

MTN 015 (143)

DEM-1 (001)

Participant ID

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

Demographics

Visit Date

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

1. What is the participant's date of birth?
 NOT APPLICABLE FOR THIS PROTOCOL

2. What is the participant's gender? male female

3. Do you earn an income of your own? yes no **→ If no, go to item 4.**

3a. How do you earn your income? *Mark all that apply.*

- formal employment
- self-employed
- other, specify: _____

4. What is your highest level of education?

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

5. How many children have you given birth to who were alive at birth?

yes no

6. Do you own your home?

7. How many rooms are in your household?

29-FEB-08

0	1
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Language

Staff Initials / Date

Demographics (DEM-1)

Purpose: This form is used to document general demographic information.

General Information/Instructions: This form is completed once for each participant, at the Screening/ Enrollment visit.

Item-specific Instructions:

- **Item 2:** This item has already been completed based on the expected study population. Please skip this item.
- **Item 3a:** Record whether the participant's source(s) of income are from formal employment (e.g., shop clerk, farmer, seamstress, teacher), self-employment (e.g., shop owner, artist, restaurant owner), or other type of employment.
- **Item 5:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 6:** Record whether or not the participant or someone in her family owns the home where she lives.

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband/partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 13:** Record whether or not the participant's husband/partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.

ACASI Tracking (ACT-1)	
Purpose:	This form is used to document participant completion of Audio Computer-assisted Self Interview (ACASI) computerized questionnaires after questionnaires have the text read at baseline or during follow-up.
General Information/ Instructions:	Complete this form at the End Period Visits, and the early termination visit, if applicable.
Item-specific Instructions:	
Item 3a:	If there were any unusual details related to the ACASI questionnaire administration or completion, or if ACASI was required but not done, write a brief explanation here. This item also may be used to document corrections to the ACASI key field data, such as Participant ID (PTID), Visit Code, or date completed.



MTN 015 (143)

ASA-1 (042)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk fields.

Visit Date

Visit Date form with dd, MMM, and yy fields.

Acute Seroconversion Assessment

Specimen Collection Date

Specimen Collection Date dd MMM yy

- 1. Last negative HIV antibody test:
2. First positive HIV antibody test:
3. First positive Western Blot HIV test:

4. Any known detectable viral load prior to today:

Form for question 4 with Not done/Not collected checkbox and Specimen Collection Date fields.

Form for question 4a with comparison operators (>, =, <) and viral copies/mL field.

Form for question 5 with Not done/Not collected checkbox and Specimen Collection Date fields.

5. Any known CD4+ result prior to today:

Form for question 5a with Absolute CD4+ field in cells/mm3.

Form for question 5a1 with CD4+ % field and not available option.

Comments: _____

Form fields for date 29-FEB-08

Acute Seroconversion Assessment (ASA-1)

Purpose: This form is used to document information about the participant's HIV seroconversion.

General Information/Instructions: This form is completed once for each participant, at the Screening/ Enrollment visit.

Item-specific Instructions:

- **Item 1:** Review the participant's parent protocol records and record the date of her most recent negative HIV antibody test result(s) documenting her status as HIV negative. This date should be before the date recorded in item 2.
- **Item 2:** Record the specimen collection date of the participant's first positive HIV antibody test result used to document her HIV seroconversion per the parent protocol's follow-up HIV testing algorithm.
- **Item 3:** Record the specimen collection date of the participant's first positive HIV Western Blot result used to document her HIV seroconversion per the parent protocol's follow-up HIV testing algorithm.
- **Item 4:** Record any known detectable HIV viral load result collected prior to this visit. If multiple viral load results prior to today are available, record the result of the most recent specimen. If no viral load results are known, mark the "Not done/Not collected" box. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
- **Item 5a:** Record any known absolute CD4+ result collected prior to this visit. If multiple absolute CD4+ results prior to today are available, record the result of the most recent specimen. If no previous absolute CD4+ results are known, mark the "Not done/Not collected" box.
- **Item 5a1:** If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 5a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.



MTN 015 (143)

MTP-1 (060)

Participant ID

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

Microbicide Trial Participation

Visit Date

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

1. Parent protocol number:.....

2. Parent protocol Participant ID:

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

3. Is the participant completing a parent protocol visit at this MTN 015 visit?

yes no

 → **If no, go to item 4.**

visit code

3a. Visit code of parent protocol visit completed today:

4. Was the participant enrolled in any other MTN study (including HPTN 035) in addition to the parent protocol recorded in item 1?

yes no

 → **If no, go to item 5.**

4a. MTN protocol number(s):

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

4b. MTN protocol Participant ID(s):

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

5. Has the participant ever been enrolled in a non-MTN microbicide clinical trial?.....

yes no

 → **If no, end of form.**

5a. Specify: _____

Comments: _____

Microbicide Trial Participation (MTP-1)

Purpose: To document the participant's parent protocol and her previous enrollment in other microbicide clinical trials.

General Information/Instructions: This form is completed only once for each participant, at the Screening/Enrollment visit.

Item-specific Instructions:

- **Items 3 and 3a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 3 "yes" and in 3a, record the visit code (regular or interim) of the parent protocol visit completed on this date.
- **Items 4a and 4b:** For response boxes that are not needed, leave the boxes blank. For example, if only one MTN protocol number is recorded in item 4a, leave the second set of MTN protocol number boxes blank.
- **Item 5a:** Specify the non-MTN microbicide study network or group, study name, and phase of study on the lines provided (e.g., "Pop Council, Carraguard Phase III").



MTN 015 (143)

ENR-1 (070)

Participant ID

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

Enrollment

Visit Date

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

1. Does this participant meet all eligibility criteria? *yes* *no* → **If no, participant is not eligible. End of form. Do not fax to SCHARP DataFax.**

2. Date study informed consent signed or thumbprinted:

dd *MMM* *yy*

3. Did the participant consent to storage and future research testing of the following samples?

3a. blood *yes* *no*

3b. vaginal fluid *yes* *no*

4. Date of seroconversion per parent protocol:

dd *MMM* *yy*

5. Is participant enrolling as a non-ART or ART participant? *non-ART* *ART* → **If ART, complete ART Enrollment, ART Initiation Information, Antiretroviral Treatment Regimen Log. End of form.**

- 5a. Reason why the participant reports not having started ART:
- participant is not receiving medical care for HIV
 - ART not recommended by the participant's health care provider/clinic
 - ART recommended but not started because of cost
 - ART recommended but not started because participant does not want to take it
 - other reason, specify: _____
 - _____
 - _____

Comments: _____

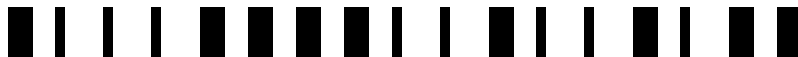
Enrollment (ENR-1)

Purpose: This form is used to document participant enrollment into the study.

General Information/Instructions: This form is completed only once for each participant, at the Screening/Enrollment visit.

Item-specific Instructions:

- **Item 4:** Record the date of identification of HIV seroconversion in the parent protocol. For participants whose parent protocol is HPTN 035, transcribe the Sample 1 specimen collection date recorded on the HIV Test Results form documenting a final HIV status of “positive.”
- **Item 5a:** Mark the reason that best explains why the participant has never used ART.



MTN 015 (143)

AEN-1 (075)

Participant ID

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

ART Enrollment

Visit Date

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

1. Date of ART initiation:

dd *MMM* *yy*

1a. Is this date known or estimated?..... *known* *estimated*

2. Is the date of ART initiation within 24 months of date of seroconversion? *yes* *no*

→ ***If yes, the Follow-up Behavioral Assessment is required at post-ART months 3, 12, and 24.***

Comments: _____

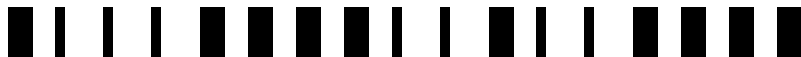
ART Enrollment (AEN-1)

Purpose: This form is used to document those participants who enroll in the study after initiation of ART or who initiate ART during the study. Completion of this form indicates the participant is being followed using the ART visit schedule/visit calendar.

General Information/Instructions: This form is completed only once for each participant, and is completed at the visit where it is determined the participant will be followed using the ART visit schedule/visit calendar.

Item-specific Instructions:

- **Item 1:** Record the date the participant first used ART. A complete date (day, month, and year) is required. If the exact day is not known, use “15” as the day and mark item 1a as “estimated.”



MTN 015 (143)

AIN-1 (079)

Participant ID

- -
 Site Number Participant Number Chk

**ART Initiation Information—
Revised**

Form Completion Date

dd *MMM* *yy*

1. What is the primary reason for initiating ART?

- CD4 meets treatment guidelines for local ART program in absence of WHO Stage 2–4 condition
- AIDS-defining condition (WHO Stage 3 or 4)
- WHO Stage 2 condition
- pregnancy
- ART initiated as part of a research study without either a CD4 or clinical criteria being met.
Indicate name/number of the study: _____
- other reason, specify: _____
- unknown (clinician cannot determine reason for ART initiation from available resources including participant report and records)

Not done/
Not collected

Specimen Collection Date

 dd *MMM* *yy*

2. Last known viral load prior to initiation of ART:

2a. HIV RNA PCR (plasma): > = < *viral copies/mL* OR target not detected

2a1. HIV RNA PCR kit lower limit of detection: 20 40 OR *viral copies/mL*

2b. Source of result: 015 clinic other research clinic other clinic

Not done/
Not collected

Specimen Collection Date

 dd *MMM* *yy*

3. Last known CD4+ result prior to initiation of ART:

3a. Absolute CD4+ *cells/mm³*

3b. CD4+ % not available OR . %

3c. Source of result: 015 clinic other research clinic other clinic

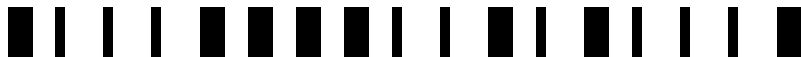
Comments:

15-FEB-13

Language

Staff Initials / Date

ART Initiation Information—Revised (AIN-1)	
Purpose:	This form is used to document the primary reason the participant initiated ART. This form is also used to document (when available) the participant's last HIV RNA PCR and CD4+ results prior to ART initiation.
General Information/Instructions:	<p>This form is completed only once for each ART participant, and is completed at the same visit that the ART Enrollment CRF is completed for the participant (the visit at which the participant enrolls in the ART track).</p> <p>Specimen Collection Date: Record the date that the specimen was collected (NOT the date results were reported or recorded on the form). A complete date is required.</p> <p>Not done/Not collected: For every test, mark either the "Not done/Not collected" box or enter a test result. If a result is not available, mark the "Not done/Not collected" box.</p>
Item-specific Instructions:	
Item 1:	Record the primary reason the participant began using ART. Mark only one response, the response that best describes the reason for ART initiation.
Item 2:	If available, record the collection date of the last known HIV viral load collected prior to the participant's first use of ART. Record the actual result in item 2a. If not available, mark the "Not done/Not collected" box and go to item 3.
Item 2a:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation. If result is "target not detected", mark the "target not detected" box and do not enter any numbers in the "viral copies/mL" boxes. If the result is "<20 Below Range" or "<40 Detected", leave the "Target not detected" box blank, and mark the "<" box and the number "00000020" or "00000040" in the "viral copies/mL" boxes. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
Item 2b:	If the result was obtained from the MTN 015 clinic lab, as part of MTN015 study procedures, mark "015 clinic." If the result was obtained from another research site/clinic, mark "other research clinic." If obtained from a non-research clinic, mark "other clinic."
Item 3:	If available, record the collection date of the last known absolute CD4+ result collected prior to the participant's first use of ART. Record the actual result in items 3a and 3a1. If not available, mark the "Not done/Not collected" box and end the form.
Item 3b:	If available, record the CD4+ percentage that was reported for the specimen in item 3. If the CD4+ percentage is not available, mark the "not available" box.



MTN 015 (143)

BBQ-1 (081)

Participant ID

- -
 Site Number Participant Number Chk

Baseline Behavioral Questionnaire

Visit Date

/ /
 dd MMM yy

I am going to ask some questions about a number of different topics. Some of these questions are personal and sensitive, but understanding your answers to them is important for this study. There are no right or wrong answers to these questions, and all of your answers will be kept confidential. If answering these questions brings up any issues or questions that you would like to discuss further with me or other study clinicians or counselors, we will make time for that after this interview. Shall we continue?

1. Which family planning methods are you currently using? Mark "none" or all that apply.

- | | | |
|---|--|---|
| <input type="checkbox"/> 1a. none → If none, go to item 2. | <input type="checkbox"/> 1g. sponge | <input type="checkbox"/> 1l. spermicide |
| <input type="checkbox"/> 1b. family planning pills or birth control pills | <input type="checkbox"/> 1h. IUD | <input type="checkbox"/> 1m. surgical sterilization (tubal ligation) |
| <input type="checkbox"/> 1c. injectable contraceptives (such as Depo-Provera) | <input type="checkbox"/> 1i. natural methods such as withdrawal or rhythm method | <input type="checkbox"/> 1n. sex with a partner who had a vasectomy |
| <input type="checkbox"/> 1d. implants (such as Norplant, jadelle) | <input type="checkbox"/> 1j. male condoms | <input type="checkbox"/> 1o. other, specify:
<i>Local Language:</i>
_____ |
| <input type="checkbox"/> 1e. vaginal ring | <input type="checkbox"/> 1k. female condoms | <i>English:</i>
_____ |
| <input type="checkbox"/> 1f. diaphragm | | |

2. In the past 3 months, how many men have you had vaginal or anal sex with? By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

If 00, go to statement above item 6 on page 2.

3. In the past 3 months, did you receive money, material goods, gifts, drugs, or shelter for vaginal sex?.....

yes	no	refuse to answer
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. In the past week, how many times did you have vaginal sex?

If 00, go to statement above item 6 on page 2.

5. In the past week, how many times did you use a male or female condom during vaginal sex?

of times

29-FEB-08

Language

Staff Initials / Date

Baseline Behavioral Questionnaire (BBQ-1)

Item-specific Instructions:

- **Item 1:** Do not read response options to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 2:** Use leading zeros when needed so that all the boxes are filled.
- **Item 3:** Record whether or not the participant received any financial and/or materials support in exchange for vaginal sex with any man. This includes things such as money, housing, food, household goods, etc.
- **Item 4:** Use leading zeros when needed so that all the boxes are filled.
- **Item 5:** Use leading zeros when needed so that all the boxes are filled. Review item 5 for mathematical consistency with item 4 (i.e., response to item 5 cannot be greater than response to item 4). If the two answers are not consistent, ask the participant the two questions again. Update the response accordingly if applicable.



MTN 015 (143)

BBQ-2 (082)

Participant ID

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

Baseline Behavioral Questionnaire

Now I am going to ask some questions about the last time you had vaginal sex.

6. When was the last time you had vaginal sex?.....

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

7. The last time you had vaginal sex, did your partner use a male condom?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

8. What is your relationship to the man with whom you last had vaginal sex?
Read each response option aloud.

<i>husband</i>	<i>boyfriend/ fiancé/ regular partner</i>	<i>friend</i>	<i>casual acquaintance</i>	<i>relative</i>	<i>other</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Was this man younger, about the same age, or older than you?

<input type="checkbox"/> younger	→	}	If younger, about the same age, or don't know, go to item 10.
<input type="checkbox"/> about the same age	→		
<input type="checkbox"/> older	→		
<input type="checkbox"/> don't know	→		

9a. Do you think he was less than 10 years older than you or 10 years or more older than you?

<input type="checkbox"/> less than 10 years
<input type="checkbox"/> 10 years or more

10. For how long have you had sexual relations with this man?

Read each response option aloud.

<i>less than a month</i>	<i>between 1 month and 6 months</i>	<i>more than 6 months but less than 12 months</i>	<i>one year or more</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	29-FEB-08
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0	1
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Language

Staff Initials / Date

Baseline Behavioral Questionnaire (BBQ-2)

Item-specific Instructions:

- **Item 6:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.



MTN 015 (143)

BBQ-3 (083)

Participant ID

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

Baseline Behavioral Questionnaire

11. Have you ever had anal sex? yes no **→ If no, go to item 14.**
12. When was the last time you had anal sex?
dd MMM yy
13. The last time you had anal sex, did your partner use a male condom? yes no
14. In the last 12 months, has your husband or regular partner ever slapped you, hit you, kicked you, thrown things at you, or done anything else to physically hurt you? yes no *no husband/partner in past 12 months*

Now I am going to ask some questions about your husband's or partner's HIV status.

15. Do you know your husband's HIV status? yes no *I do not have a husband* **→ If no or do not have a husband, go to item 18.**
16. What is his status? *negative* *positive* *refuse to answer* **→ If negative or refuse to answer, go to item 18.**
17. Has your husband taken HIV medication (ARVs) prescribed by a health care provider/doctor/nurse? yes no *don't know* *refuse to answer*
18. Do you know your partner's HIV status? By partner, I mean a man you have sex with on a regular basis, but who is not your husband. yes no *I do not have a partner* **→ If no or do not have a partner, go to item 21 on page 4.**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	29-FEB-08
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0	1
Language	

Baseline Behavioral Questionnaire (BBQ-3)

Item-specific Instructions:

- **Item 11:** Definition for anal sex: when a man puts his penis inside your anus.
- **Item 12:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 14:** If the participant has had no husband or regular partner in the past 12 months, select the “no husband/partner in past 12 months” response option.



MTN 015 (143)

BBQ-4 (084)

Participant ID

- -
 Site Number Participant Number Chk

Baseline Behavioral Questionnaire

19. What is his status?.....
- negative positive refuse to answer
- **If negative or refuse to answer, go to item 21.**
20. Has your partner taken HIV medication (ARVs) prescribed by a health care provider/doctor/nurse?
- yes no don't know refuse to answer

Now I am going to ask some questions about your HIV status.

21. Since you have been diagnosed, have you told any of the following people that you have HIV?

Read each response option 21b–21n aloud.

- | | | |
|--|--|--|
| yes no
<input type="checkbox"/> <input type="checkbox"/> | 21a. I have told no one | → If yes, go to item 26 on page 7. |
| yes no N/A
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21b. husband | → If no or N/A, do not ask items 22 and 23 on page 5. |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21c. male partner/boyfriend | → If no or N/A, do not ask items 24 and 25 on page 6. |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21d. sister | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21e. brother | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21f. mother | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21g. father | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21h. your children | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21i. other relative | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21j. friend or neighbor | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21k. church member | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21l. community elder | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21m. health care provider/doctor/nurse | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 21n. other, specify: | |

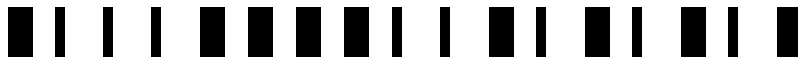
Local Language: _____

English: _____

Baseline Behavioral Questionnaire (BBQ-4)

Item-specific Instructions:

- **Item 20:** Definition for anal sex: when a man puts his penis inside your anus.
- **Item 21:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 21a:** If the participant tells you she has not told anyone she has HIV, mark the “yes” box for 21a and go to item 26.
- **Item 21n:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

BBQ-5 (085)

Participant ID

- -
 Site Number Participant Number Chk

Baseline Behavioral Questionnaire

No data recorded on this page

22. When did you tell your husband that you have HIV?
Read each response option aloud except "don't remember."

- immediately after learning I have HIV
- within 1 month of learning I have HIV
- more than 1 month but less than 1 year after diagnosis
- one year or more after diagnosis
- don't remember

23. Did your husband do any of the following after he learned you have HIV?
Read each response option aloud.

- | | | |
|--------------------------|--------------------------|--|
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | 23a. became angry |
| <input type="checkbox"/> | <input type="checkbox"/> | 23b. beat you |
| <input type="checkbox"/> | <input type="checkbox"/> | 23c. became very sad |
| <input type="checkbox"/> | <input type="checkbox"/> | 23d. moved out of the house |
| <input type="checkbox"/> | <input type="checkbox"/> | 23e. made you leave your house |
| <input type="checkbox"/> | <input type="checkbox"/> | 23f. suggested you see a doctor |
| <input type="checkbox"/> | <input type="checkbox"/> | 23g. started using a condom |
| <input type="checkbox"/> | <input type="checkbox"/> | 23h. refused to have sex with you |
| yes | no | <i>don't know</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> 23i. took another partner or wife |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | 23j. other, specify: |

Local Language: _____

English: _____

Baseline Behavioral Questionnaire (BBQ-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 and the Staff Initials/Date.
- **Item 23:** If the participant has had no husband or regular partner in the past 12 months, select the “no husband/partner in past 12 months” response option.
- **Item 23j:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

BBQ-6 (086)

Participant ID

Site Number			Participant Number						Chk		

Baseline Behavioral Questionnaire

No data recorded on this page

24. When did you tell your partner that you have HIV? By partner I mean a man you have sex with on a regular basis but who is not your husband.

Read each response option aloud except "don't remember."

- immediately after learning I have HIV
- within 1 month of learning I have HIV
- more than 1 month but less than 1 year after diagnosis
- one year or more after diagnosis
- don't remember

25. Did your partner do any of the following after he learned you have HIV?

Read each response option aloud.

- | | | |
|--------------------------|--------------------------|--|
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | 25a. became angry |
| <input type="checkbox"/> | <input type="checkbox"/> | 25b. beat you |
| <input type="checkbox"/> | <input type="checkbox"/> | 25c. became very sad |
| <input type="checkbox"/> | <input type="checkbox"/> | 25d. moved out of the house |
| <input type="checkbox"/> | <input type="checkbox"/> | 25e. made you leave your house |
| <input type="checkbox"/> | <input type="checkbox"/> | 25f. suggested you see a doctor |
| <input type="checkbox"/> | <input type="checkbox"/> | 25g. started using a condom |
| <input type="checkbox"/> | <input type="checkbox"/> | 25h. refused to have sex with you |
| yes | no | <i>don't know</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> 25i. took another partner or wife |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | 25j. other, specify: |

Local Language: _____

English: _____

29-FEB-08

0	1
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Language

Staff Initials / Date

Baseline Behavioral Questionnaire (BBQ-6)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
- **Item 25j:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

BBQ-7 (087)

Participant ID

Site Number			Participant Number						Chk		

Baseline Behavioral Questionnaire

- | | <i>yes</i> | <i>no</i> | <i>refuse to answer</i> |
|---|--------------------------|--------------------------|--------------------------|
| 26. Have you seen a health care provider/doctor/nurse for HIV care or treatment since being diagnosed as HIV positive?..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. Have you seen a traditional healer for HIV care or treatment since being diagnosed as HIV positive? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 28. Have you taken any HIV medication (ARVs) prescribed by a health care provider/doctor/nurse since being diagnosed as HIV positive? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 29. Have you taken any HIV medication (ARVs) prescribed by a traditional healer since being diagnosed as HIV positive?..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 30. Have you received help or support for any of the following from the government, churches, or other community organizations? | | | |

Read each response option aloud.

- | <i>yes</i> | <i>no</i> | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 30a. food |
| <input type="checkbox"/> | <input type="checkbox"/> | 30b. clothing |
| <input type="checkbox"/> | <input type="checkbox"/> | 30c. housing |
| <input type="checkbox"/> | <input type="checkbox"/> | 30d. money other than study incentives/reimbursement |
| <input type="checkbox"/> | <input type="checkbox"/> | 30e. other, specify: |

Local Language: _____

English: _____

Baseline Behavioral Questionnaire (BBQ-7)

Item-specific Instructions:

- **Item 30d:** If the participant only received money as part of study incentives or study reimbursement, check “no” for response option 30d.
- **Item 30e:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

BBQ-8 (088)

Participant ID

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Site Number

Participant Number

Chk

Baseline Behavioral Questionnaire

Now I am going to ask some questions about how you have been feeling lately, i.e., your emotions and feelings.

Read each response option aloud.

- | | <i>not at all</i> | <i>a little</i> | <i>quite a bit</i> | <i>extremely</i> | <i>don't understand/
don't know</i> |
|--|--------------------------|--------------------------|--------------------------|--------------------------|---|
| 31. During the past month how much would you say you have felt blue? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 32. During the past month how much would you say you have felt trapped or caught? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 33. During the past month how much would you say you have had difficulty falling or staying asleep? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 34. During the past month how much would you say you have worried too much about things? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 35. During the past month how much would you say your heart has been pounding or racing? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 36. During the past month how much would you say you have cried easily? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 37. During the past month how much would you say you have felt hopeless about the future? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 38. During the past month how much would you say you have experienced dizziness, faintness, or weakness? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Thank you for completing the interview with me today.

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Baseline Behavioral Questionnaire (BBQ-8)

Item-specific Instructions:

- **Items 31–38:** These questions are an index of depression. The index assesses whether the respondent is depressed by summing responses to all the questions, not from a response to any individual item/question. Therefore, all questions must be asked.
 - For each item 31–38:
 - Read each item and response option exactly as it is worded.
 - Mark “don’t understand/don’t know” if the participant’s response is she does not know
 - Mark “don’t understand/don’t know” if the participant can’t answer the question because she does not understand the question
 - Mark “don’t understand/don’t know” if the participant answers the question but you think she did not understand the question. Also, mark the response box selected by the participant.
- **Item 31:** “Blue” means sad.
- **Item 32:** This question refers to feeling emotionally trapped and not physically “trapped or caught.”
- **Item 35:** This question refers to pounding or racing of one’s heart that is not a result of physical activity.
- **Item 38:** This question refers to a feeling of “dizziness, faintness, weakness” that is not a result of physical activity.



Participant ID

Site Number - Participant Number - Chk

Baseline Behavioral Questionnaire—Version 2

Visit Date

dd MMM yy

I am going to ask some questions about a number of different topics. Some of these questions are personal and sensitive, but understanding your answers to them is important for this study. There are no right or wrong answers to these questions, and all of your answers will be kept confidential. If answering these questions brings up any issues or questions that you would like to discuss further with me or other study clinicians or counselors, we will make time for that after this interview. Shall we continue?

1. Which family planning methods are you currently using? Mark "none" or all that apply.

- 1a. none -> Go to item 2. 1b. family planning pills or birth control pills. 1c. injectable contraceptives (such as Depo-Provera). 1d. implants (such as Norplant, jadelle). 1e. vaginal ring. 1f. diaphragm. 1g. sponge. 1h. IUD. 1i. natural methods such as withdrawal or rhythm method. 1j. male condoms. 1k. female condoms. 1l. spermicide. 1m. surgical sterilization (tubal ligation). 1n. sex with a partner who had a vasectomy. 1o. other, specify: Local Language: English:

2. Have you seen a health care provider/doctor/nurse for HIV care or treatment since being diagnosed as HIV positive? yes no refuse to answer

3. Have you seen a traditional healer for HIV care or treatment since being diagnosed as HIV positive? yes no refuse to answer

4. Have you taken any HIV medication (ARVs) prescribed by a health care provider/doctor/nurse since being diagnosed as HIV positive? yes no refuse to answer

5. Have you taken any HIV medication (ARVs) prescribed by a traditional healer since being diagnosed as HIV positive? yes no refuse to answer

6. Have you received help or support for any of the following from the government, churches, or other community organizations?

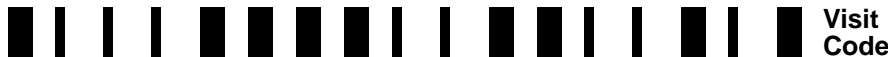
Read each response option aloud.

- yes no 6a. food 6b. clothing 6c. housing 6d. money other than study incentives/reimbursement 6e. other, specify: Local Language: English:

Baseline Behavioral Questionnaire—Version 2 (BQ-1)

Item-specific Instructions:

- | | |
|-----------------|---|
| Item 1: | Do not read response options to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the "other, specify" box and record the participant's verbatim response. Also provide the English translation in the space provided. |
| Item 6d: | If the participant only received money as part of study incentives or study reimbursement, check "no" for response option 6d. |
| Item 6e: | If "other, specify" is marked, be sure to record the participant's verbatim response. Also provide the English translation in the space provided. |



MTN 015 (143)

NSV-1 (101)

Visit Code

0

1

Participant ID

Site Number - Participant Number - Chk

Non-ART Study Visit

Visit Date

dd MMM yy

1. Has the participant initiated ART since her last study visit? yes no

If yes, complete ART Enrollment, ART Initiation Information, Antiretroviral Treatment Regimen Log, and ART Study Visit forms. End of form.

1a. Reason why the participant reports not having started ART:

- participant is not receiving medical care for HIV
ART not recommended by the participant's health care provider/clinic
ART recommended but not started because of cost
ART recommended but not started because participant does not want to take it
other reason, specify:

2. Is the participant completing a parent protocol visit at this MTN 015 visit? yes no If no, end of form.

2a. Visit code of parent protocol visit completed today: visit code

Comments:

Non-ART Study Visit (NSV-1)

Purpose: This form is used to document non-ART follow-up visits.

General Information/Instructions: Complete this form **once** at each required non-ART follow-up visit. Do **not** complete this form at the Screening/Enrollment visit or at interim study visits. For interim study visits, complete the Interim Visit form.

Item-specific Instructions:

- **Visit Code:** Only visit codes assigned to non-ART visits should be recorded. Non-ART visits are assigned visit codes ranging from 02.0 through 28.0.
- **Item 1:** Mark “yes” if the participant reported initiation of ART use for the very first time at this visit. Once this item is marked “yes”, end the form. This form should not be completed any more for the participant, as a “yes” response indicates the participant is now being followed per the ART visit schedule.
- **Item 1a:** Mark the reason that best explains why the participant has never used ART.
- **Items 2 and 2a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 2 “yes” and in 2a, record the visit code (regular or interim) of the parent protocol visit completed on this date.



MTN 015 (143)

ASV-1 (110)

Visit Code

. 0

1

Participant ID

- -

Site Number

Participant Number

Chk

ART Study Visit

Visit Date

dd

MMM

yy

1. Is the participant completing a parent protocol visit at this MTN 015 visit?

yes

no

→ **If no, end of form.**

1a. Visit code of parent protocol visit completed today:

visit code

.

Comments: _____

ART Study Visit (ASV-1)

Purpose: This form is used to document ART follow-up visits.

General Information/Instructions: Complete this form **once** at each required ART follow-up visit. Do **not** complete this form at the Screening/Enrollment visit or for ART interim study visits. For ART interim study visits, complete the Interim Visit form.

Item-specific Instructions:

- **Visit Code:** Only visit codes assigned to ART visits should be recorded. ART visits are assigned visit codes ranging from 30.0 through 57.0.
- **Items 1 and 1a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 1 “yes” and in 1a, record the visit code (regular or interim) of the parent protocol visit completed on this date.



MTN 015 (143)

SCS-1 (121)

Participant ID

Site Number			Participant Number						Chk	

Seroconversion Symptoms

Visit Date

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

Symptom	Reported during the 3 months prior to seroconversion?			If yes, Onset Date			Resolve Date			Ongoing
	yes	no	don't know	<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	
1. Headache	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
2. Pharyngitis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
3. Skin rash	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
4. Myalgia/arthralgia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
5. Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
6. Fever	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
7. Lymphadenopathy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>
8. Weight loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/>

Comments: _____

29-FEB-08

Language

Staff Initials / Date

Seroconversion Symptoms (SCS-1)

Purpose: This form is used to document information about symptoms the participant may have experienced during the 3 months prior to HIV seroconversion.

General Information/Instructions: This form is completed once for each participant, at the Screening/ Enrollment visit. When determining what seroconversion symptoms were experienced, use the date recorded on the MTN 015 Enrollment form, item 4 as the seroconversion date. Review the participant's parent protocol study records, including interval medical history and Adverse Experience Log forms, to determine if the participant reported experiencing the symptom anytime during the 3 months prior to HIV seroconversion.

If the participant's parent protocol study records are not available, mark all items "don't know" and record the reason why in the "Comment" field.

Item-specific Instructions:

- **Items 1 through 8:** Mark either the "yes," "no," or "don't know" box for each of these items. If, after reviewing the participant's parent protocol records per the general instruction above, you cannot determine if the participant did or did not experience the symptom, mark "don't know."

For each symptom marked "yes," record an onset date and a resolve date. At minimum, a month and year are required for these dates. If the symptom is not resolved at the time of the visit, mark the "ongoing" box.



Visit Code

□□.□□

MTN 015 (143)

STR-1 (131)

Participant ID

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

Initial Collection Date

□□ □□□□ □□
dd MMM yy

Sexually Transmitted Diseases Results

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

1. VAGINAL WET PREP

Not done 1a. Homogeneous vaginal discharge negative positive
1b. pH □□ → If > 4.5 mark as positive. →
1c. Whiff test negative positive
1d. Clue cells ≥ 20% negative positive
1e. Trichomonads negative positive
1f. Buds and/or hyphae (yeast) negative positive

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

2. STD SEROLOGY

2a. Syphilis screening test non-reactive reactive
2a1. Titer 1: □□□□ → If non-reactive, go to item 3a.
2b. Syphilis confirmatory test negative positive

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

3. OTHER STD TESTS

3a. N. gonorrhoea negative positive
3b. C. trachomatis negative positive

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

4. Trichomonas Rapid Test negative positive
5. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ negative positive

Comments: _____

Sexually Transmitted Diseases Results (STR-1)

Purpose: This form is used to document sexually transmitted disease test results obtained during the study.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.

Initial Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Complete date required.

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a different day than the Initial Collection Date. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. Complete date required.

Not done/Not collected: For each item, mark *either* the “Not done/Not collected” box *or* enter a test result(s). For items 1a–1f, mark the “Not done” box if a particular test is not done.

Item-specific Instructions:

- **Item 1a:** Only mark “negative” or “positive” if a clinical work-up for BV is performed. If homogenous vaginal discharge is observed but BV work-up is not done, mark this item as “Not done” and record the abnormal discharge on the Pelvic Exam Diagrams and Medical History Log non-DataFax forms.
- **Item 2a1:** Remember to use leading zeros when recording syphilis titer level. For example, a titer level of 1:4 is recorded as “1:0004.”
- **Items 3a and 3b:** If a result of “indeterminate” is received, do not record this result. Repeat the testing and/or specimen collection until a result of “positive” or “negative” is received, and record that result on the form. Also record “Alternate Collection Date” if additional specimens are collected for this testing.



Visit Code

MTN 015 (143)

LAB-1 vb(149)

Participant ID

- -
 Site Number Participant Number Chk

Laboratory Results—Revised--
Version 2

Initial Collection Date

dd MMM yy

Not done/
Not collected 1. T CELL SUBSETS

Alternate Collection Date
 dd MMM yy

cells/mm³
 1a. Absolute CD4+

Not available OR . %
 1b. CD4+

Not done/
Not collected 2. HIV RNA

Alternate Collection Date
 dd MMM yy

2a. HIV RNA PCR (plasma): > = <
 viral copies/mL target not detected OR

2a1. HIV RNA PCR kit lower limit of detection: 20 40 OR
 viral copies/mL

Not done 2b. Second HIV RNA PCR (plasma): > = <
 viral copies/mL target not detected OR

2b1. HIV RNA PCR kit lower limit of detection: 20 40 OR
 viral copies/mL

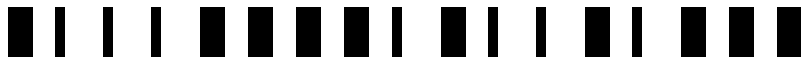
Not done/
Not collected 3. PREGNANCY TEST

Alternate Collection Date
 dd MMM yy

negative positive
 3a. Test result → If positive, complete Pregnancy Report and History form.

Comments:

Laboratory Results—Revised--Version 2 (LAB-1)	
Purpose:	This form is used to document absolute CD4+, HIV plasma RNA, and pregnancy test results obtained during the study.
General Information/ Instructions:	<p>Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.</p> <p>Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.</p> <p>Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a day after the Initial Collection Date. A specimen collected for the same visit but on a later date should be recorded on the same form only when obtained within the same visit window. A complete date is required.</p> <p>Not done/Not collected: For every test, mark either the "Not done/Not collected" box or enter a test result. If a result is not available, mark the "Not done/Not collected" box.</p>
Item-specific Instructions:	
Item 1a:	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
Item 2a:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation. If result is "target not detected", mark the "target not detected" box and do not enter any numbers in the "viral copies/mL" boxes. If the result is "<20 Below Range" or "<40Detected", leave the "Target not detected" box blank, and mark the "<" box and the number "00000020" or "00000040" in the "viral copies/mL" boxes. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
Item 2b:	If a second HIV RNA PCR result was obtained for the specimen, record the result here (refer to instructions for item 2a above) and complete item 2b. If a second HIV RNA PCR result was not obtained for the specimen, mark the "Not done" box and go to item 3.
Item 3:	Note that a Pregnancy Report and History form is required to be completed once for each pregnancy, not for each positive pregnancy test result.



MTN 015 (143)

ATA-1 (151)

Visit Code .

1

Participant ID

- -

Site Number

Participant Number

Chk

Antiretroviral Therapy Adherence

Visit Date

/ /

dd

MMM

yy

1. Have you been prescribed any HIV medication (ARVs) today or since the last visit?.....

yes

no

If no, end of form. Do not fax pages 2-4.

2. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ Have you missed any of your HIV medication (ARVs)?

- within the past week
- 1-2 weeks ago *→ If 1-2 weeks ago, go to item 5 on page 2.*
- 2-4 weeks ago *→ If 2-4 weeks ago, go to item 5 on page 2.*
- 1-3 months ago *→ If 1-3 months ago, go to item 5 on page 2.*
- more than 3 months ago *→ If more than 3 months ago, end of form. Do not fax pages 2-4.*
- never miss taking HIV medication (ARVs) *→ If never miss taking medicine, end of form. Do not fax pages 2-4.*
- don't know

NO LONGER APPLICABLE FOR THIS PROTOCOL

3. During the past 4 days, **for how many days** have you missed taking **all your HIV medication (ARVs)**?

none

1 day

2 days

3 days

4 days

Go to item 7 on page 2.

4. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ Some people find that they forget to take their HIV medication (ARVs) on weekend days. Did you miss any of your HIV medication (ARVs) last Saturday or Sunday?

yes

NO LONGER APPLICABLE FOR THIS PROTOCOL

Antiretroviral Therapy Adherence (ATA-1)

The intent of items 1 and 3 is to assess the participant's access to and uptake of HIV care and treatment. The questions measure adherence to medication/ARVs and factors that influence adherence to ARVs.



MTN 015 (143)

ATA-2 (152)

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Antiretroviral Therapy Adherence

5. ~~Now I'm going to ask you about the HIV medication (ARVs) you have been prescribed and if you have missed taking any of the HIV medication (ARVs) in the past 2 weeks, and in the past 30 days. If you only took a portion of a dose on one or more of these days, report the dose as being missed.~~

	Med code	Abbreviation/Name of your drugs	# of prescribed doses missed (past 2 weeks)	# of prescribed doses missed (past 30 days)
5a.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5b.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5c.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5d.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5e.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

NO LONGER APPLICABLE FOR THIS PROTOCOL

6. ~~How many days have you not been able to take your HIV medication (ARVs) in the past 30 days because you did not have pills and could not get more?~~

of days

yes no

7. Have you **taken any HIV medication (ARVs)** in the **past month**?

8. In the **past month**, how often have you **missed taking your HIV medication (ARVs)** because you:

Read each response option aloud.

	never	rarely	sometimes	often
8a. wanted to avoid side effects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8b. could not follow dietary instructions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8c. were sharing ART with other family members and friends?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8d. religious beliefs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Antiretroviral Therapy Adherence (ATA-2)

The intent of items 7 and 8 is to assess the participant's access to and uptake of HIV care and treatment. The questions measure adherence to medication/ARVs and factors that influence adherence to ARVs.



MTN 015 (143)

ATA-3 (153)

Visit Code

1

Participant ID

- -

Site Number Participant Number Chk

Antiretroviral Therapy Adherence

Read each response option aloud.

	<i>never</i>	<i>rarely</i>	<i>sometimes</i>	<i>often</i>
8e. do not fully understanding the regimen and its requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8f. were traveling away from home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8g. had transportation problems getting to the clinic?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8h. lost pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8i. had too many pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8j. had a bad event happen that you felt was related to taking the pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8k. forgot?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8l. ran out of pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8m. were busy doing other things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8n. tired of taking too many pills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8o. other illness or health problems got in the way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8p. stigmatization (what others may say or discover about my disease)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8q. fear of stigmatization within the home (e.g., not wanting the husband to know)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Antiretroviral Therapy Adherence (ATA-3)

Item-specific Instructions:

- **Item 8p:** This question refers to stigmatization from people outside one's family.



MTN 015 (143)

ATA-4 (154)

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Antiretroviral Therapy Adherence

Read each response option aloud.

	<i>never</i>	<i>rarely</i>	<i>sometimes</i>	<i>often</i>
8r. pills got damaged from heat or getting wet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8s. were too ill to attend clinic to collect drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8t. pills getting stolen (e.g., while in transit in a taxi/ bus station)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8u. having to wake up very early to commute and no time to eat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8v. didn't think they would really work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8w. were bothered by your dreams?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8x. clinic or doctor did not have pills for you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8y. other, specify below:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Local Language: _____				
English: _____				

Antiretroviral Therapy Adherence (ATA-4)

Item-specific Instructions:

- **Item 8y:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



Visit Code 1

Participant ID

- -

Form Completion Date

Family Planning

1. What method(s) of contraception/family planning has the participant used since her last parent protocol visit?
Mark "none" or all that apply.

- 1a. none
- 1b. spermicide
- 1c. diaphragm
- 1d. sponge
- 1e. intrauterine device (IUD)
- 1f. oral contraceptives/birth control pills
- 1g. injectable contraceptives (such as Depo-Provera)
 - 1g1. Type: Depo Depo subq NET-EN Cyclofem other
- 1h. (Ortho Evra) The Patch
- 1i. implants
- 1j. female condoms
- 1k. natural methods such as the withdrawal or rhythm method
- 1l. male condoms
- 1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)
- 1n. sex with partner who had a vasectomy
- 1o. other, specify: _____

Update Concomitant Medications Log, as needed.

2. Has the participant had or started her menstrual period since her last parent protocol visit?

yes no → If no, end of form.

2a. First day of last menstrual period:

dd MMM yy

2b. Last day of last menstrual period:

dd MMM yy OR ongoing

Comments:

Family Planning (FP-1)

Purpose: This form is used to document the methods of contraception/family used by the participant during the study. It is completed at enrollment and when contraception methods have changed.

Item-specific Instructions:

Item 1:	Mark any method(s) of contraception/family planning the participant reports using since her last parent protocol visit. If any response boxes for items 1e–1i are marked, update the Concomitant Medications (CM) Log as needed.
Item 1g1:	Mark the specific type of injectable contraception used by the participant. <ul style="list-style-type: none">• Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle.• Depo subq: mark when the sub-cutaneous route of Depo is used.• NET-EN: also known as Mesigyna.• Cyclofem: also known as Lunelle.
Item 2a:	The first day of the last menstrual period is the first day of bleeding.
Item 2b:	The last day of the last menstrual period is the last day of bleeding.



Visit Code

□□.□□

MTN 015 (143)

SS-1 (161)

Participant ID

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

Specimen Storage

Initial Collection Date

□□ □□□□ □□
dd MMM yy

Alternate Collection Date

dd MMM yy
□□ □□□□ □□

□□ □□□□ □□

□□ □□□□ □□

□□ □□□□ □□

□□ □□□□ □□

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
1. Plasma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
2. PBMC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
3. Serum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
4. Vaginal swab	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
5. Cervicovaginal lavage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

Comments: _____

Specimen Storage (SS-1)

Purpose: This form is used to document collection and storage of MTN 015 specimens that will be tested at a lab other than the local site laboratory.

General Information/Instructions: Only record specimens collected for MTN 015 on this form. Do not record specimens collected for the participant's parent study. Check the information on this form against the MTN 015 LDMS Specimen Tracking Sheet completed for this visit to make sure the information is the same.

Initial Collection Date: Record the date that the first specimen(s) was *collected* for this visit. Complete date required.

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a different day than the Initial Collection Date. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window.

Item-specific Instructions:

- **Items 1–5:** If the specimen is not required to be collected and stored at this visit, mark “not required.” If the specimen is required to be stored, but for some reason it is not stored at this visit, mark “not stored” and record the reason why on the line provided.

MTN 015 (143)

FBQ-1 (181)

Visit Code [][] . []

1

Participant ID

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

Follow-up Behavioral Questionnaire

Visit Date

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

I am now going to ask you some questions about a number of different topics. Some of these questions are personal and sensitive, but understanding your answers to them is important for this study. There are no right or wrong answers to these questions, and all of your answers will be kept confidential. If answering these questions brings up any issues or questions that you would like to discuss further with me or other study clinicians or counselors, we will make time for that after this interview. Shall we continue?

- 1. Are you currently married? yes no **→ If no, go to item 8 on page 2.**
- 2. Are you currently living with your husband? yes no

Your last interview was _____ (Interviewer will tell the respondent when her last interview was).

- 3. Are you married to the same man you told us about at your last interview in _____ (month of last interview from above)? yes no don't remember **→ If yes, go to item 8 on page 2.**

- 4. Is your husband older, about the same age, or younger than you?

younger about the same age older don't know

→ If younger, about the same age, or don't know, go to item 5.

- 4a. Do you think he is less than 10 years older than you or 10 years or more older than you?

less than 10 years 10 years or more

- 5. Does your husband have more than one wife or sexual partner? yes no don't know

[][] [x] 29-FEB-08

01

Follow-up Behavioral Questionnaire (FBQ-1)

Item-specific Instructions:

- **Items 1 and 2:** Emphasize “currently.”



MTN 015 (143)

FBQ-2 (182)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

6. Does your husband provide you with financial and/or material support? yes no

7. What is your husband's highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary school, not complete
- secondary school, complete
- attended college or university
- don't know

8. Do you currently have a partner? By partner, I mean a man you have sex with on a regular basis but who is not your husband. yes no **→ If no, go to statement above item 15 on page 4.**

9. Are you currently living with your partner? yes no

Your last interview was _____ (Interviewer will tell the respondent when her last interview was).

10. Is your current partner the male sexual partner you told us about at your last interview in _____ (month of last interview from above)? yes no don't remember **→ If yes, go to statement above item 15 on page 4.**

Follow-up Behavioral Questionnaire (FBQ-2)

Item-specific Instructions:

- **Item 6:** Record whether or not the participant's husband provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 8:** Emphasize "currently." Allow the woman to use her own definition of "regular partner."
- **Item 9:** Emphasize "currently."



MTN 015 (143)

FBQ-3 (183)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

No data recorded on this page

11. Is your sexual partner younger, about the same age, or older than you?

- younger
- about the same age
- older
- don't know

If younger, about the same age, or don't know, go to item 12.

11a. If older, do you think he is less than 10 years older than you or 10 years or more older than you?

- less than 10 years
- 10 years or more

12. Does your partner have more than one wife or sexual partner? *yes no don't know*

13. Does your partner provide you with financial and/or material support? *yes no*

14. What is your partner's highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary school, not complete
- secondary school, complete
- attended college or university
- don't know

29-FEB-08

Language

Follow-up Behavioral Questionnaire (FBQ-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 and the Staff Initials/Date.
- **Item 13:** Record whether or not the participant's partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.



MTN 015 (143)

FBQ-4 (184)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

I am now going to ask you some questions about sexual behavior. Again, some of these questions are personal and sensitive, but understanding sexual behavior is important for this research study. There are no right or wrong answers to these questions, and all of your answers will be kept confidential. Shall we continue?

15. In the past 3 months, how many men have you had vaginal or anal sex with?

of men

If 000, go to item 23 on page 5.

16. In the past week, how many times did you have vaginal sex?

of times

If 00, go to item 18.

17. In the past week, how many times did you use a male or female condom during vaginal sex?

of times

18. In the last 3 months, when was the last time you had vaginal sex?

dd MMM yy

19. What is your relationship to the man with whom you last had sex?

Read each response option aloud.

<i>husband</i>	<i>boyfriend/ fiancé/ regular partner</i>	<i>friend</i>	<i>casual acquaintance</i>	<i>relative</i>	<i>other</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. Was this man younger, about the same age, or older than you?

younger →

about the same age →

older →

don't know →

If younger, about the same age, or don't know, go to item 21 on page 5.

20a. Do you think he was less than 10 years older than you or 10 years or more older than you?

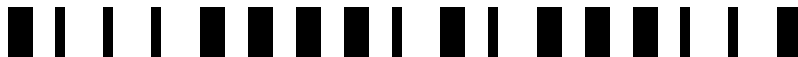
less than 10 years

10 years or more

Follow-up Behavioral Questionnaire (FBQ-4)

Item-specific Instructions:

- **Item 15:** Use leading zeros when needed so that all boxes are filled.
- **Item 16:** Use leading zeros when needed so that all boxes are filled.
- **Item 17:** Use leading zeros when needed so that all boxes are filled. Review item 17 for mathematical consistency with item 16 (i.e., response to item 17 cannot be greater than response to item 16). If the two answers are not consistent, ask the participant the two questions again. Update the response accordingly if applicable.
- **Item 18:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.



MTN 015 (143)

FBQ-5 (185)

Visit Code

Participant ID

- -

Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

21. The last time you had vaginal sex, did your partner use a male condom? yes no

22. In the past 3 months, did you receive money, material goods, gifts, drugs, or shelter for vaginal sex? yes no refuse to answer

23. In the past 3 months, did you have anal sex? yes no

24. Which family planning methods are you currently using? Mark "none" or all that apply.

- 24a. none → *If none, go to statement above item 25.*
- 24b. family planning pills or birth control pills
- 24c. injectable contraceptives (such as Depo-Provera)
- 24d. implants (such as Norplant, jadelle)
- 24e. vaginal ring
- 24f. diaphragm
- 24g. sponge
- 24h. IUD
- 24i. natural methods such as withdrawal or rhythm method
- 24j. male condoms
- 24k. female condoms
- 24l. spermicide
- 24m. surgical sterilization (tubal ligation)
- 24n. sex with a partner who had a vasectomy
- 24o. other, specify:
Local Language: _____
English: _____

Now I am going to ask some questions about your husband's or partner's HIV status.

25. Do you know your husband's HIV status? yes no I do not have a husband
 If no or do not have a husband, go to item 28 on page 6.

26. What is his status? negative positive refuse to answer
 If negative or refuse to answer, go to item 28 on page 6.

27. Since your last interview, has your husband taken HIV medication (ARVs) prescribed by a health care provider/doctor/nurse? yes no don't know refuse to answer

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Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-5)

Item-specific Instructions:

- **Item 23:** Definition for anal sex: when a man puts his penis inside your anus.
- **Item 24:** These response options are not read aloud to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

FBQ-6 (186)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

28. Do you know your partner's HIV status? By partner, I mean a man you have sex with on a regular basis, but who is not your husband.
- yes no I do not have a partner
- If no or do not have a partner, go to item 31.
29. What is his status?
- negative positive refuse to answer
- If negative or refuse to answer, go to item 31.
30. Since your last interview, has your partner taken HIV medication (ARVs) prescribed by a health care provider/doctor/nurse?
- yes no don't know refuse to answer

31. Since your last interview, have you told any of the following people that you have HIV?

Read each response option 31b-31n aloud.

yes no

31a. I have told no one —> **If yes, go to item 36 on page 9.**

yes no N/A

31b. husband —> **If no or N/A, do not ask items 32 and 33 on page 7.**

31c. male partner/boyfriend —> **If no or N/A, do not ask items 34 and 35 on page 8.**

31d. sister

31e. brother

31f. mother

31g. father

31h. your children

31i. other relative

31j. friend or neighbor

31k. church member

31l. community elder

31m. health care provider/doctor/nurse

31n. other, specify:

Local Language: _____

English: _____

29-FEB-08

Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-6)

Item-specific Instructions:

- **Item 31a:** If the participant tells you she has not told anyone she has HIV, mark the “yes” box for 31a and go to item 36.
- **Item 31n:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.

MTN 015 (143)

FBQ-7 (187)

Visit Code .

Participant ID

- -

Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

No data recorded on this page

Read each response option aloud except "don't remember."

32. When did you tell your husband that you have HIV?

- immediately after learning I have HIV
- within 1 month of learning I have HIV
- more than 1 month but less than 1 year after diagnosis
- one year or more after diagnosis
- don't remember

33. Did your husband do any of the following after he learned you have HIV?

Read each response option aloud.

yes no

- 33a. became angry
- 33b. beat you
- 33c. became very sad
- 33d. moved out of the house
- 33e. made you leave your house
- 33f. suggested you see a doctor
- 33g. started using a condom
- 33h. refused to have sex with you

yes no *don't know*

- 33i. took another partner or wife
- 33j. other, specify:

Local Language: _____

English: _____

29-FEB-08

Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-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 and the Staff Initials/Date.
- **Item 33j:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

FBQ-8 (188)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

No data recorded on this page

34. When did you tell your partner that you have HIV? By partner I mean a man you have sex with on a regular basis but who is not your husband.

Read each response aloud except "don't remember."

- immediately after learning I have HIV
- within 1 month of learning I have HIV
- more than 1 month but less than 1 year after diagnosis
- one year or more after diagnosis
- don't remember

35. Did your partner do any of the following after he learned you have HIV?

Read each response option aloud.

yes no

- 35a. became angry
- 35b. beat you
- 35c. became very sad
- 35d. moved out of the house
- 35e. made you leave your house
- 35f. suggested you see a doctor
- 35g. started using a condom
- 35h. refused to have sex with you

yes no don't know

35i. took another partner or wife

35j. other, specify:

Local Language: _____

English: _____

29-FEB-08

Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-8)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
- **Item 35j:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.

MTN 015 (143)

FBQ-9 (189)

Visit Code

Participant ID

- -

Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

36. Since your last interview, have you seen a health care provider/ doctor/nurse for HIV care or treatment? *yes* *no* *don't know* *refuse to answer*
37. Since your last interview, have you seen a traditional healer for HIV care or treatment?
38. Since your last interview, have you taken any HIV medication (ARVs) prescribed by a health care provider/doctor/nurse?
39. Since your last interview, have you taken any HIV medication (ARVs) prescribed by a traditional healer?
40. Since your last interview, have you received help or support for any of the following from the government, churches, or other community organizations?
- yes* *no*
- 40a. food
- 40b. clothing
- 40c. housing
- 40d. money other than study incentives/reimbursement
- 40e. other, specify:
Local Language: _____
English: _____

Now I am going to ask some questions about how you have been feeling lately, i.e., your emotions and feelings.

Read each response option aloud.

41. During the past month how much would you say you have felt blue? *not at all* *a little* *quite a bit* *extremely* *don't understand/ don't know*
42. During the past month how much would you say you have felt trapped or caught?

29-FEB-08

Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-9)

Item-specific Instructions:

- **Items 36 and 37:** These questions assess the participant's access to HIV care and treatment, and utilization of HIV support services available in the community.
- **Items 38–40:** These questions assess the participant's access to HIV care and treatment, and utilization of HIV support services available in the community.
- **Items 41–42:** These questions are an index of depression. The index assesses whether the respondent is depressed by summing responses to all the questions, not from a response to any individual item/question. Therefore, all questions must be asked.
 - For each item 41–42:
 - Read each item and response option exactly as it is worded.
 - Mark “don't understand/don't know” if the participant's response is she does not know
 - Mark “don't understand/don't know” if the participant can't answer the question because she does not understand the question
 - Mark “don't understand/don't know” if the participant answers the question but you think she did not understand the question. Also, mark the response box selected by the participant.
- **Item 41:** “Blue” means sad.
- **Item 42:** This question refers to feeling emotionally trapped and not physically “trapped or caught.”



MTN 015 (143)

FBQ-10 (190)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire

- | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|
| | | <i>not at all</i> | <i>a little</i> | <i>quite a bit</i> | <i>extremely</i> | <i>don't understand/
don't know</i> |
| 43. During the past month how much would you say you have had difficulty falling or staying asleep? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 44. During the past month how much would you say you have worried too much about things? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 45. During the past month how much would you say your heart has been pounding or racing? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 46. During the past month how much would you say you have cried easily? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 47. During the past month how much would you say you have felt hopeless about the future? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 48. During the past month how much would you say you have experienced dizziness, faintness, or weakness? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Thank you for completing the interview with me today.

29-FEB-08

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Language

Staff Initials / Date

Follow-up Behavioral Questionnaire (FBQ-10)

Item-specific Instructions:

- **Items 43–48:** These questions are an index of depression. The index assesses whether the respondent is depressed by summing responses to all the questions, not from a response to any individual item/question. Therefore, all questions must be asked.
 - For each item 43–48:
 - Read each item and response option exactly as it is worded.
 - Mark “don’t understand/don’t know” if the participant’s response is she does not know
 - Mark “don’t understand/don’t know” if the participant can’t answer the question because she does not understand the question
 - Mark “don’t understand/don’t know” if the participant answers the question but you think she did not understand the question. Also, mark the response box selected by the participant.
- **Item 45:** This question refers to pounding or racing of one’s heart that is not a result of physical activity.
- **Item 48:** This question refers to a feeling of “dizziness, faintness, weakness” that is not a result of physical activity.



Visit Code . 0 1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire—Version 2

Visit Date

dd MMM yy

I am now going to ask some questions about a number of different topics. Some of these questions are personal and sensitive, but understanding your answers to them is important for this study. There are no right or wrong answers to these questions, and all of your answers will be kept confidential. If answering these questions brings up any issues or questions that you would like to discuss further with me or other study clinicians or counselors, we will make time for that after this interview. Shall we continue?

1. Are you currently married? yes no —————▶ *If no, go to item 8 on page 2.*

2. Are you currently living with your husband? yes no

Your last interview was _____ (Interviewer will tell the respondent when her last interview was).

3. Are you married to the same man you told us about at your last interview in _____ (month of last interview from above)? yes no don't remember
—————▶ *If yes, go to item 8 on page 2.*

4. Is your husband older, about the same age, or younger than you?
 younger —————▶
 about the same age —————▶
 older
 don't know —————▶
—————▶ *If younger, about the same age, or don't know, go to item 5.*

4a. Do you think he is less than 10 years older than you or 10 years or more older than you? less than 10 years 10 years or more

5. Does your husband have more than one wife or sexual partner? yes no don't know

6. Does your husband provide you with financial and/or material support? yes no

7. What is your husband's highest level of education?
- no schooling
 - primary school, not complete
 - primary school, complete
 - secondary school, not complete
 - secondary school, complete
 - attended college or university
 - don't know

Follow-up Behavioral Questionnaire—Version 2 (FQ-1)
Item-specific Instructions:
Items 1 and 2: Emphasize "currently."



Visit Code 0 1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire—Version 2

8. Do you currently have a partner? By partner, I mean a man you have sex with on a regular basis but who is not your husband. yes no ———▶ *If no, go to item 15 on page 3.*

9. Are you currently living with your partner? yes no

Your last interview was _____ (Interviewer will tell the respondent when her last interview was).

10. Is your current partner the male sexual partner you told us about at your last interview in _____ (month of last interview from above)? yes no don't remember
————▶ *If yes, go to item 15 on page 3.*

11. Is your sexual partner younger, about the same age, or older than you?
 younger ———▶
 about the same age ———▶
 older
 don't know ———▶
————▶ *If younger, about the same age, or don't know, go to item 12.*

11a. If older, do you think he is less than 10 years older than you or 10 years or more older than you? less than 10 years 10 years or more

12. Does your partner have more than one wife or sexual partner? yes no don't know

13. Does your partner provide you with financial and/or material support? yes no

14. What is your partner's highest level of education?
- no schooling
 - primary school, not complete
 - primary school, complete
 - secondary school, not complete
 - secondary school, complete
 - attended college or university
 - don't know

Follow-up Behavioral Questionnaire—Version 2 (FQ-2)
Item-specific Instructions:
Item 13: Record whether or not the participant's partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.



Visit Code 0 1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavioral Questionnaire—Version 2

15. Which family planning methods are you currently using? Mark "none" or all that apply.

- 15a. none → **Go to item 16.**
- 15b. family planning pills or birth control pills
- 15c. injectable contraceptives (such as Depo-Provera)
- 15d. implants (such as Norplant, jadelle)
- 15e. vaginal ring
- 15f. diaphragm
- 15g. sponge
- 15h. IUD
- 15i. natural methods such as withdrawal or rhythm method
- 15j. male condoms
- 15k. female condoms
- 15l. spermicide
- 15m. surgical sterilization (tubal ligation)
- 15n. sex with a partner who had a vasectomy
- 15o. other, specify:
Local Language: _____
English: _____

16. Since your last interview, have you seen a health care provider/ doctor/nurse for HIV care or treatment? *yes* *no* *don't know* *refuse to answer*

17. Since your last interview, have you seen a traditional healer for HIV care or treatment?

18. Since your last interview, have you taken any HIV medication (ARVs) prescribed by a health care provider/doctor/nurse?

19. Since your last interview, have you taken any HIV medication (ARVs) prescribed by a traditional healer?

20. Since your last interview, have you received help or support for any of the following from the government, churches, or other community organizations?

Read each response option aloud.

yes *no*

 20a. food

 20b. clothing

 20c. housing

 20d. money other than study incentives/reimbursement

 20e. other, specify: *Local Language:* _____
English: _____

Follow-up Behavioral Questionnaire—Version 2 (FQ-3)

Item-specific Instructions:

Item 15: Do not read response options to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the "other, specify" box and record the participant's verbatim response. Also provide the English translation in the space provided.

Items 16–20: These questions assess the participant's access to HIV care and treatment, and utilization of HIV support services available in the community.

Item 20d: If the participant only received money as part of study incentives or study reimbursement, check "no" for response option 20d.

Item 20e: If "other, specify" is marked, be sure to record the participant's verbatim response. Also provide the English translation in the space provided.



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

MTN 015 (143)

TXR-1 (301)

Participant ID

- -

Site Number Participant Number Chk

Antiretroviral Treatment Regimen Log

1.

Medication Code <input type="text" value=""/> <input type="text" value=""/>	Date Started <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <i>dd MMM yy</i>	Staff Initials/Log Entry Date
Date Stopped <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> OR <input type="checkbox"/> Continuing at end of study		Stop Code(s) <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Dose/Units		
Frequency Mark only one. <input type="checkbox"/> <i>prn</i> <input type="checkbox"/> <i>qd</i> <input type="checkbox"/> <i>tid</i> <input type="checkbox"/> <i>qhs</i> <input type="checkbox"/> <i>qxh: every___ hrs</i> <input type="text" value=""/> <input type="text" value=""/> <input type="checkbox"/> <i>once</i> <input type="checkbox"/> <i>bid</i> <input type="checkbox"/> <i>qid</i> <input type="checkbox"/> <i>other, specify: _____</i>		

2.

Medication Code <input type="text" value=""/> <input type="text" value=""/>	Date Started <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <i>dd MMM yy</i>	Staff Initials/Log Entry Date
Date Stopped <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> OR <input type="checkbox"/> Continuing at end of study		Stop Code(s) <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Dose/Units		
Frequency Mark only one. <input type="checkbox"/> <i>prn</i> <input type="checkbox"/> <i>qd</i> <input type="checkbox"/> <i>tid</i> <input type="checkbox"/> <i>qhs</i> <input type="checkbox"/> <i>qxh: every___ hrs</i> <input type="text" value=""/> <input type="text" value=""/> <input type="checkbox"/> <i>once</i> <input type="checkbox"/> <i>bid</i> <input type="checkbox"/> <i>qid</i> <input type="checkbox"/> <i>other, specify: _____</i>		

3.

Medication Code <input type="text" value=""/> <input type="text" value=""/>	Date Started <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <i>dd MMM yy</i>	Staff Initials/Log Entry Date
Date Stopped <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> OR <input type="checkbox"/> Continuing at end of study		Stop Code(s) <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Dose/Units		
Frequency Mark only one. <input type="checkbox"/> <i>prn</i> <input type="checkbox"/> <i>qd</i> <input type="checkbox"/> <i>tid</i> <input type="checkbox"/> <i>qhs</i> <input type="checkbox"/> <i>qxh: every___ hrs</i> <input type="text" value=""/> <input type="text" value=""/> <input type="checkbox"/> <i>once</i> <input type="checkbox"/> <i>bid</i> <input type="checkbox"/> <i>qid</i> <input type="checkbox"/> <i>other, specify: _____</i>		

Antiretroviral Treatment Regimen Log (TXR-1)

Purpose: This form is used to document HIV antiretroviral treatments used by the participant. Only antiretroviral treatments are recorded on this form.

General Information/Instructions: Fax this form to SCHARP DataFax each time it is modified or updated.

Item-specific Instructions:

- **Page:** Number the pages sequentially starting with page 001.
- **Medication Code:** Record the medication code from the MTN 015 Antiretroviral Medication Code List. If the antiretroviral medication is not listed, record "99" for the medication code. If the participant is involved in a ART investigational study where she is blinded to which ART medications she is using, record "98."
- **Date Started:** At minimum, a month and year are required.
- **Staff Initials/Log Entry Date:** Record the staff initials and date of the staff member who records the date started.
- **Date Stopped:** The date stopped should remain blank until the medication is stopped or held. If a date stopped is recorded, at minimum, a month and year are required. If the participant is using the medication at the time of study termination, mark the "Continuing at end of study" box and leave the "Stop Code(s)" boxes blank.
- **Stop Code(s):** Record the code(s) for the reason(s) the medication was stopped. See the MTN 015 Antiretroviral Medication Stop Code List for a listing of available stop codes. If more than four stop codes apply, record the codes for the reasons that most strongly influence the decision to stop the medication.
- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response boxes and initial and date. For combination medications, record the dosage of three main medications.
- **Frequency Abbreviations:**

prn as needed	qd every day	tid three times daily	qhs at bedtime
once one time	bid twice daily	qid four times daily	qhx every x hours



MTN 015 (143)

IV-1 (350)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Interim Visit

Visit Date

dd MMM yy

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

- 1a. participant report of ART initiation —▶ **Complete ART Enrollment, ART Initiation Information, Antiretroviral Treatment Regimen Log, and ART Study Visit forms.**
- 1b. clinical follow-up
- 1c. other, specify: _____

2. Besides this Interim Visit form, what other DataFax study forms were completed for this visit? *Mark "none" or all that apply.*

- 2a. none —▶ **Go to item 3.**
- 2b. Laboratory Results–Revised
- 2c. Sexually Transmitted Diseases Results
- 2d. Pregnancy Report and History
- 2e. other, specify: _____

3. Is the participant completing a parent protocol visit at this MTN 015 visit?

yes no —▶ **If no, end of form.**

3a. Visit code of parent protocol visit completed today:

visit code .

Comments: _____

Interim Visit (IV-1)

Purpose: This form is used to document follow-up interim visits.

General Information/Instructions: Complete this form for interim visits only. For required study follow-up visits, complete a Non-ART Study Visit or ART Study Visit form.

Item-specific Instructions:

- **Visit Code:** Only interim visit codes should be recorded.
- **Item 1a:** Mark this box if the participant reported initiation of ART use for the very first time at this (non-ART) interim visit. If this box is marked, a non-ART interim visit code should be recorded on the form
- **Item 2:** If item 1a is marked, note that all other forms completed for the interim visit should have an ART visit code assigned - contact SCHARP for clarification in these cases.
- **Items 3 and 3a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 2 “yes” and in 2a, record the visit code (regular or interim) of the parent protocol visit completed on this date.



MTN 015 (143)

SH-1 (371)

Visit Code

□□.□□

1

Participant ID

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

Social Harms Assessment

Visit Date

□□ □□□□ □□
dd MMM yy

1. Since your last interview, have you had any problems with the following people as a result of being in the study: **Read each response option aloud.**

yes no

- 1a. your husband or partner?
- 1b. people at home/family?
- 1c. your friends/personal relationships?
- 1d. people at work?
- 1e. people at school?
- 1f. your doctor, nurse, midwife, or other health care provider?
- 1g. your landlord or property owner?
- 1h. other people, specify:

Local Language: _____
English: _____

If all are marked no, go to item 5 on page 3.

2. Please describe the problem:

Local Language: _____
English: _____

NOTE: Item 3 is not read aloud.

3. **Clinic Staff:** Was this problem assessed to be possibly, probably, or definitely related to MTN 015 study participation or procedures?

<i>possibly related</i>	<i>probably related</i>	<i>definitely related</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

□□□ 29-FEB-08

01

Language

Staff Initials / Date

Social Harms Assessment (SH-1)

Items 1–3 ask about problems the participant may have encountered as a result of being **in the study**.

Item-specific Instructions:

- **Item 1:** Emphasize “in the study.” If “yes” is marked for item 1h, record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 2:** Describe the problem. Do **not** record the participant’s verbatim response - describe the problem in your own words so that the nature of the problem is clear. Provide the English translation in the space provided.
- **Item 3:** This is not an interviewer-administered item. If the participant reports more than one social harm, mark this item based on the social harm that relates most strongly to MTN015 study participation or procedures.



MTN 015 (143)

SH-2 (372)

Visit Code

□□□

1

Participant ID

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

Social Harms Assessment

No data recorded on this page

4. Has this problem/any of these problems resulted in...

4a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. yes no

4a1. Please describe the problem:

Local Language:

English:

If no, go to item 4b.

4b. physical harm to you? For example, has anyone physically hurt you as a result of this problem. yes no

4b1. Please describe the problem:

Local Language:

English:

If no, go to item 4c.

4c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn an income. yes no

4c1. Please describe the problem:

Local Language:

English:

If no, go to item 4d on page 3.

Social Harms Assessment (SH-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 and the Staff Initials/Date.
- **Items 4a1–4c1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

MTN 015 (143)

SH-3 (373)

Visit Code

□□.□

1

Participant ID

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

Social Harms Assessment

4d. physical or other harm to your children? yes no

4d1. Please describe the problem:

Local Language:

English:

If no, go to item 5.

5. Since your last interview, have you had any problems with the following people as a result of being HIV positive: Read each response option aloud.

yes

no

5a. your husband or partner?

5b. people at home/family?

5c. your friends/personal relationships?

5d. people at work?

5e. people at school?

5f. your doctor, nurse, midwife, or other health care provider?

5g. your landlord or property owner?

5h. other people, specify:

Local Language: _____

English: _____

If all are marked no, end of form. Do not fax pages 4-5.

Social Harms Assessment (SH-3)

Item-specific Instructions:

- **Item 4d1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 5** asks about problems the participant may have encountered as a result of being **HIV-positive**.
 - Emphasize "HIV-positive." If "yes" is marked for item 5h, be sure to record the participant's verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

SH-4 (374)

Visit Code

□□.□

Participant ID

□□□-□□□□□-□

Site Number

Participant Number

Chk

Social Harms Assessment

6. Please describe the problem:

Local Language: _____

English: _____

7. Has this problem/any of these problems resulted in...

7a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. yes no

7a1. Please describe the problem:

Local Language:

English:

If no, go to item 7b.

7b. physical harm to you? For example, has anyone physically hurt you as a result of this problem. yes no

7b1. Please describe the problem:

Local Language:

English:

If no, go to item 7c on page 5.

Social Harms Assessment (SH-4)

Item-specific Instructions:

Items 6–7 ask about problems the participant may have encountered as a result of being **HIV-positive**.

- **Item 6:** Describe the problem. Do **not** record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. Provide the English translation in the space provided.
- **Items 7a1 and 7b1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

MTN 015 (143) SH-5 (375)

Visit Code

1

Participant ID

Participant ID form with Site Number, Participant Number, and Chk fields.

Social Harms Assessment

7c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn an income.

yes no checkboxes

If no, go to item 7d.

7c1. Please describe the problem: Local Language:

Local Language description line

English:

English description line

7d. physical or other harm to your children?

yes no checkboxes

If no, end of form.

7d1. Please describe the problem: Local Language:

Local Language description line

English:

English description line

Social Harms Assessment (SH-5)

Item-specific Instructions:

- **Items 7c1 and 7d1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.



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

MTN 015 (143)

HA-1 (410)

Participant ID

- -
 Site Number Participant Number Chk

HIV/AIDS-associated Events Log

No events occurred throughout study. Staff Initials/Date _____
 End of form. Fax to SCHARP DataFax.

1. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed probable unknown <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study dd MMM yy	
1a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

2. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed probable unknown <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study dd MMM yy	
2a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

3. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed probable unknown <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study dd MMM yy	
3a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

4. HIV/AIDS Event Code: <input type="text"/> <input type="text"/>	Visit Code at which this event was first reported: <input type="text"/> <input type="text"/> . <input type="text"/>	Clinical Diagnosis: confirmed probable unknown <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> Ongoing at end of study dd MMM yy	
4a. Is this an AIDS-defining illness? <input type="checkbox"/> yes <input type="checkbox"/> no		

HIV/AIDS-associated Events Log (HA-1)

Purpose: This form is used to document HIV/AIDS-associated events experienced by the participant while on-study.

General Information/Instructions: Record only events that appear on the MTN 015 HIV/AIDS-associated Event Code List. Fax this form to SCHARP DataFax each time it is modified or updated.

Item-specific Instructions:

- **Page:** Number the pages sequentially starting with page 001.
- **HIV/AIDS Event Code:** Record the event code as listed on the MTN 015 HIV/AIDS-associated Event Code List. Whenever possible, obtain medical records so that you have as much information as possible about the event.
- **Visit Code:** Record the visit code at which the event was first reported or observed.
- **Clinical Diagnosis:** Refer to the *WHO Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-related Disease in Adults and Children*. Mark “confirmed” if the listed criteria for definitive diagnosis have been met. Mark “probable” if the listed clinical diagnosis criteria have been met. If the definitive and clinical diagnosis are the same, and the criteria have been met, mark “confirmed.” Mark “unknown” if neither the clinical nor definitive diagnosis criteria have been met. Do not wait for a clinical or definitive diagnosis to be made before faxing the form to SCHARP DataFax. Mark “unknown” and update the item once a clinical or definitive diagnosis is available.
- **Date Started:** At minimum, month and year are required.
- **Date Stopped:** If a date stopped is recorded, at minimum, month and year are required. At the participant’s Termination visit, the “Date Stopped” must be recorded for each event or illness OR the “Ongoing at end of study” box must be marked.
- **Staff Initials/Log Entry Date:** Enter the staff initials and date of the staff member who records the date started.
- **Is this an AIDS-defining illness?:** Use the MTN 015 HIV/AIDS-associated Event Code List to help determine whether the event is an AIDS-defining illness. Contact the MTN 015 Protocol Chair with any questions about whether the event is an AIDS-defining illness.



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

MTN 015 (143)

NCM-1 (416)

Participant ID

- -
 Site Number Participant Number Chk

Non-ART Concomitant Medications Log

No medications taken throughout study. _____
 Staff Initials/Date
 End of form.
 Fax to SCHARP DataFax.

1. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

2. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

3. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

4. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

5. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

6. Medication Code: If medication code is 99, specify: _____ Staff Initials/Entry Date _____
 Date Started Date Stopped OR Continuing at end of study
 dd MMM yy dd MMM yy

Non-ART Concomitant Medications Log (NCM-1)

Purpose: This form is used to document participant use of non-antiretroviral (ART) medications. Only record the following types of non-ART medications on this form: drugs for opportunistic infection prophylaxis or treatment; hormonal contraceptives, and single-dose nevirapine used for prevention of mother-to-child transmission (pMTCT) of HIV.

General Information/Instructions: Fax this form to SCHARP DataFax each time it is modified or updated.

Item-specific Instructions:

- **Page:** Number the pages sequentially starting with page 001.
- **Medication Code:** Record the medication code from the MTN 015 Non-ART Concomitant Medication Code List. If the hormonal contraception or opportunistic infection prophylaxis/treatment medication is not listed, record “99” as the code and specify the medication in the box provided.
- **Staff Initials/Date:** Record the staff initials and date of the staff member who records the date started.
- **Date Started:** At minimum, a month and year are required.
- **Date Stopped:** The date stopped should remain blank until the medication is stopped or held. If a date stopped is recorded, at minimum, a month and year are required. If the participant is using the medication at the time of study termination, mark the “Continuing at end of study” box and leave the date stopped blank.



MTN 015 (143)

PR-1 (440)

Visit Code .

1

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Report and History

PREGNANCY REPORT

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

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

PREGNANCY HISTORY

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

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

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

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

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

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

3f. Number of therapeutic/elective abortions:

3g. Number of ectopic pregnancies:

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

Comments: _____

Pregnancy Report and History (PR-1)

Purpose: Complete this form to report a pregnancy of a study participant.

General Information/Instructions: Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific instructions:

- **Item 1:** Complete date required. Record best estimate if date not known.
- **Item 2:** Complete date required.



Visit Code

1

MTN 015 (143)

PO-1 (441)

Participant ID

--
Site Number Participant Number Chk

Pregnancy Outcome

Outcome unknown at end of study. _____
Staff Initials/Date
▶ End of form. Fax to SCHARP DataFax.

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

2. OUTCOME #1

dd MMM yy

2a. Outcome Date

2b. Specify Outcome: Mark only one.

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

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

If only one outcome, end of form.

3. OUTCOME #2

dd MMM yy

3a. Outcome Date

3b. Specify Outcome: Mark only one.

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

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

Comments: _____

29-FEB-08

01

Language

Staff Initials / Date

Pregnancy Outcome (PO-1)

Purpose: This form is used to report the pregnancy outcome(s) of a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff. A Pregnancy Outcome form is required for each Pregnancy Report and History form that is completed for a participant.

General Information/Instructions: If an outcome is unknown at study end, mark the “Outcome unknown at end of study” box at the top of the page and fax to DataFax. When the outcome is known, draw a line through this box, record the outcome, and refax. A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SCHARP for guidance on how to complete this form.

Item-specific Instructions:

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



MTN 015 (143)

MV-1 (463)

Visit Code

0

1

Participant ID

Site Number - Participant Number - Chk

Missed Visit

Form Completion Date

dd MMM yy

1. Target Visit Date: dd MMM yy

2. Reason visit was missed. Mark only one.

- unable to contact participant
unable to schedule visit within the window
participant refused visit
participant incarcerated/in prison
participant admitted to a health care facility
participant withdrew from the study -> Complete a Termination form.
participant deceased -> Complete a Termination form.
other, specify:

visit not required per protocol

Comments:

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.
 - **Visit not required per protocol:** For participants enrolling as non-ART, complete a Missed Visit form with this item marked for each non-ART follow-up visit whose window has already closed by the time of MTN 015 Enrollment. Also complete a Missed Visit form with this item marked for the visit whose window includes the date of MTN 015 Enrollment. For participants who enroll as ART, or who switch to ART after enrollment, complete a Missed Visit form with this item marked for each ART follow-up visit whose window has already closed by the time of ART Enrollment.



MTN 015 (143)

PT-1 (465)

Participant ID

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

Participant Transfer

Form Completion Date

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

1. Name of transferring study site: _____

2. Name of receiving study site: _____

3. Visit Code of last completed contact with participant: .

4. Date participant records were sent to receiving study site:
dd MMM yy

Comments: _____

29-FEB-08

Participant Transfer (PT-1)

Purpose: Complete this form when a participant is transferring to another study clinic/site.

General Information/Instructions: The Participant Transfer form is completed by the transferring site (the site that the participant is leaving).

For more information on Participant Transfer and Receipt, refer to the protocol, Study Specific Procedures (SSPs), and/or Manual of Operations (MOP).

Item-specific instructions:

- **Item 4:** Complete date required.



MTN 015 (143)

PRC-1 (466)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk

Site Number Participant Number Chk

Participant Receipt

Form Completion Date

Form Completion Date form with boxes for dd, MMM, and yy

dd MMM yy

Note: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site: [dd][MMM][yy]

yes no

4. Did participant provide informed consent for specimen storage at receiving study site? []

[] -> If no, end of form.

4a. Date informed consent for specimen storage signed: [dd][MMM][yy]

Comments: _____

[] [] [] [x] 29-FEB-08

01 Language

Staff Initials / Date

Participant Receipt (PRC-1)

Purpose: Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.

General Information/Instructions: The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).

For more information on Participant Transfer and Receipt, refer to the protocol, Study Specific Procedures (SSPs), and/or Manual of Operations (MOP).

Item-specific instructions:

- **Participant ID: Do not** assign a new Participant ID. Record the Participant ID assigned by the original study site.
- **Item 3:** Complete date required.
- **Item 4a:** Complete date required.



MTN 015 (143)

ESI-1 (489)

Participant ID

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

End of Study Inventory

Form Completion Date

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

1. For each schedule in which this participant was enrolled, what is the **highest** visit code (scheduled or interim) recorded on a form submitted via DataFax?

1a. Non-ART visit schedule

visit code

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

1b. ART visit schedule

visit code *not applicable*

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

OR

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

of interim visits

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

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

3a. Non-ART Concomitant Medications Log *page #*

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

3b. Antiretroviral Treatment Regimen Log *page #*

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

no pages submitted

OR

3c. HIV/AIDS-associated Events Log *page #*

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

End of Study Inventory (ESI-1)

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

- **Form Completion Date:** Complete date required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 1a:** If a participant enrolled into MTN 015 after ART initiation (that is, she was always followed using the post-ART initiation visit schedule), record "01.0" for this item.
- **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.

Termination (TM-1)

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

General Information/Instructions: A complete date is required, unless termination is due to death.

Item-specific Instructions:

- **Item 1:** Complete date 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.



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

Page

Participant ID

--
Site Number Participant Number Chk

Protocol Deviation Log

Form Completion Date

dd MMM yy

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

Protocol Deviation Log (PDL-1)

Purpose: This form documents and reports protocol deviations identified for study participants.

General Information/Instructions:

Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

Item-specific Instructions:

Page: Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

Item 2: Record the date the event occurred (start date).

Item 5: Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

Item 6: Briefly describe the specific details of the deviation.

Item 9: Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Code	Description	Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.	14	Lab assessment deviation: Include missed, or incomplete lab specimen collection.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.	15	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
08	Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.	16	Staff performing duties that they are not qualified to perform: Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
09	Improper AE/EAE follow-up: Use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.	17	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
10	Unreported AE: Site staff become aware of an AE, but do not report it per protocol requirements.	18	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly.
11	Unreported EAE: Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.	21	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
12	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.	22	Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.
13	Physical assessment deviation: Include missed or incomplete physical/pelvic/rectal exam assessments.	99	Other

Not a DataFax form. Do not fax to DataFax.

MTN 015 (143)

Participant ID

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

Medical History Log

Page

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	
	Resolve Date (dd-MMM-yy)		

Comments

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	
	Resolve Date (dd-MMM-yy)		

Comments

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	
	Resolve Date (dd-MMM-yy)		

Comments

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	
	Resolve Date (dd-MMM-yy)		

Comments

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Medical History Log (non-DataFax)

Purpose: This form is used to document and track all medical conditions experienced by the participant while on-study. This includes diagnosed medical conditions as well as participant self-reported symptoms.

General Information/Instructions: Review this log at every visit. If a condition has no Resolve Date listed, assess the status of that condition at the visit. This form is a non-DataFax form. Do not fax to SCHARP Data-Fax.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.
- **Medical Condition:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms.
- **Onset Date:** At a minimum, month and year are required.
- **Staff Initials/Log Entry Date:** Enter the staff initials and date of the staff member who records the onset date.
- **Resolve Date:** At a minimum, month and year are required. Record one of the following, as appropriate:
 - the date on which the participant no longer experiences the medical condition,
 - the date of the study visit or specimen collection at which the change in status/resolution is first noted,**or**
 - if condition is continuing at end of study, record “CES” in the space provided.

Not a DataFax form. Do not fax to DataFax.

MTN 015 (143)

Page 1 of 1

Participant ID

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

Physical Exam

Exam Date

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

VITAL SIGNS

1. Height	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>cm</i>	4. BP	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>mmHg</i>
2. Weight	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>kg</i>	5. Pulse	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>per minute</i>	
3. Body Temp	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<i>°C</i>					

Staff Initials / Date

FINDINGS

	<i>not done</i>	<i>normal</i>	<i>abnormal</i>	Notes:
6. HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
7. Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Chest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
15. General Appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
16. Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
17. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
18. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
19. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Comments: _____

Physical Exam (non-DataFax)

Purpose: This form is used to document physical exam assessments (complete and targeted) performed during the study.

General Information/Instructions: This form is a non-DataFax form - do not fax to SCHARP DataFax. Refer to the protocol and/or study visit checklist to determine which portions of the physical exam assessment are required for the visit.

Item-specific Instructions:

- **Items 1–5:** If the item is not required, line through the response boxes and write “not required” in the white space. Initial and date.
- **Items 6–19:** For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in the notes. If not evaluated (includes assessments that are not required), mark the “not done” box. HEENT refers to head, eyes, ears, nose, and throat.
 - **Items 17–19:** If abnormal, specify the body system being referenced and describe the findings in the notes.

Not a DataFax form. Do not fax to DataFax.

MTN 015 (143)

Page 1 of 1

Participant ID

- -

Site Number Participant Number Chk

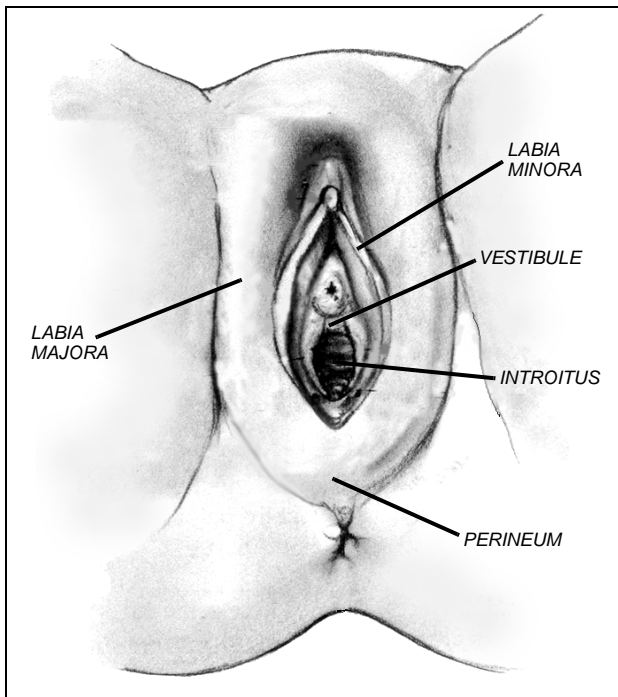
Exam Date

dd MMM yy

Pelvic Exam Diagrams

no normal variants or abnormal findings observed

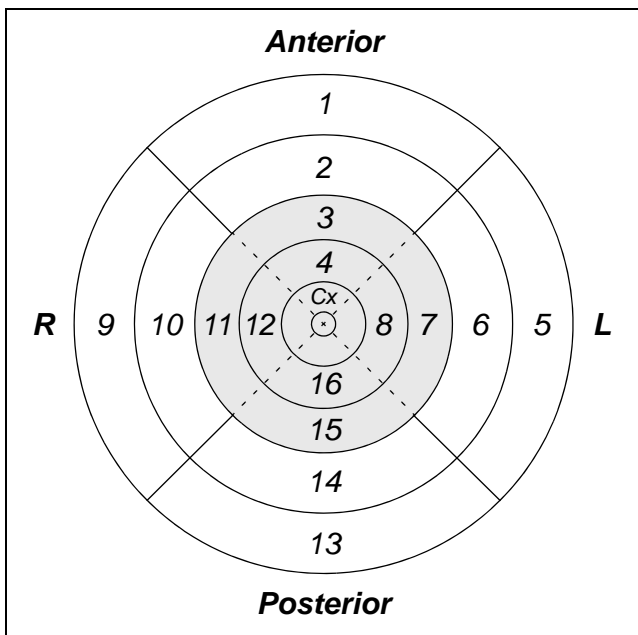
External Genitalia



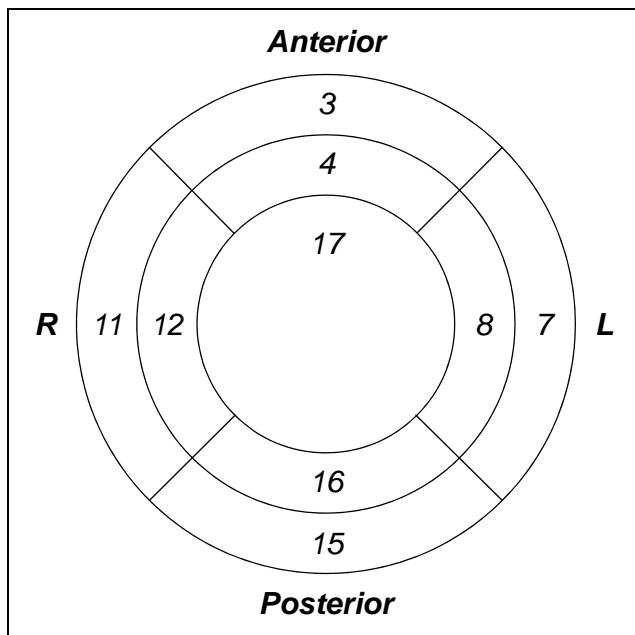
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



29-FEB-08

Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)

Purpose: This form is used to document all variants of normal and all abnormal findings observed during study pelvic examinations.

General Information/Instructions: This is a non-DataFax form. Do not fax to SCHARP DataFax.

Item-specific Instructions:

- If no variants of normal or abnormal findings are observed mark the “no normal variants or abnormal findings observed” box.
- Documenting findings on the cervix: If helpful, draw the os in the center of the diagram labeled “Cervix” (lower right corner).
- Documenting cervical or vaginal discharge or blood in vagina: Record “cerv discharge,” “vag discharge,” or “blood in vag” on or near the appropriate diagram.

Concomitant Medications Log (non-DataFax)

Purpose: This form is used to document all medication(s) *other than* HIV antiretrovirals, drugs for opportunistic infection prophylaxis or treatment, and hormonal contraceptives used by the participant during the study. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs

General Information/Instructions: Review this log at every visit. If a medication has no date stopped listed, assess the status of the medication at the visit. This is a non-DataFax form. Do not fax to SCHARP DataFax.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”
- **Medication:** Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.
- **Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
- **Staff Initials/Log Entry Date:** Enter the staff initials and date of the staff member who records the date started.
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year is required.
- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response boxes and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
- **Route Abbreviations:**
For medications administered via a skin patch, mark the “other, specify” box and record “transdermal”
 - **PO** oral
 - **IM** intramuscular
 - **IV** intravenous
 - **TOP** topical
 - **IHL** inhaled
 - **VAG** vaginal
 - **REC** rectal
- **Frequency Abbreviations:**

prn as needed	qd every day	tid three times daily	qhs at bedtime
once one time	bid twice daily	qid four times daily	qhx every x hours