1. What is your date of birth? .................
   If unknown, record age: ____________ years

2. What is your gender? ......................
   male    female    other
   yes     no

3. Do you consider yourself to be transgender?
   If no, go to statement above item 4.

   3a. Which of the following do you consider yourself to be?
   - Male-to-Female transgender
   - Female-to-Male transgender
   - other, specify: Local Language: ________________  English: ________________

   3b. Which describes your current anatomy?
   - I have a penis
   - I have a vagina

   Items 4 and 5 are for Brazil participants only. If participant is in Thailand, go to item 6 on page 2. If participant is in Zambia, go to item 7 on page 2.

4. Do you consider yourself to be Latino/a? ....
   yes    no

5. What is your race? Mark all that apply.
   - 5a. Asian
   - 5b. Black
   - 5c. Mixed Race
   - 5d. Native
   - 5e. White
   - 5f. other, specify: Local Language: ________________  English: ________________

   (Note: Latino/a is not a race.)
Demographics (DEM-1)

Item-specific instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant’s estimate of their age. Do not complete both answers.

- **Item 2:** This item must be self-identified by the participant.

- **Item 3a:** A male-to-female transgender individual is a person born as a man and living as a woman either by dressing, acting, and/or having undergone surgery. A female-to-male transgender individual is a person born as a woman and living as a man either by dressing, acting, and/or having undergone surgery.

- **Items 3a and 5f:** If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
Participant ID

Demographics

Item 6 is for Thailand participants only. If participant is in Zambia, go to item 7. If participant is in Brazil, go to item 8 on page 3.

6. What is your ethnic group? Mark all that apply.

- 6a. Akha
- 6b. Hmong
- 6c. Karen
- 6d. Kahu
- 6e. Lisu
- 6f. Lua
- 6g. Tai Yai
- 6h. Thai
- 6i. Yao
- 6j. other, specify: Local Language: _____________________  English: _____________________

Item 7 is for Zambia participants only. If participant is in Brazil or Thailand, go to item 8 on page 3.

7. What is your ethnic group or tribe? Mark all that apply.

- 7a. Bemba
- 7b. Lozi
- 7c. Nyanja
- 7d. Tonga
- 7e. other African tribe, specify: Local Language: _____________________  English: _____________________
- 7f. other, specify: Local Language: _____________________  English: _____________________

No data recorded on this page.
Demographics (DEM-2)

Item-specific instructions:

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

- **Items 6j and 7f**: If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
8. In which country were you born?

- [ ] Brazil
- [ ] Thailand
- [ ] Zambia
- [ ] Congo DR
- [ ] Rwanda
- [ ] Tanzania
- [ ] Zimbabwe
- [ ] other, specify ISO Code: □□□

9. What language(s) do you speak fluently? *Mark all that apply.*

- [ ] 9a. Portuguese
- [ ] 9b. Thai
- [ ] 9c. Akha
- [ ] 9d. Karen
- [ ] 9e. Bemba
- [ ] 9f. Nyanja
- [ ] 9g. Lozi
- [ ] 9h. Tonga
- [ ] 9i. Luvale
- [ ] 9j. English
- [ ] 9k. other, specify: *Local Language: __________________________ English: __________________________*
Demographics (DEM-3)

Item-specific instructions:

• **Item 8:** If the participant is from a country other than those listed, record the ISO country code as listed in the Data Management Section of the Study Specific Procedures (SSP).

• **Item 9:** If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
10. What is your religion?

- [ ] Afro-Brazilian religion
- [ ] Buddhism
- [ ] Christianity
- [ ] Hinduism
- [ ] Islam
- [ ] Judaism
- [ ] Spiritism/Kardecism
- [ ] indigenous religion
- [ ] no religion
- [ ] other, specify:  

  Local Language: __________________________  English: __________________________

11. How often do you attend religious services?

- [ ] more than once a week
- [ ] about once a week
- [ ] a few times a month
- [ ] about once a month
- [ ] a few times a year
- [ ] very rarely
- [ ] never
Demographics (DEM-4)

Item-specific instructions:

- **Item 10:** “Christianity” includes Catholicism, Anglicanism, Protestantism, Evangelism, Pentecostalism, and any other Christian denomination. “No religion” includes atheism and agnosticism.

  If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
12. What is your current marital status?

- never married
- married
- separated/divorced
- widowed

13. What is your current work situation? *Mark all that apply.*

- 13a. unemployed
- 13b. electronics/mechanic
- 13c. accounting
- 13d. student
- 13e. teacher
- 13f. farming/agriculture
- 13g. artist
- 13h. retired
- 13i. domestic worker (e.g., cook, clean, child care)
- 13j. housewife (not for pay)
- 13k. religious work
- 13l. military/police
- 13m. government
- 13n. sex worker
- 13o. health care (e.g., doctor, nurse)
- 13p. business (e.g., manager, office work)
- 13q. skilled labor (e.g., required training)
- 13r. driver
- 13s. unskilled labor (no training)
- 13t. other, specify:

  *Local Language: ____________________

  *English: ____________________
Demographics (DEM-5)

Item-specific instructions:

- **Item 12**: This question is about marriage only, not a living arrangement. We ask if the participant lives with their sex partner(s) later. “Married” includes both monogamous marriages and polygamous marriages.

- **Item 13t**: If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
14. How many people does your household income support (including yourself)?

- □ no household income
- □ 1, only me
- □ 2–3 people
- □ 4–6 people
- □ 7–9 people
- □ 10 people or more

15. What kind of housing do you live in? Mark all that apply.

- □ 15a. own house/condominium/apartment
- □ 15b. rent house/condominium/apartment
- □ 15c. rent room
- □ 15d. staff quarters
- □ 15e. stay with relative(s)
- □ 15f. stay with friend(s)
- □ 15g. none/homeless
- □ 15h. other, specify:

  Local Language: _____________________  English: _____________________
Demographics (DEM-6)

Item-specific Instructions:

• **Item 15h:** If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
16. How many people live with you?

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1–5</th>
<th>6–10</th>
<th>11–15</th>
<th>16+</th>
</tr>
</thead>
<tbody>
<tr>
<td>I live alone</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

If 0, go to item 17.

16a. Who lives with you? *Mark all that apply.*

- [ ] 16a1. spouse/partner
- [ ] 16a2. your children/partner’s children
- [ ] 16a3. parent(s) and/or grandparent(s)
- [ ] 16a4. other relative(s)
- [ ] 16a5. friend(s)
- [ ] 16a6. other renter(s)
- [ ] 16a7. other, specify: *Local Language: ______________________________* *English: ______________________________*

17. Which of the following utilities do you have on the premises? *Mark all that apply.*

- [ ] 17a. electricity
- [ ] 17b. running water
- [ ] 17c. telephone or mobile phone
- [ ] 17d. toilet with plumbing
- [ ] 17e. pit latrine
Demographics (DEM-7)

Item-specific instructions:

- **Item 16a7**: If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

- **Item 17d**: A toilet with plumbing is any toilet that is connected to a sewer but it can be indoors or outdoors, flushing or nonflushing.
18. How many living biological children do you have?

- 0
- 1–3
- 4–6
- 7–10
- more than 10

18a. Do you want to have (more) biological children in the future? ..........................  

19. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- technical training, not complete
- technical training, complete
- college or university, not complete
- college or university, complete

20. How comfortable are you with reading?

- I cannot read
- I can read some things but prefer to have everything read to me
- I can read most things but prefer to have complicated things read to me
- I have no trouble reading at any level

Comments:  Local Language: _______________________________  English: _______________________________
Demographics (DEM-8)

Item-specific instructions:

- **Item 18:** Encourage the participant to make their best guess if they do not know how many living biological children they have.

- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
1. Was the ACASI questionnaire administered? .................................
   □ yes  □ no  If yes, go to item 2.

   1a. Indicate the reason(s) ACASI was not administered. Mark all that apply.
   □ 1a1. computer problem, specify:  
       Local Language: __________________________  English: __________________________
   □ 1a2. participant not comfortable with computer
   □ 1a3. participant decision
   □ 1a4. clinical staff oversight
   □ 1a5. other reason, specify:  
       Local Language: __________________________  English: __________________________

   End of form. Do not fax pages 2 and 3 to SCHARP DataFax.

2. Was the ACASI questionnaire completed? .................................
   □ yes  □ no  If yes, go to item 3 on page 2

   2a. Indicate the reason(s) ACASI was not completed. Mark all that apply.
   □ 2a1. computer problem, specify:  
       Local Language: __________________________  English: __________________________
   □ 2a2. participant not comfortable with computer
   □ 2a3. participant not comfortable with questions
   □ 2a4. questionnaire took too long
   □ 2a5. other reason, specify:  
       Local Language: __________________________  English: __________________________

Comments:  

Local Language: __________________________

English: __________________________

□ □ □ X 13-NOV-09  01
ACASI Administration (ACA-1)

Purpose: This form is used to confirm that SCHARP has received all of the ACASI data. It is also used to document the participant’s experience with ACASI.

Item-specific Instructions:

- **Items 1a1 and 2a1:** If the “computer problem, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
- **Items 1a5 and 2a5:** If the “other reason, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
3. ACASI administration:

☐ web browser  \[\text{Go to item 4.}\]

☐ local connection

3a. Why was the local connection used?

☐ off-site/mobile unit

☐ internet connection problem

☐ other reason, specify: 

\[
\begin{array}{ll}
\text{Local} & \text{Language: } \\
\text{English: }
\end{array}
\]

3b. Was the data synchronized?

☐ yes

☐ no  \[\text{If no, specify reason:}\]

\[
\begin{array}{ll}
\text{Local} & \text{Language: } \\
\text{English: }
\end{array}
\]

4. Was the questionnaire read to the participant instead of self-administered? .................................................................

☐ yes  ☐ no  \[\text{If no, go to item 5 on page 3.}\]

4a. Why was the questionnaire read to the participant? \textit{Mark all that apply.}

☐ 4a1. participant had difficulty reading/illiterate

☐ 4a2. participant had difficulty understanding questions

☐ 4a3. participant had difficulty using computer

☐ 4a4. other, specify: 

\[
\begin{array}{ll}
\text{Local} & \text{Language: } \\
\text{English: }
\end{array}
\]
ACASI Administration (ACA-2)

Item-specific Instructions:

- **Item 3a:** If the “other reason, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.

- **Item 4a4:** If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
Participant ID

Site Number - Participant Number - Chk

Did the participant provide comments or feedback about the ACASI questionnaire? .................................................................

5a. Indicate the participant’s comments. Mark all that apply.

☐ 5a1. questionnaire was too long/took too much time to complete

☐ 5a2. questions were confusing

☐ 5a3. didn’t like using computer

☐ 5a4. questions were too personal

☐ 5a5. difficult to remember behavior over 3-month time period

☐ 5a6. liked using computer

☐ 5a7. liked the confidentiality of using computer

☐ 5a8. other, specify: Local Language: ___________________________________________________________

English: ___________________________________________________________

If no, end of form.
ACASI Administration (ACA-3)

Item-specific Instructions:

- **Item 5a8:** If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
The following questions are about any sexual abuse or violence you may have experienced in your life.

1. When you were growing up (before 16 years old), did you experience any serious physical violence? By physical violence, I mean were you ever hit, hit with an object, punched, kicked, or beaten up in a way that resulted in injury, severe pain, or other serious harm.  
   - yes  
   - no

2. When you were growing up (before 16 years old), did you ever have any unwanted sexual experiences? By sexual experiences, I mean sexual touching or sexual intercourse.  
   - yes  
   - no

3. Have you ever had a sexual partner (including a current or former spouse, boy/girlfriend, or other sexual partner) who has hit, slapped, kicked, pushed, shoved, or otherwise physically hurt you?  
   - yes  
   - no

4. Has anyone (including a current or former spouse, boy/girlfriend, or other sexual partner) ever tried to force you to have sex when you didn’t want to?  
   - yes  
   - no

We are now going to ask you some questions about your health and healthcare.

5. When were you first diagnosed with HIV?  
   - dd MMM yy

   a. Have ever been told by a doctor, nurse, or other medical provider that you have any of the following?  
      - Syphilis  
      - yes  
      - no  
      
      - Go to item 7.

   b. Has a doctor, nurse, or other medical provider told you this in the last 3 months (including this visit)?  
      - yes  
      - no

   6. Go to item 8.

   7. Gonorrhea  
      - yes  
      - no

   8. Chlamydia  
      - yes  
      - no  
      
      - Go to item 9 on page 2.

   If yes to any, complete Medical Event Log.

-  -  - X  13-NOV-09
Enrollment (ENR-1)

Item-specific Instructions:

- **Item 5**: At a minimum, month and year are required.
<table>
<thead>
<tr>
<th>Item</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Go To Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>9. Herpes simplex _____________________________________________________</td>
<td></td>
<td></td>
<td>a. Have ever been told by a doctor, nurse, or other medical provider that you have any of the following?</td>
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<td>Go to item 10.</td>
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<td>10.</td>
<td>10. Hepatitis A _______________________________________________________</td>
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<td>Go to item 11.</td>
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<td>11.</td>
<td>11. Hepatitis B _______________________________________________________</td>
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<td>Go to item 12.</td>
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<td>12.</td>
<td>12. Hepatitis C _______________________________________________________</td>
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<td>Go to item 13.</td>
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<td>13.</td>
<td>13. Trichomonas _______________________________________________________</td>
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<td>Go to item 14.</td>
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<td>14.</td>
<td>14. Other STI, specify: ______________________________________________</td>
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<td>English: ____________________________</td>
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<td></td>
<td>If yes to any, complete Medical Event Log.</td>
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<td>Go to item 15.</td>
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<td>15.</td>
<td>15. Vaginitis _________________________________________________________</td>
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<td>Go to item 16.</td>
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<td>16.</td>
<td>16. Cervicitis _______________________________________________________</td>
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<td>Go to item 17.</td>
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<td>17.</td>
<td>17. Pelvic Inflammatory Disease _______________________________________</td>
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<td>Go to item 18.</td>
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<tr>
<td>18.</td>
<td>18. Are you currently pregnant? ..................................................</td>
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</table>

Items 15–18 are for female participants only. Male participants go to item 19 on page 3.
Enrollment (ENR-2)

Item-specific Instructions:

- **Item 14:** Do not include vaginitis, cervicitis, or pelvic inflammatory disease. These items are captured in items 15, 16, and 17 for female participants.
19. During the **last 3 months**, including today, have you had any of the following symptoms?

- [ ] yes  19a. unusual genital or anal/rectal discharge
- [ ] yes  19b. unusual genital or anal/rectal pain
- [ ] yes  19c. a sore or ulcer in your genital or anal/rectal area

20. During clinic visits for HIV-related care, have you **ever** received information about preventing HIV transmission and how you can stay healthy? **Showcard #2**

- [ ] never
- [ ] only one time
- [ ] once in awhile
- [ ] most of the time
- [ ] at every visit

**ADMINISTRATIVE QUESTION**

*Do not read out loud to participant.*

21. Did the participant consent to long-term specimen storage? ............................................  

- [ ] yes
- [ ] no

Comments:  

**Local Language:** __________________________________________  **English:** __________________________________________

[ ] [ ] [ ] [ ] [ ] 13-NOV-09
Enrollment (ENR-3)

Item-specific Instructions:

- **Comments**: Record comments in the local language, as applicable. Record in English prior to faxing.
We are now going to ask you some questions about your current regular sex partners. A regular partner is someone with whom you are in a steady sexual relationship, such as a spouse or boyfriend/girlfriend.

1. Do you currently have any regular sex partners? ........................................... yes no  If no, go to item 14 on page 4.

If you currently have more than one regular sex partner, for the purpose of this questionnaire, please choose one partner who you consider to be your “primary” partner and answer the following questions for that individual. We will then ask you about any other regular sex partners you may have.

2. Do you live with your primary partner? .................................................. yes no

3. What is your primary partner’s current work situation? Mark all that apply.

- 3a. unemployed
- 3b. electronics/mechanic
- 3c. accounting
- 3d. student
- 3e. teacher
- 3f. farming/agriculture
- 3g. artist
- 3h. retired
- 3i. domestic worker (e.g., cook, clean, child care)
- 3j. housewife (not for pay)
- 3k. religious work
- 3l. military/police
- 3m. government
- 3n. sex worker
- 3o. health care (e.g., doctor, nurse)
- 3p. business (e.g., manager, office work)
- 3q. skilled labor (e.g., required training)
- 3r. driver
- 3s. unskilled labor (no training)
- 3t. other, specify:

Local Language: _________________________________

English: _________________________________
Sexual Partner Questionnaire (SPQ-1)

Item-specific Instructions:

- **Item 3t:** If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
4. When was the last time your primary partner was tested for HIV?

☐ within the last 3 months
☐ more than 3 months to 6 months ago
☐ more than 6 months to a year ago
☐ more than 1 year to 3 years ago
☐ more than 3 years ago
☐ don’t know
☐ never been tested ➔ Go to item 7 on page 3.

5. What is the current HIV status of your primary partner?

☐ HIV negative
☐ confirmed HIV positive ➔ If HIV negative or don’t know, go to item 7 on page 3.
☐ don’t know

5a. How often does your primary partner receive medical care for his/her HIV?

☐ never
☐ every few years
☐ once per year
☐ 2–4 times per year
☐ more than 4 times per year
☐ don’t know
Sexual Partner Questionnaire (SPQ-2)

Item-specific Instructions:

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

- **Item 5**: Only mark “confirmed HIV-positive” if the participant is certain of their partner’s status.

- **Item 5a**: Receiving medical care includes seeing a health care provider and/or going to a clinic.
6. Is your primary partner currently taking antiretroviral drugs (ARV) for his/her HIV? .................................................................
   yes  no  don't know

7. During your relationship, do you think your primary partner has ever had a sexual partner other than you at any time? .........................
   yes  no  don't know

   If no or don't know, go to item 8.

7a. Do you think your primary partner currently has a sexual partner other than you? ..............................................................
   yes  no  don't know

Now we're going to ask you some questions about any other regular sex partners you may currently have.

8. How many regular sexual partners do you currently have other than the primary partner we already discussed?
   none (0)  one (1)  two (2)  three (3)  four or more (4+)
   If none, go to item 14 on page 4.

   If four or more, specify number of partners:  

9. How many of these other regular sex partners do you currently live with? .................................................................

10. How many of these other regular sex partners contribute to your household income? .................................................................

11. How many of these other regular sex partners do you think currently have sexual partners other than you? ............................................

12. How many of these other regular sex partners do you know were tested for HIV within the last 3 months? ............................................
Sexual Partner Questionnaire (SPQ-3)

Item-specific instructions:

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

- **Items 9–12**: The participant’s answer cannot be more than the additional number of other current regular sex partners they indicated in item 8.
13. How many of these other regular sex partners do you know are confirmed HIV-positive? .................................................................

13a. Of these HIV-positive partners, how many do you know have received medical care for their HIV in the last 6 months? ............

13b. Of these HIV-positive partners, how many do you know are currently taking antiretroviral drugs (ARV) for their HIV? ..........

14. In the past 3 months, have you had a new sex partner (someone with whom you have not had sex ever before)? ...........................................

14a. In the past 3 months, where have you met your new sex partner(s)? Mark all that apply.

- Social gathering, wedding, or party
- Introduced by friend or family member
- Work place
- School/college/university
- Bathhouse or spa
- Sex club
- Public cruising area/park
- On the street
- Bar
- Dance club/night club
- Internet
- Private sex party
- Casino
- Hotel
- Homeless shelter
- Other, specify: Local Language: ________________ English: ________________

If 00, go to item 14.

If no, end of form.
Sexual Partner Questionnaire (SPQ-4)

Item-specific instructions:

- **Items 13a–13b**: The participant’s answer cannot be more than the number of confirmed HIV-positive partners they indicated in item 13.

- **Item 14q**: If the “Other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
The following questions are asking what you think people in your community think about sex, condom use, and HIV. These questions are not asking you about your own opinion but what you think the general opinion in your community is. We will ask about your opinion in the next section.

**Showcard #1**

In my community...

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. people believe it is prestigious for men to have multiple sex partners.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. people believe that men who have sex with multiple partners are immoral.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. people believe that women who have sex with multiple partners are immoral.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. people believe that it is difficult for young people to have only one sexual partner.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. it is difficult to introduce condoms in a relationship when the couple has already been having unprotected sex.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. asking to use a condom suggests that you distrust your partner.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. there is an expectation to have unprotected sex once married.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. there is an obligation to have children and therefore engage in unprotected sex.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. men fear that their partner(s) will leave them if they (the man) ask to use a condom.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. women fear that their partner(s) will leave them if they (the woman) ask to use a condom.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13-NOV-09
Cultural Questionnaire (CQ-1)

No additional instructions.
Showcard #1
In my community...

11. women are obligated to be submissive to their husbands, and therefore cannot ask their husbands to use condoms. ..........................................................
   
   agree

12. it is harder for younger people to ask their partners to use a condom if their partner is older. ....................
   
   strongly disagree

13. it is harder for people from a lower social status to ask their partners to use a condom if their partner is from a higher social status. .................................
   
   strongly agree

14. it is harder for people from ethnic or racial minority communities to ask their partners to use a condom if their partner is not a minority. .................................
   
   disagree

15. people believe that only prostitutes use condoms. .................................................................
   
   strongly disagree

16. the livelihood of individuals who engage in sex work is dependent on having unprotected sex. ................
   
   strongly agree

17. condoms are not used often because they are too expensive. ..................................................
   
   strongly disagree

18. it is believed that people with HIV have contracted the disease because they have engaged in immoral behavior. .................................................................
   
   strongly disagree

19. people believe that women with HIV have engaged in prostitution. ................................................
   
   strongly disagree

20. people believe that women with HIV have engaged in sex with many partners. ..............................
   
   strongly disagree
Cultural Questionnaire (CQ-2)

Item-specific instructions:

• **Item 13:** This question asks about individuals who are, or are perceived to be, less educated or less affluent (or less important in society due to a combination of these factors) than their sex partner.
Sample: Do not fax to DataFax

HPTN 063 (163)
CQ-3 (103)

Cultural Questionnaire (CQ-3)

Page 3 of 5

Participant ID

Site Number - Participant Number - Chk

Cultural Questionnaire

Showcard #1
In my community...

21. sex workers will lose income if they disclose that they are HIV positive. ............................................................

22. people believe that women cannot transmit HIV to others. .................................................................

23. people who feel better after taking ART are more likely to have unsafe sex. ........................................

The following questions are asking about your opinion. We want to know what you think about sex, HIV transmission, and condoms.

Showcard #1

24. I can't transmit HIV if the amount of the HIV virus in my blood is undetectable. ........................................

25. I am more likely to engage in unsafe sex if I know that the amount of the HIV virus in my blood is undetectable. .................................................................

26. Since HIV is treatable, I do not believe that it is important for me to use condoms. .............................

27. If I have unprotected sex with another HIV-infected person, I can acquire their type of the HIV virus. .......

28. If I am the receptive partner during sex (in other words, my partner is putting his penis inside of my mouth, anus, or vagina) I cannot transmit HIV to my partner.

29. I only have sex with other HIV-infected people. ...........................................................

0 1

Language Staff Initials / Date

N:\hivnet\forms\PTN_063\forms\p063_cultural_quest.fm

13-NOV-09
Cultural Questionnaire (CQ-3)

No additional instructions.
<table>
<thead>
<tr>
<th>Showcard #1</th>
<th>strongly disagree</th>
<th>disagree</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>30. I believe that condoms will protect me from STIs.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>31. I only engage in unprotected sex in order to have a baby.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>32. I will lose status in my community if I am not a father or mother.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>33. My partner(s) pressures me to have unprotected sex.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>34. My partner(s) will think I am unfaithful if I ask to use a condom.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>35. My partner(s) will think that I believe they are unfaithful if I ask to use a condom.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>36. I believe that using condoms decreases intimacy between partners.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>37. I feel that condoms make sex less pleasurable.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>38. I am embarrassed to get condoms at the store.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>39. I find it difficult to find a place to get condoms.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Cultural Questionnaire (CQ-4)

No additional instructions.
The following questions are asking how you feel about disclosing your HIV status.

**Showcard #1**

40. I usually tell my sex partner(s) about my HIV positive status. .................................................................

41. I don’t ask someone about their HIV status before having sex. .................................................................

42. If my sex partner does not disclose his/her HIV status to me, I do not tell them mine. ................................

43. I fear discrimination if I disclose my HIV positive status to others. ............................................................

44. I fear being kicked out of my house if I disclose my HIV positive status to others. ......................................

45. I fear being kicked out of my community if I disclose my HIV positive status to others. ............................

46. I am afraid of violence if I disclose my HIV positive status to others. ........................................................

47. I am afraid of losing my job if I disclose my HIV positive status to my boss or others. .................................
Cultural Questionnaire (CQ-5)

No additional instructions.
Now we are going to ask you some questions about your health in general over the past 4 weeks.

1. In general, would you say your health is:
   
   ___ excellent
   ___ very good
   ___ good
   ___ fair
   ___ poor

2. During the past 4 weeks, has your health kept you from working at a job, doing work around the house, or going to school?
   
   ___ yes, for all of the time
   ___ yes, for some of the time
   ___ no

3. During the past 4 weeks, how much pain have you had (e.g., headache, muscle pain, back pain, stomach ache)?
   
   ___ none
   ___ very mild
   ___ mild
   ___ moderate
   ___ severe
   ___ very severe
Quality of Life (QOL-1)
No additional instructions.
4. During the **past 4 weeks**, how much has your physical health or emotional problems interfered with your normal social activities (e.g., socializing with friends or family)? *Showcard #8*

- [ ] not at all
- [ ] a little bit
- [ ] moderately
- [ ] quite a bit
- [ ] extremely

5. During the **past 4 weeks**, have you been unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

- [ ] yes, for all of the time
- [ ] yes, for some of the time
- [ ] no

6. During the **past 4 weeks**, how much did pain interfere with your normal work (including housework)? *Showcard #8*

- [ ] not at all
- [ ] a little bit
- [ ] moderately
- [ ] quite a bit
- [ ] extremely
Quality of Life (QOL-2)

No additional instructions.
7. How much, if at all, does your health now limit you in the following activities? **Showcard #9**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, Limited a Lot</th>
<th>Yes, Limited a Little</th>
<th>No, Not Limited at All</th>
</tr>
</thead>
<tbody>
<tr>
<td>7a. The kind or amounts of vigorous activities you can do, like lifting heavy objects or running.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7b. The kind or amounts of moderate activities you can do, like going to the market.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7c. Walking uphill or climbing a few flights of stairs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7d. Eating, dressing, bathing, or toileting.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. How much of the time during the past 4 weeks...

**Showcard #10**

<table>
<thead>
<tr>
<th>Activity</th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a. Has your health limited your social activities, like visiting with family and friends?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8b. Did you have trouble keeping your attention on any activity for long?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8c. Did you have difficulty reasoning and solving problems?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8d. Have you been nervous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8e. Have you felt very sad or depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Quality of Life (QOL-3)
No additional instructions.
Quality of Life (QOL-4)

8. How much of the time during the **past 4 weeks**...

*Showcard #10*

8f. did you feel tired or fatigued? ..........................
   - all of the time
   - most of the time
   - a good bit of the time
   - some of the time
   - a little of the time
   - none of the time

8g. did you have enough energy to do the things you wanted to do? ............
   - all of the time
   - most of the time
   - a good bit of the time
   - some of the time
   - a little of the time
   - none of the time

8h. have you been a happy person? ...........................
   - all of the time
   - most of the time
   - a good bit of the time
   - some of the time
   - a little of the time
   - none of the time

8i. have you had trouble remembering things? ........
   - all of the time
   - most of the time
   - a good bit of the time
   - some of the time
   - a little of the time
   - none of the time

9. These are some statements about your general health. Please tell us how true they are for you.

*Showcard #11*

9a. My health is excellent. ..............................
   - definitely true
   - mostly true
   - don't know
   - mostly false
   - definitely false

9b. I have been feeling bad lately. ............
   - definitely true
   - mostly true
   - don't know
   - mostly false
   - definitely false
Quality of Life (QOL-4)

No additional instructions.
Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

**Showcard #12**

1. I was bothered by things that usually don't bother me.

2. I did not feel like eating; my appetite was poor.

3. I felt that I could not shake off the blues even with help from my family or friends.

4. I felt I was just as good as other people.

5. I had trouble keeping my mind on what I was doing.

6. I felt depressed.

7. I felt that everything I did was an effort.

8. I felt hopeful about the future.

9. I thought my life had been a failure.

10. I felt fearful.

11. My sleep was restless.

12. I was happy.
Mental Health and Social Support (MHS-1)

No additional instructions.
### Mental Health and Social Support (MHS-2)

#### Showcard #12

<table>
<thead>
<tr>
<th>Statement</th>
<th>rarely or none of the time (less than 1 day)</th>
<th>some or a little of the time (1–2 days)</th>
<th>occasionally or a moderate amount of time (3–4 days)</th>
<th>most or all of the time (5–7 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. I talked less than usual.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>15. People were unfriendly.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>16. I enjoyed life.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>17. I had crying spells.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18. I felt sad.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19. I felt that people disliked me.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>20. I could not “get going.”</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

We are interested in how you feel about the following statements. Listen to each statement carefully. Indicate how you have felt about each statement in the past 4 weeks.

#### Showcard #13

<table>
<thead>
<tr>
<th>Statement</th>
<th>strongly disagree</th>
<th>disagree</th>
<th>neutral</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. There is a special person who is around when I am in need.</td>
<td>☐</td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>22. There is a special person with whom I can share my joys and sorrows.</td>
<td>☐</td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>23. There is a special person in my life who cares about my feelings.</td>
<td>☐</td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Mental Health and Social Support (MHS-2)

No additional instructions.
**Showcard #13**

<table>
<thead>
<tr>
<th>Question</th>
<th>strongly disagree</th>
<th>disagree</th>
<th>neutral</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>24. My family really tries to help me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. I can talk about my problems with my family.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. My family is willing to help me make decisions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. My friends really try to help me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. I can talk about my problems with my friends.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. I have friends with whom I can share my joys and sorrow.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mental Health and Social Support (MHS-3)

No additional instructions.
Now, we are going to ask you some questions about drugs and alcohol that you may have taken in the past 3 months.

1. Have you used any drugs in the past 3 months? This includes anything you may have smoked, injected, inhaled, swallowed, huffed, or snorted. ...............

   a. have you used ___?
   b. did you ever inject ___?
   c. on about how many days did you use ___?
   d. did you ever use this drug within 2 hours before, after, or during sex?

2. Marijuana/ weed, hashish
   yes no don't know
   Go to item 3.

3. Inhaled nitrites/ poppers/ ampules
   yes no don't know
   Go to item 4.

4. Rock cocaine/ crack
   yes no don't know
   Go to item 5.

5. Powder cocaine/ coke
   yes no don't know
   Go to item 6.

6. Anabolic steroids
   yes no don't know
   Go to item 7 on page 2.
Substance and Alcohol Use (SAU-1)

Item-specific instructions:

- **Item 1:** Interviewer may read from the list of drugs in item 2 to ensure that the participant has not used any substance before skipping out of items 2 through 27.

- **Items 2–22:** Read every drug listed unless it is specifically indicated as not available in your country. Only mark N/A if your country is designated.
<table>
<thead>
<tr>
<th>Substance and Alcohol Use</th>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

**In the last 3 months...**

<table>
<thead>
<tr>
<th>Item</th>
<th>Substance Used</th>
<th>Injection</th>
<th>Days Used</th>
<th>Before/During Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Female hormones (not including birth control)</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
<tr>
<td>8. Methamphetamine/crystal/tina/speed</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
<tr>
<td>9. Heroin</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
<tr>
<td>10. Opium or codeine or tramadol</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
<tr>
<td>11. MDMA/ecstasy/E</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
<tr>
<td>12. GHB/GBL or BD/G</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
<td>yes no</td>
</tr>
</tbody>
</table>

No data recorded on this page.
Substance and Alcohol Use (SAU-2)

Item-specific Instructions:

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

- **Items 2–22:** Read every drug listed unless it is specifically indicated as not available in your country. Only mark N/A if your country is designated.
**Substance and Alcohol Use (SAU-3)**

**Participant ID**

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

In the last 3 months...

<table>
<thead>
<tr>
<th></th>
<th>a. have you used ___?</th>
<th>b. did you ever inject ___?</th>
<th>c. on about how many days did you use ___?</th>
<th>d. did you ever use this drug within 2 hours before, after, or during sex?</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>PCP/dust/dipper (alone or with marijuana)</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 14.</td>
</tr>
<tr>
<td>N/A</td>
<td>Shrooms/acid/LSD/tinner</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td>(Zambia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 15.</td>
</tr>
<tr>
<td>15.</td>
<td>Viagra/Cialis/Levitra (prescribed or not)</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 16.</td>
</tr>
<tr>
<td>N/A</td>
<td>Non-prescribed Vicodin</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td>(Thailand, Zambia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 17.</td>
</tr>
<tr>
<td>N/A</td>
<td>Non-prescribed Oxycontin</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td>(Thailand)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 18.</td>
</tr>
<tr>
<td>18.</td>
<td>Benzine/Petrol</td>
<td>yes</td>
<td>no</td>
<td>don't know</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Go to item 19 on page 4.</td>
</tr>
</tbody>
</table>

☐☐☐☐ X 13-NOV-09

N:\hivnet\forms\PTN_063\forms\p063_substance_use.fm
Substance and Alcohol Use (SAU-3)

Item-specific Instructions:

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

- **Items 2–22**: Read every drug listed unless it is specifically indicated as not available in your country. Only mark N/A if your country is designated.
### Substance and Alcohol Use (SAU-4)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Last 3 Months</th>
<th>a. Have you used ___?</th>
<th>b. Did you ever inject ___?</th>
<th>c. On about how many days did you use ___?</th>
<th>d. Did you ever use this drug within 2 hours before, after, or during sex?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glue</td>
<td></td>
<td>yes no don't know</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-hour</td>
<td></td>
<td>yes no don't know</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bostik</td>
<td></td>
<td>yes no don't know</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketamine</td>
<td></td>
<td>yes no don't know</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>yes no don't know</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Local language:

<table>
<thead>
<tr>
<th>Language</th>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No data recorded on this page.

Go to item 24 on page 5.
Substance and Alcohol Use (SAU-4)

Item-specific Instructions:

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

- **Items 2–22**: Read every drug listed unless it is specifically indicated as not available in your country. Only mark N/A if your country is designated.

- **Item 23**: If no other drug is specified, mark the “N/A” box.

If the “other drug, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
### Substance and Alcohol Use (SAU-5)

**Participant ID**

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

**Substance and Alcohol Use**

| Visit Code | 1 | Page 5 of 7 |

#### In the **last 3 months**...

<table>
<thead>
<tr>
<th></th>
<th>a. have you used ___?</th>
<th>b. did you ever inject ___?</th>
<th>c. on about how many <strong>days</strong> did you use ___?</th>
<th>d. did you ever use this drug within 2 hours before, after, or during sex?</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>Other drug, specify:</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td>Local language:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>English:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Other drug, specify:</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td>Local language:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>English:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Go to item 25.**

26. In the **past 3 months** have you ever thought that your drug use has been a problem? ................................................................. yes no

27. In the **past 3 months** have your friends, family, sexual partner(s), or others thought that your drug use has been a problem? ................. yes no don't know

---

No data recorded on this page.
Substance and Alcohol Use (SAU-5)

Item-specific Instructions:

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

- **Items 24 and 25:** If no other drug is specified, mark the “N/A” box.

  If the “other drug, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
Now we will ask you some questions about alcohol use.

28. In the **last 3 months**, have you used alcohol? ..................................................

28a. On about how many **days** did you use alcohol? .................................

28b. Did you use alcohol within 2 hours before, after, or during sex?

29. How often do you have a drink containing alcohol?
   **Showcard #14**
   - [ ] never  \(\rightarrow\) **If never, go to item 37 on page 7.**
   - [ ] monthly or less
   - [ ] 2 to 4 times a month
   - [ ] 2 to 3 times a week
   - [ ] 4 or more times a week

30. How many drinks containing alcohol do you have on a typical day when you are drinking?
   **Showcard #15**
   - [ ] 1 or 2
   - [ ] 3 or 4
   - [ ] 5 or 6
   - [ ] 7, 8, or 9
   - [ ] 10 or more

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

   **Showcard #16**
   - [ ] never
   - [ ] less than monthly
   - [ ] monthly
   - [ ] weekly
   - [ ] daily or almost daily

   **If “never” AND the response to item 30 is “1 or 2,” go to item 37 on page 7.**
Substance and Alcohol Use (SAU-6)

No additional instructions.
32. How often during the last 3 months have you found that you were not able to stop drinking once you had started? ..............

33. How often during the last 3 months have you failed to do what was normally expected from you because of drinking?

34. How often during the last 3 months have you needed a first drink in the morning to get yourself going after a heavy drinking session? ..............................................

35. How often during the last 3 months have you had a feeling of guilt or remorse after drinking? ..............................................

36. How often during the last 3 months have you been unable to remember what happened the night before because you had been drinking? ..............................................

37. In the past 3 months have you or someone else ever been injured as a result of your drinking? .................................................................

38. In the last 3 months, has a relative, friend, a doctor, or another health worker ever been concerned about your drinking or suggested you cut down? .................................................................
Substance and Alcohol Use (SAU-7)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID, Visit Code, and the Staff Initials/Date.
Now we are going to ask you about your use of antiretroviral drugs (ARV) for HIV.

1. Have you ever taken ARV for your HIV? This does not include vitamins, herbs, or other medications that you may take to feel better. ......................................

1a. When did you first start taking ARV? .......................................................

1b. In the last 3 months, have you taken ARV? ...........................................

Some people with HIV have many pills or medications to take at different times during the day. Many people find it hard to always remember to take these, for example:

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to all the instructions, such as “with food,” “on an empty stomach,” “every 8 hours,” or “with plenty of fluids.”
- Some people decide to skip pills to avoid side effects or to just not take pills that day.

We are trying to understand the challenges people with HIV face when trying to take all their pills or medication. Don’t worry about telling us if you don’t take all your pills or medication. We would like to know what is really happening, not just what you think we want to hear.
ARV Adherence (AA-1)

No additional instructions.
2. Thinking about the last 3 months, on average, how would you rate your ability to take all your ARV as your doctor prescribed? *Showcard #5*

- [ ] very poor
- [ ] poor
- [ ] fair
- [ ] good
- [ ] very good
- [ ] excellent

3. When was the last time you missed taking any of your ARV?

- [ ] within past week
- [ ] 1–2 weeks ago
- [ ] more than 2 to 4 weeks ago
- [ ] more than 1 to 2 months ago
- [ ] more than 2 months ago
- [ ] never missed taking ARV

4. In the last 3 months, please indicate the reasons you have not taken all your ARV. *Mark all that apply. (Note: Item 4 continues on page 3.)*

- [ ] 4a. you couldn’t pay for the bills
- [ ] 4b. you wanted to avoid side effects
- [ ] 4c. you could not follow the dietary instructions
- [ ] 4d. you were sharing your ARV with others
- [ ] 4e. your religious beliefs prohibited it

---

End of form. Do not fax page 3 to SCHARP DataFax.
ARV Adherence (AA-2)

No additional instructions.
4. In the **last 3 months**, please indicate the reasons you have not taken all your ARV. **Mark all that apply.**

- [ ] 4f. you did not fully understand the regimen and its requirements
- [ ] 4g. you were traveling away from home
- [ ] 4h. you had transportation problems getting to the clinic
- [ ] 4i. your medications were lost or stolen
- [ ] 4j. you had a negative experience which you believe was related to the medication
- [ ] 4k. you forgot
- [ ] 4l. you ran out of medication
- [ ] 4m. you were too busy doing other things
- [ ] 4n. you were tired of taking so many pills
- [ ] 4o. other illness or health problems got in your way
- [ ] 4p. you feared stigmatization (fear of what others may say or discover about your HIV status)
- [ ] 4q. you were too ill to attend clinic to collect medications
- [ ] 4r. you don’t believe they really work
- [ ] 4s. the clinic or doctor did not have any medication available
- [ ] 4t. other, specify:  
  **Local Language:** ________________________________  
  **English:** ________________________________
ARV Adherence (AA-3)

Item-specific Instructions:

- **Item 4t**: If the “other, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
<table>
<thead>
<tr>
<th>Specimen Collection Date</th>
<th>N/A</th>
<th>dd</th>
<th>MMM</th>
<th>yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Total lymphocytes</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Absolute CD4+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. HIV RNA PCR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>prior to ARV Initiation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Code of method used:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b. Is result detectable?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. HIV RNA PCR of Plasma - Current</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4a. Code of method used:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4b. Is result detectable?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CD4/Viral Load History (CDV-1)

**Purpose:** The purpose of this form is to collect CD4 and viral load history from the participant’s HIV clinic records.

**General Information/Instructions:** This form is completed by medical record review. Refer to the Clinical Procedures section in the Study Specific Procedures (SSP) for instructions on conducting a medical record review.

- **Results Reporting**
  - If the lab did not produce test results in the units used on this form, the results must be converted before the CRF is faxed to SCHARP. Refer to the Data Management section of the 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 lab did not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

**Item-specific instructions:**

- **N/A:** Mark the “N/A” box if this data was unavailable after conducting a medical record review or if the participant has never initiated ARV treatment.
- **Items 1 and 2:** If more than one test result is available, use the most recent specimen collection date and results.
- **Item 3:** If more than one HIV RNA PCR is available, please use the most recent one prior to ARV initiation. If this information was already reported at a prior visit, mark the “N/A” box.
- **Items 3 and 4:** Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record “0003100” in the value. For any value, if the value reported is < 400 copies, mark the less than (<) box and record “0000400” in the value.
- **Item 4:** To be considered “current,” the HIV RNA PCR must be within 6 months of today’s date with no ARV initiation in the interim.
- **Items 3a and 4a:** Use the table below to record the code of the method of HIV RNA PCA used. If code 9 (other) is used, record the method in the space provided in the local language, as applicable. Record in English prior to faxing.

<table>
<thead>
<tr>
<th>Code</th>
<th>Method</th>
<th>Lower limit–Upper limit (copies/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Roche AMPLICOR Monitor - standard</td>
<td>400–750,000</td>
</tr>
<tr>
<td>2</td>
<td>Roche AMPLICOR Monitor - ultra</td>
<td>50–100,000</td>
</tr>
<tr>
<td>3</td>
<td>Abbott Real-time HIV</td>
<td>40–10,000,000</td>
</tr>
<tr>
<td>4</td>
<td>Roche COBAS Ampliprep/COBAS Taqman HIV</td>
<td>48–10,000,000</td>
</tr>
<tr>
<td>5</td>
<td>Versant HIV 3.0 (Branch DNA assay by Chiron/Bayer)</td>
<td>50–500,000</td>
</tr>
<tr>
<td>9</td>
<td>Other (specify in space provided)</td>
<td></td>
</tr>
</tbody>
</table>
### 4c. Why does this participant have a detectable plasma viral load? *Mark all that apply.*

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 4c1.</td>
<td>recent system illness</td>
</tr>
<tr>
<td>☐ 4c2.</td>
<td>vaccination</td>
</tr>
<tr>
<td>☐ 4c3.</td>
<td>obvious nonadherence to ARV</td>
</tr>
<tr>
<td>☐ 4c4.</td>
<td>treatment-naive</td>
</tr>
<tr>
<td>☐ 4c5.</td>
<td>on ARV &lt; 24 weeks</td>
</tr>
<tr>
<td>☐ 4c6.</td>
<td>newly confirmed virologic failure</td>
</tr>
<tr>
<td>☐ 4c7.</td>
<td>ongoing virologic failure</td>
</tr>
</tbody>
</table>

**Date confirmed:**

- dd
- MMM
- yy

**Local Language:**

- ________________________________

**English:**

- ________________________________

**Comments:**

**Local Language:**

- ________________________________

**English:**

- ________________________________

13-NOV-09

- ☒ Language
- ☒ Staff Initials / Date
CD4/Viral Load History (CDV-2)

Item-specific instructions:

- **Item 4c8:** If the “other, specify” box is marked, record response in the local language, as applicable. Record in English prior to faxing.

- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
1. **SYPHILIS SEROLOGY**  
   **non-reactive**  
   reactive  
   
   1a. Screening test (RPR) ...........  
   If non-reactive, end of form.  
   
   1a1. Syphilis titer ...........  
   1:  
   
   1b. Confirmatory test ............  
   (TPHA, MHA-TP, FTA, or TPPA)  
   negative  
   positive  
   If negative, end of form.  

**Item 2 is for Enrollment only. For follow-up visits, go to item 3.**  

2. Has the participant ever been treated for syphilis? ...........  
   yes  
   no  
   don’t know  
   
   2a. How was this treatment reported? .......................  
   self-report  
   documentation  
   Go to item 4.  

**Item 3 is for follow-up visits only. For Enrollment Visit, go to item 4.**  

3. Since the last visit, has the participant been treated for syphilis?  
   yes  
   no  
   don’t know  
   
   3a. How was this treatment reported? .......................  
   self-report  
   documentation  
   Go to item 4.  

4. Diagnosis:  
   new active infection  
   treated infection  
   indeterminate response  

Comments:  
Local Language:  
English:  

N:\hivnet\forms\PTN_063\forms\p063_syphilis_test.fm
Syphilis Test Results (STR-1)

**General Information/Instructions:** Complete this form at the Enrollment Visit, 6-month Follow-up Visit, and 12-month Follow-up Visit. Record test results as they become available from the local lab. Fax this form to SCHARP DataFax when the final test results are available and recorded.

**Results Reporting**
- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.

**Item-specific instructions:**
- **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. Record a complete date.
- **Items 2 and 3:** If medical records are not available, this question should be asked directly to the participant during the study visit.
- **Item 4:** This diagnosis is based on the answers to items 1b and 2, or the decision of the syphilis committee. Refer to the Clinical Procedures section in the Study Specific Procedures (SSP). Diagnosis can be changed and refaxed if new information becomes available.
- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
<table>
<thead>
<tr>
<th>Specimen Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Code: SS-1</td>
</tr>
<tr>
<td>Site Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alternate Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>dd</td>
</tr>
</tbody>
</table>

1. Rectal swab ............ | not required | stored | not stored | Reason (local language): |
| | | | | |

2. Vaginal swab ............ | not required | stored | not stored | Reason (local language): |
| (female only) | | | |

3. Urine .................... | not required | stored | not stored | Reason (local language): |

4. Plasma .................... | not required | stored | not stored | Reason (local language): |

Comments: **Local Language:** ____________________________  **English:** ____________________________
Specimen Storage (SS-1)

General Information/Instruction: Complete this form at the Enrollment Visit, 6-month Follow-up Visit, and 12-month Follow-up Visit.

Item-specific instructions:

• Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

• Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.

• Items 1–4: If the “not stored” box is marked, record reason in the local language, as applicable. Record in English prior to faxing.

• Item 2: Mark “not required” for male participants only. For any problems with collection and/or handling, mark “not stored” and specify the reason.

• Comments: Record comments in the local language, as applicable. Record in English prior to faxing.
The following questions are about any sexual abuse or violence you may have experienced in your life

1. In the past 3 months, did a sexual partner (including a current or former spouse, boy/girlfriend, or other sexual partner) hit, slap, kick, push, shove, or otherwise physically hurt you? .......................................................... yes no

2. In the past 3 months, did anyone (including a current or former spouse, boy/girlfriend, or other sexual partner) try to force you to have sex when you didn’t want to? ......................... yes no

We are now going to ask you about your health and healthcare.

3. In the past 3 months (including this visit), have you been told by a doctor, nurse, or other medical provider that you have any of the following?

   yes no
   3a. Syphilis
   3b. Gonorrhea
   3c. Chlamydia
   3d. Herpes simplex
   3e. Hepatitis A
   3f. Hepatitis B
   3g. Hepatitis C
   3h. Trichomonas
   3i. Other STI, specify: Local Language: ____________ English: ____________  

   If yes to any, complete Medical Event Log.

Items 3j–4 are for female participants only. Male participants go to item 5 on page 2.

   yes no
   3j. Vaginitis
   3k. Cervicitis
   3l. Pelvic Inflammatory Disease

   If yes to any, complete Medical Event Log.

4. Are you currently pregnant? .......................................................... yes no
Follow-up (FU-1)

Item-specific Instructions:

- **Item 3i:** Do not include vaginitis, cervicitis, or pelvic inflammatory disease. These items are captured in items 3j, 3k, and 3l for female participants.

  If the “Other STI, specify” box is marked, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.
5. During the **last 3 months**, including today, have you had any of the following symptoms?

   - yes  no
   - □  □  5a. unusual genital or anal/rectal discharge
   - □  □  5b. unusual genital or anal/rectal pain
   - □  □  5c. a sore or ulcer in your genital or anal/rectal area

6. In the **past 3 months**, during clinic visits for HIV-related care, have you ever received information about preventing HIV transmission and how you can stay healthy?

   **Showcard #2**

   - □  never
   - □  only one time
   - □  once in awhile
   - □  most of the time
   - □  at every visit
Follow-up (FU-2)

No additional instructions.
Medical Event Log (MEL-1)

1. At which visit was this form completed? ...........................................

2. Record diagnosis code for this event: ............................................

2a. Specify:

   Local Language: __________________________________________________

   English: __________________________________________________________

3. Diagnosis type: .................................................................

4. Date of diagnosis: ..............................................................

5. Was the participant treated? .................................................

6. How was this event identified? ..............................................

   diagnosis by study staff (STIs only)
   participant self-report only
   participant self-report confirmed by medical record review
   medical record review only

Comments: 

Local Language: __________________________________________________

English: __________________________________________________________

Language: 0 1
Staff Initials / Date: 13-NOV-09
Medical Event Log (MEL-1)

**Purpose:** The purpose of this form is to document the participant’s comorbidities. For the definition of a medical event, refer to Clinical Procedures section of the Study Specific Procedures (SSP).

**General Information/Instructions:** A medical event can be identified by study staff diagnosis, participant report, and/or during a medical record review. Refer to Clinical Procedures section of the SSP for instructions on conducting a medical review.

**Item-specific instructions:**

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

- **Item 2 Diagnosis Code:** Refer to the Medical Event Code List in the Clinical Procedures section of the SSP. If a diagnosis is later found to be incorrect, draw a line through the diagnosis code and record the correct code.

- **Item 2a:** Indicate the specific type and/or physical location of the event. Record the diagnosis in the local language, as applicable. Record in English prior to faxing.

- **Item 3:** Recurrent is defined as an event that recurs after it has clinically resolved after treatment.

- **Item 4:** Date of diagnosis is the date on which the confirmed or probable diagnosis was made by a doctor, nurse, or other medical provider. If a diagnosis is later found to be incorrect, draw a line through the diagnosis date and record the date of the correct diagnosis. At a minimum, month and year are required.

- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
### ARV History Log (AHL-1)

**Participant ID**

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

**ARV History Log**

#### 1. ARV Code

<table>
<thead>
<tr>
<th>ARV Code</th>
<th>Local language</th>
<th>English</th>
</tr>
</thead>
</table>

#### Frequency

- prn
- qd
- tid
- qhs
- qxh

- other, specify: Local language: __________

#### ARV use confirmed by:

- Participant self-report
- Medical record review

#### Staff Initials/Log Entry Date

**Date Started**

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

**Date Stopped**

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

**OR**

- Continuing at end of study

**Date Started**

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

**Date Stopped**

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

**Staff Initials/Log Entry Date**

#### 2. ARV Code

<table>
<thead>
<tr>
<th>ARV Code</th>
<th>Local language</th>
<th>English</th>
</tr>
</thead>
</table>

#### Frequency

- prn
- qd
- tid
- qhs
- qxh

- other, specify: Local language: __________

#### ARV use confirmed by:

- Participant self-report
- Medical record review

#### Staff Initials/Log Entry Date

**Date Started**

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

**Date Stopped**

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

**OR**

- Continuing at end of study

**Date Started**

<table>
<thead>
<tr>
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</table>

**Date Stopped**

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

#### 3. ARV Code

<table>
<thead>
<tr>
<th>ARV Code</th>
<th>Local language</th>
<th>English</th>
</tr>
</thead>
</table>

#### Frequency

- prn
- qd
- tid
- qhs
- qxh

- other, specify: Local language: __________

#### ARV use confirmed by:

- Participant self-report
- Medical record review

#### Staff Initials/Log Entry Date

**Date Started**

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

**Date Stopped**

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

**OR**

- Continuing at end of study

**Date Started**

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

**Date Stopped**

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

#### 4. ARV Code

<table>
<thead>
<tr>
<th>ARV Code</th>
<th>Local language</th>
<th>English</th>
</tr>
</thead>
</table>

#### Frequency

- prn
- qd
- tid
- qhs
- qxh

- other, specify: Local language: __________

#### ARV use confirmed by:

- Participant self-report
- Medical record review

#### Staff Initials/Log Entry Date

**Date Started**

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

**Date Stopped**

<table>
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<tr>
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</tr>
</thead>
</table>

**OR**

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**Date Started**

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

**Date Stopped**

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

#### 13-NOV-09

**Language**

N:\hivnet\forms\PTN_063\forms\p063_arv_history_log.fm
ARV History Log (AHL-1)

**Purpose:** The purpose of this form is to document the participant’s antiretroviral drug use history.

**General Information/Instructions:** This form can be completed by participant report or a medical record review. Refer to the Clinical Procedures section of the Study Specific Procedures (SSP) for instructions on conducting a medical record review.

When to fax this form:
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

**Item-specific instructions:**
- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any ARV History Log pages after faxing, unless instructed by SCHARP.
- **No ARV use ever reported:** Mark this box at the Termination visit if no ARV drugs were ever reported being taken by the participant.
- **ARV Code:** Refer to the ARV Code List in the Clinical Procedures section of the SSP. For combination medications, record the first three main active ingredients. If ARV Code is “999/other,” record the generic name in the local language, as applicable. Record in English prior to faxing.
- **Date Started:** 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 are required.
- **Frequency:** Below is a list of common frequency abbreviations. If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.

<table>
<thead>
<tr>
<th>prn</th>
<th>as needed</th>
<th>qd</th>
<th>every day</th>
<th>tid</th>
<th>three times daily</th>
<th>qhs</th>
<th>at bedtime</th>
</tr>
</thead>
<tbody>
<tr>
<td>once</td>
<td>one time</td>
<td>bid</td>
<td>twice daily</td>
<td>qid</td>
<td>four times daily</td>
<td>qxh</td>
<td>every x hours</td>
</tr>
</tbody>
</table>
Social Impact Log (SIL-1)

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:


2. Onset date: ............................................

3. Reported at visit: ....................................

4. Social impact code: ................................

Social Impact Codes: See back for definitions.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Personal Relationships</td>
</tr>
<tr>
<td>02</td>
<td>Travel/Immigration</td>
</tr>
<tr>
<td>03</td>
<td>Employment</td>
</tr>
<tr>
<td>04</td>
<td>Education</td>
</tr>
<tr>
<td>05</td>
<td>Medical/Dental</td>
</tr>
<tr>
<td>06</td>
<td>Health Insurance</td>
</tr>
<tr>
<td>07</td>
<td>Life Insurance</td>
</tr>
<tr>
<td>08</td>
<td>Housing</td>
</tr>
<tr>
<td>09</td>
<td>Military/Other</td>
</tr>
<tr>
<td>10</td>
<td>Government Agency</td>
</tr>
</tbody>
</table>

Comments:

Local Language: 


English:


13-NOV-09

Note: Number pages sequentially (01, 02, 03) for each participant
Social Impact Log (SIL-1)

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

**Item-specific instructions:**

- **Item 1:** Describe the social impact in the local language, as applicable. Record in English prior to faxing.
- **Item 3:** If a participant reports a negative social impact outside of a regularly scheduled visit, complete this log and the Interim Visit form and enter the same interim visit code on both forms.
- **Item 4:** Use the following definitions to code the social impact:

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Personal Relationships Had negative experiences with family, friends, significant others, or sex partners because of participation in this study.</td>
</tr>
<tr>
<td>02</td>
<td>Travel/Immigration Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.</td>
</tr>
<tr>
<td>03</td>
<td>Employment Been turned down for a new job, lost a job, or experienced other problems at work.</td>
</tr>
<tr>
<td>04</td>
<td>Education Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.</td>
</tr>
<tr>
<td>05</td>
<td>Medical/Dental Been refused medical or dental treatment, or treated negatively by a health care provider.</td>
</tr>
<tr>
<td>06</td>
<td>Health Insurance Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.</td>
</tr>
<tr>
<td>07</td>
<td>Life Insurance Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.</td>
</tr>
<tr>
<td>08</td>
<td>Housing Had trouble getting or keeping housing, or had other problems related to housing.</td>
</tr>
<tr>
<td>09</td>
<td>Military/Other Government Agency Had a problem with the military or any other government agencies.</td>
</tr>
<tr>
<td>10</td>
<td>Other Had other problems not covered in the codes above.</td>
</tr>
</tbody>
</table>

- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
1. What is the reason for this interim visit? *Mark all that apply.*

- [ ] 1a. to report a social impact
- [ ] 1b. STI testing
- [ ] 1c. other, specify: _____________________________________________

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

- [ ] 2a. Social Impact Log
- [ ] 2b. Syphilis Test Results
- [ ] 2c. Medical Event Log
- [ ] 2d. other, specify: _____________________________________________

Comments:  

Local Language: __________________________ English: __________________________

13-NOV-09
Interim Visit (IV-1)

**Purpose:** Complete this form when an interim visit occurs during study follow-up.

**General Information/Instructions:** Any other forms completed for this visit must have the same Visit Code as this Interim Visit form.

**Item-specific Instructions:**
- **Items 1c and 2d:** If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
Missed Visit (MV-1)

1. Target Visit Date: 

2. Reason visit was missed. Mark only one.

- 2a. unable to contact participant
- 2b. unable to schedule appointment(s) within allowable window
- 2c. participant refused visit
- 2d. participant incarcerated
- 2e. participant admitted to a health care facility
- 2f. participant withdrew from the study → Complete a Termination form.
- 2g. participant deceased → Complete a Termination form.
- 2h. other, specify:

Local Language:                           English:                           

Comments:

Local Language:                           English:  

Language: 01  Staff Initials / Date: 13-NOV-09
Missed Visit (MV-1)

**Purpose:** 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).

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

**Item-specific Instructions:**

- **Item 1:** Record the target date of the visit. A complete date is required.
- **Item 2:** Record the reason the participant missed the visit.
- **Item 2h:** If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.
- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
1. What is the highest visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax? ............................................

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

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

   3a. Social Impact Log .........................

   3b. ARV History Log ............................

   3c. Medical Event Log ..........................

Comments:

Local Language: 

English: 

Language: 

Staff Initials / Date: 01

0 1

13-NOV-09
End of Study Inventory (ESI-1)

**Purpose:** This form is used to confirm that SCHARP has received all study data for a given participant.

**General Information/Instructions:** Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).

**Item-specific instructions:**

- **Form Completion Date:** A complete date is 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 3c:** Record the highest page number of the Medical Events Log submitted for this participant, even if that page was marked for deletion.
- **Comments:** Record comments in the local language, as applicable. Record in English prior to faxing.
<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

**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
   - [ ] 2b. death, *indicate date and cause if known*
     - 2b1. date of death dd  MMM  yy  OR  [ ] date unknown
     - 2b2. cause of death ___________________________ OR  [ ] cause unknown
   - [ ] 2c. participant refused further participation, specify: *NOT APPLICABLE FOR THIS PROTOCOL.*
   - [ ] 2d. participant relocated, no follow-up planned
   - [ ] 2e. investigator decision, specify: *NOT APPLICABLE FOR THIS PROTOCOL.*
   - [ ] 2f. unable to contact participant
   - [ ] 2g. HIV infection
   - [ ] 2h. inappropriate enrollment
   - [ ] 2i. invalid ID due to duplicate screening/enrollment
   - [ ] 2j. other, specify: *Local Language: ___________________________  English: ___________________________

3. **Early Study Closure**

   - [ ] 2l. early study closure

**Comments:**  
*Local Language: ___________________________  English: ___________________________*
Termination (TM-1)

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

Item-specific Instructions:

• **Item 1**: A complete date is required.

• **Item 2**: Mark only the primary reason for termination.
  - **Item 2a**: Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
  - **Item 2b1**: At a minimum, the month and year are required.
  - **Item 2l**: Early study closure: Only mark 2l when instructed by SCHARP.

• **Items 2cm, 2f, and 2k**: If the “other, specify” box is marked, record the response in the local language, as applicable. Record in English prior to faxing.

• **Comments**: Record comments in the local language, as applicable. Record in English prior to faxing.