anal sex I mean when your penis was in his anus. ......................................................

17a. How many of these times did you use a condom from start to finish? .................................................................................................

18. During the last month, how many times have you had receptive anal sex with a male partner? By receptive anal sex I mean when his penis was in your anus. ....................................................................................................

18a. How many of these times did your partner use a condom from start to finish? ............................................................................................

19. Thinking now about all of your sex partners in the last 6 months (that is, since_________), how many did you give money, drugs, goods, or shelter to in exchange for sex? ....................................................................

20. Of all your sex partners in the last 6 months, how many gave you money, drugs, goods, or shelter in exchange for sex? .........................

21. Of all your sex partners in the last 6 months, how many were new sex partners? By new I mean you had sex with them for the first time in the last 6 months..........................................................
SEXUAL BEHAVIOR QUESTIONS—FEMALE

Instruction: Items 22–36 for females only. If participant is male, end of form.

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 a honestly as you can.

22. During the last 6 months (that is, since ________), have you had vaginal or anal sex with any male partners? By vaginal or anal sex I mean his penis was in your vagina or in your anus. ............................................................
   yes
   no
   If no, end of form.

23. During the last 6 months, with how many different male partners have you had vaginal or anal sex? ............................................................

24. Do you have a primary male sex partner? By primary I mean a husband, boyfriend, or steady partner. ............................................................
   yes
   no
   If no, go to item 30 on page 9.

25. What is this partner’s HIV status? ............................................................
   negative
   positive
   don’t know

26. Does this partner inject drugs? ............................................................
   yes
   no
   don’t know
Risk Assessment (RA-8)

Primary Partner

*Read to participant:* The following questions ask about your sexual practices with your primary male partner.

27. During the last 6 months, on average, how often have you had vaginal sex with your primary male partner? By vaginal sex I mean his penis was in your vagina. *Show Card #4.*

- [ ] less than once every 3 months
- [ ] less than once per month
- [ ] about once per month
- [ ] about two or three times per month
- [ ] about once per week
- [ ] 2–3 times per week
- [ ] more than 3 times per week

28. During the last month (that is, since _________), how many times have you had vaginal sex with your primary male partner? 

28a. How many of these times did he use a condom from start to finish?

29. During the last 6 months (that is, since _________), how many times have you had anal sex with your primary male partner? By anal sex I mean his penis was in your anus.

29a. How many of these times did he use a condom from start to finish?

If 0, go to item 29.
30. During the last 6 months (that is, since ________), have you had vaginal or anal sex with a male who was not a primary partner? By vaginal or anal sex I mean his penis was in your vagina or in your anus. ......................

   □ yes  □ no

If no, go to item 34.

31. During the last 6 months, on average, how often have you had vaginal sex with a male who was not your primary partner? By vaginal sex I mean his/their penis was in your vagina. Show Card #4.

   □ less than once every 3 months
   □ less than once per month
   □ about once per month
   □ about two or three times per month
   □ about once per week
   □ 2–3 times per week
   □ more than 3 times per week

32. During the last month (that is, since ________), how many times have you had vaginal sex with a male who was not your primary partner?..............

32a. How many of these times did he/they use a condom from start to finish? ..............................................................................................................

If 0, go to item 33 on page 10.
33. During the last 6 months (that is, since __________), how many times have you had anal sex with a male who was not your primary partner? By anal sex, I mean his/their penis was in your anus. ....................................................... If 0, go to item 34.

33a. How many of these times did he/they use a condom from start to finish? ........................................................................................................

Read to participant: The following questions ask about all of your sex partners in the last 6 months.

34. Thinking now about all of your sex partners in the last 6 months, how many gave you money, drugs, goods, or shelter in exchange for sex? .........

35. Of all your sex partners in the last 6 months, how many did you give money, drugs, goods, or shelter to in exchange for sex? ......................

36. Of all your sex partners in the last 6 months, how many were new sex partners? By new I mean you had sex with them for the first time in the last 6 months..............................................................
Local Lab Results

Not Done/Not Collected

Sample Collection Date

dd MMM yy

1. HIV EIA ......................
   negative positive indeterminate
   If negative, end of form.

Specimen Collection Date

dd MMM yy

2. Rapid HIV EIA ..............
   negative reactive
   If negative, end of form.

Specimen Collection Date

dd MMM yy

3. Western Blot/IFA ..........
   negative positive indeterminate
   If negative, end of form.

Specimen Collection Date

dd MMM yy

4. Western Blot/IFA ..........
   negative positive indeterminate
   If Screening visit, participant is not eligible to enroll. Complete Eligibility Checklist. If Follow-up visit, terminate and complete Termination form.

Comments: Local Language ____________________________________________________________

Comments: English ________________________________________________________________

07-FEB-02

SAMPLE 01

/hivnet/forms/PTN_033_PPS/forms/local_lab_results.fm
**Statistical Center for HIV/AIDS Research & Prevention (SCHARP)**

**Participant Encounter (PE-1)**

**Participant ID**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Visit Code**

| 1 |

**Visit Code**

| 1 |

**Encounter Date**

<table>
<thead>
<tr>
<th>dd</th>
<th>MMM</th>
<th>yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-FEB-02</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Participant Encounter**

1. **Visit/contact method:**

- [ ] in person
- [ ] telephone
- [ ] other: Local Language ________________ English ________________

2. **Reason for visit/contact:**

- [ ] scheduled visit/contact
- [ ] interim visit/contact (Mark all that apply):
  - [ ] presumed HIV exposure
  - [ ] risk-reduction counseling
  - [ ] HIV pre-test counseling
  - [ ] HIV post-test counseling
  - [ ] referral
  - [ ] other: Local Language ________________ English ________________

3. **Were specimens collected for HIV testing at this visit/contact?**

- [ ] yes
- [ ] no

4. **Visit/contact location:**

- [ ] study site facility
- [ ] own home
- [ ] drug treatment/rehabilitation facility
- [ ] home of friend/relative
- [ ] other: Local Language ________________ English ________________

5. **Referrals provided: Mark all that apply.**

- [ ] none
- [ ] health care
- [ ] HIV-related case management
- [ ] mental health services
- [ ] HIV prevention
- [ ] family/child services
- [ ] drug treatment
- [ ] HPTN protocol: Local Language ________________ English ________________
- [ ] needle exchange
- [ ] other: Local Language ________________ English ________________
- [ ] health insurance

- [ ] Language
- [ ] Staff Initials / Date
Instructions: Complete this form when a participant has missed a scheduled visit. For Visit Code, enter the visit code of the scheduled visit that was missed. Fax the form to DataFax according to the timeline included in the Study Specific Procedures Manual.

Reason Visit Missed:
Mark only one.

☐ Unable to contact participant; date of last contact with participant: dd MMM yy

☐ Refused visit.

☐ Incarcerated.

☐ Institutionalized.

☐ Missed scheduled appointment(s), reason unknown.

☐ Withdrawn from the study. → Complete a Termination form.

☐ Deceased. → Complete a Termination form.

☐ Other, please specify: Local Language ____________________________

English ____________________________

Comments: Local Language _______________________________________

______________________________________________________________

Comments: English ____________________________________________

______________________________________________________________
**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: Local Language

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Comments: English

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

□□□□□□□□□ 07-FEB-02  SAMPLE

/hivnet/forms/PTN_033_PPS/forms/comments.fm
Study: HIV Prevention Preparedness Study
Site: [Site Name]

As of today's date, I verify that:

- The study participants listed by ID number below are all of the participants from my site for whom data were submitted to SCHARP in the HPTN 033 study.
- To the best of my knowledge, the data transmitted to SCHARP for these participants as of 12-MAR-04 are complete and accurate.

Please fax by 15-MAR-04 to SCHARP: 206-667-4805.
Instructions: Complete this form whenever a participant terminates from the study.

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 (please indicate date and cause if known).

   Cause of death: [ ] Local Language ____________________________ OR [ ] Cause unknown
   [ ] English ____________________________

   Date of death [ ] [ ] [ ] OR [ ] Date unknown
   [ ] [ ] [ ]

   2c. Early termination. Please indicate primary reason below. Mark only one.
   [ ] Participant refused further participation.
   [ ] Participant unable to adhere to visit schedule.
   [ ] Participant relocated, no remote follow-up planned.
   [ ] Investigator decision, please specify: [ ] Local Language ____________________________ [ ] English ____________________________
   [ ] Unable to contact participant.
   [ ] HIV positive.
   [ ] Inappropriate enrollment.
   [ ] Invalid ID due to duplicate screening/enrollment.
   [ ] Other reason, please specify: [ ] Local Language ____________________________ [ ] English ____________________________

Comments: [ ] Local Language ____________________________________________

Comments: [ ] English ____________________________________________

07-FEB-02 00 00 01

/hivnet/forms/PTN_033_PPS/forms/termination.fm