

Screening and Enrollment

Required forms

- Enrollment (ENR-1)
- Microbicide Trial Participation (MTP-1)
- Demographics (DEM-1) (*Site to add Local Language version*)
- Baseline Behavioral Questionnaire (BBQ-1~BBQ-8) (*Site to add Local Language version*)
- Baseline Behavioral Questionnaire–Version 2 (BQ-1) (*Site to add Local Language version*)
- ACASI Tracking (ACT-1)
- Acute Seroconversion Assessment (ASA-1)
- Seroconversion Symptoms (SCS-1)
- Specimen Storage (SS-1)
- Laboratory Results–Revised–Version 2 (LAB-1)
- Sexually Transmitted Diseases Results (STR-1)
- Family Planning (FP-1)

If Applicable:

- Non-ART Concomitant Medications Log (NCM-1)
- ART Enrollment (AEN-1)
- ART Initiation Information–Revised (AIN-1)
- Antiretroviral Treatment Regimen Log (TXR-1)
- Antiretroviral Therapy Adherence (ATA-1~ATA-4)
- HIV/AIDS-associated Events Log (HA-1)
- Pregnancy Report and History (PR-1)
- Pregnancy Outcome (PO-1)
- Missed Visit (MV-1)
- Protocol Deviation Log (PDL-1)

This page intentionally left blank.

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)

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: _____

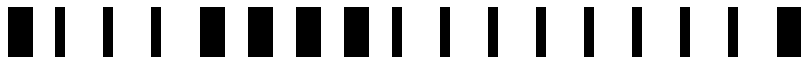
Microbicide Trial Participation (MTP-1)

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)

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
---	---

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.

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

0	1
---	---

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.

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

<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

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.

- | | | |
|-------------------------------------|------------------------------------|-----------------------------------------------------------------------------------------------|
| <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | 21a. I have told no one —————▶ If yes, go to item 26 on page 7. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <i>N/A</i> |
| <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"/> | 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"/> | 21d. sister |
| <input type="checkbox"/> | <input type="checkbox"/> | 21e. brother |
| <input type="checkbox"/> | <input type="checkbox"/> | 21f. mother |
| <input type="checkbox"/> | <input type="checkbox"/> | 21g. father |
| <input type="checkbox"/> | <input type="checkbox"/> | 21h. your children |
| <input type="checkbox"/> | <input type="checkbox"/> | 21i. other relative |
| <input type="checkbox"/> | <input type="checkbox"/> | 21j. friend or neighbor |
| <input type="checkbox"/> | <input type="checkbox"/> | 21k. church member |
| <input type="checkbox"/> | <input type="checkbox"/> | 21l. community elder |
| <input type="checkbox"/> | <input type="checkbox"/> | 21m. health care provider/doctor/nurse |
| <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
---	---

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"/> | <input type="checkbox"/> | 30a. food |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30b. clothing |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30c. housing |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30d. money other than study incentives/reimbursement |
| <input type="checkbox"/> | <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.

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.

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

<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

Acute Seroconversion Assessment

Visit 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>	

Specimen Collection Date

dd MMM yy

- Last negative HIV antibody test:
- First positive HIV antibody test:
- First positive Western Blot HIV test:

<input type="checkbox"/>	Specimen Collection Date		
	<i>dd</i>	<i>MMM</i>	<i>yy</i>
Not done/ Not collected	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

4. Any known detectable viral load prior to today:

4a. HIV RNA PCR (plasma)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>viral copies/mL</i>			
				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<input type="checkbox"/>	Specimen Collection Date		
	<i>dd</i>	<i>MMM</i>	<i>yy</i>
Not done/ Not collected	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

5. Any known CD4+ result prior to today:

5a. Absolute CD4+	<i>cells/mm³</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
-------------------------	-----------------------------	-------------------------------------------------------------------------------------

5a1. CD4+ %	<i>not available</i>	<input type="checkbox"/>	OR	<input type="text"/> <input type="text"/>	.	<input type="text"/>	%
-------------------	----------------------	--------------------------	----	-------------------------------------------	---	----------------------	---

Comments: _____

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

0	1
---	---

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)

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	dd	MMM	yy	dd	MMM	yy	
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)

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.

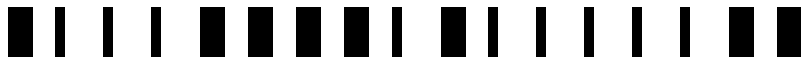
Initial Collection Date: Record the date that the first specimen(s) was *collected* for this visit. Complete date required.

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.

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.



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

1d. Clue cells ≥ 20%

1e. Trichomonads

1f. Buds and/or hyphae (yeast)

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

2. STD SEROLOGY

non-reactive reactive

2a. Syphilis screening test

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

negative positive

3a. N. gonorrhea

3b. C. trachomatis

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

4. Trichomonas Rapid Test

negative positive

5. NO LONGER APPLICABLE FOR THIS PROTOCOL

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.

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.