SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) DEM-1 (001)

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Demographics

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

I will start by asking you some general questions about yourself.

1. What is your date of birth?..... ☐☐ ☐☐☐ ☐☐ → If unknown, record age: ☐☐ *years*
dd *MMM* *yy*

2. What is your gender? ..... *male* ☐ *female* ☒

3. Are you currently married? ..... *yes* ☐ *no* ☐ → ***If yes, go to item 5.***

4. Do you currently have a primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis or who you consider to be your main partner. ..... *yes* ☐ *no* ☐ → ***If no, go to item 12 on page 2.***

5. How old is your husband/primary sex partner? ..... ☐☐ *years* *don't know* ☐

6. Are you currently living with him? ..... *yes* ☐ *no* ☐

7. Does he have any sex partners other than you? ..... *yes* ☐ *no* ☐ *don't know* ☐

8. Does he provide you with financial and/or material support?..... *yes* ☐ *no* ☐

9. What is his average monthly income? *Record in local currency.* ..... ☐☐☐☐☐☐☐☐☐ *don't know* ☐ *no income* ☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

N:\hivnet\forms\MTN_003\forms\m003_dem.fm

0 1
Language

_____
Staff Initials / Date

Demographics (DEM-1)

Purpose: This interviewer-administered form is used to collect participants' demographic and socioeconomic information.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: There is no visit code field on this form, since this form is only completed at the Screening Part 1 Visit. If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. ***NOTE:*** *participant must be between the ages of 18 and 40 years (inclusive) at the time of screening to be eligible for study participation.*
- **Item 4:** Record whether or not the participant **currently** has a primary sex partner.
- **Item 5:** Read aloud "husband" or "primary sex partner," depending on the participant's response to item 3 and item 4 (if not currently married). If the participant does not know her husband's or primary partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 8:** Record whether or not the participant's husband or primary partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 9:** Record the husband's or primary partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

  For example, if the income is 2,145 record:

0	*0*	*0*	*0*	*0*	*2*	*1*	*4*	*5*

  If the husband's or primary partner's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) DEM-2 (002)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

10. What is his 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

11. Is he circumcised? By circumcised, I mean when the foreskin of the penis is removed. ..... ***Use visual aid.***

	yes	*no*	*don't know*
	☐	☐	☐

12. Do you earn an income of your own? .....

yes	*no*	
☐	☐	→ ***If no, go to item 13.***

12a. What is your average monthly income?
Record in local currency. .....

[ ][ ][ ][ ][ ][ ][ ][ ][ ]

12b. How do you earn your income?
Mark all that apply. .....

formal employment	*self-employed*	*other, specify*
☐	☐	☐

Local Language: _____ *English:* _____

13. What is your highest level of education?

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

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband or primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 11:** The intent of this item is to capture the circumcision status of the participant's husband/primary sex partner at the time this form is administered (Screening Part 1). If the participant's husband/primary sex partner (as reported in items 3–4) is circumcised after the Screening Part 1 Visit, do not update the response to item 11.
- **Item 12a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

  For example, if the income is 2,145 record: | *0* | *0* | *0* | *0* | *0* | *2* | *1* | *4* | *5* |

  If the participant's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 12b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) DEM-3 (003)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

14. How many children have you given birth to who were alive at birth? [ ][ ] *# of children*

15. Do you, or does someone in your family, own the house you are currently living in? ..... *yes* [ ] *no* [ ]

16. How many rooms are in the house you are currently living in? ..... [ ][ ] *# of rooms*

17. What is your ethnic group or tribe? ..... [ ][ ] *ethnic/tribe code*
If other, specify:

Local Language: _____ *English:* _____

***Interviewer**: Complete item 18 after the interview.*

18. Where was the participant referred/recruited from?..... [ ][ ] *recruitment code*

Demographics (DEM-3)

Item-specific Instructions:

- **Item 14:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 15:** Record whether or not the participant (or someone in her extended family) owns the house she lives in.
- **Item 16:** Do not count bathrooms as rooms.
- **Item 17:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant responds with "other," record, "99" and the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE
01 - Chichewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona
02 - Lombwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele
03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe
04 - Tumbuka	10 - Colored		15 - Lozi	06 - White
05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other
06 - White	06 - White		06 - White	
99 - Other	99 - Other		99 - Other	

- **Item 18:** This is not an interviewer-administered item. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-1 (060)

Participant ID

Site Number – Participant Number – Chk

Baseline Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. As part of this research study, you will be asked questions about yourself, your sexual behaviors and reproductive health. We are all concerned about HIV/AIDS and how it is affecting women in our community. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential, and none of your answers will affect your ability to participate in this research study.

1. Have you talked with any of the following people about your participation in this research study? You can answer "yes" to more than one item.

		yes	no	N/A
1a.	Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
1b.	Other sex partners?	☐	☐	☐
1c.	Your mother or father?	☐	☐	☐
1d.	Your sister or brother?	☐	☐	☐
1e.	Other family member?	☐	☐	☐
1f.	A friend or neighbor?	☐	☐	☐
1g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
1h.	An elder or community leader?	☐	☐	☐
1i.	Anyone else? If yes, specify:	☐	☐	☐

Local Language: _____ *English:* _____

Baseline Behavior Assessment (BBA-1)

Purpose: This form is used to collect baseline information about the participant's sexual behaviors and vaginal hygiene practices. This is a mixed form; items 1–6e are interviewer-administered, and items 7–9a are not. This form is administered only once to each enrolled participant as part of her Enrollment visit.

Item-specific Instructions:

Note: There is no visit code field on this form since this form is only administered at the Enrollment visit.

- **Item 1:** Read each item 1a–1i aloud and mark the participant's answer. If "yes" is marked for item 1i, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-2 (061)

Participant ID

Site Number – Participant Number – Chk

Baseline Behavior Assessment

The next few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

2. In the **past 4 weeks** have you had vaginal sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 4.***

The next question is about vaginal sex in the **past 7 days**.

3. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → ***If 00, go to item 4.***

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

3a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** *# of acts with condom* ☐☐ → ***If 00, go to statement above item 5.***

4. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → ***If no, go to statement above item 5.***

4a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

The next questions are about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

5. In the **past 3 months**, have you had a menstrual period? ..... *yes* ☐ *no* ☐ → ***If no, end of interview. Go to statement above item 7 on page 3.***

Baseline Behavior Assessment (BBA-2)

Item-specific Instructions:

- **Item 3:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record “00” for this item.
- **Item 3a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record “00” for this item.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-3 (062)

Participant ID

Site Number – Participant Number – Chk

Baseline Behavior Assessment

6. In the **past 3 months**, what have you used during your menstrual period? You can answer "yes" to more than one item.

		yes	*no*
6a.	Paper or cloth or cotton wool—put inside the vagina?	☐	☐
6b.	Paper or cloth or cotton wool—placed in underwear?	☐	☐
6c.	Tampon?	☐	☐
6d.	Sanitary pad?	☐	☐
6e.	Anything else? If yes, specify:	☐	☐

Local Language: _____ *English:* _____

This is the end of this part of the interview. Thank you for taking the time to answer these questions.

***Interviewer**: Please complete items 7–9a below by transcribing data from the participant's Screening Part 1 Eligibility form (non-DataFax).*

7. *Screening Part 1 Eligibility form, item 6: .....* ☐☐ *# of vaginal sex acts*
   → ***If 00, go to item 9.***

8. *Screening Part 1 Eligibility form, item 7: .....* ☐☐ *# of vaginal sex acts with condom*

		yes	*no*
9.	*Screening Part 1 Eligibility form, item 8: .....*	☐	☐ → ***If no, end of form.***

		male condom	*female condom*
9a.	*Screening Part 1 Eligibility form, item 8a: .....*	☐	☐

Baseline Behavior Assessment (BBA-3)

Item-specific Instructions:

- **Item 6:** Read each item 6a–6e aloud and mark the participant's answer. If “yes” is marked for item 6e be sure to record the participant's verbatim response. Also provide the English translation in the space provided.
- **Items 7, 8, 9, and 9a:** These items are not interviewer-administered. These items must be completed by transcribing data from the participant’s Screening Part 1 Eligibility form (non-DataFax). For items 7 and 8, use leading zeros when needed so that all the boxes are filled.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-1 (210)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? ..... *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** *# of acts with condom* ☐☐ → *If 00, go to statement below item 3a.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 4 weeks or more, go to statement above item 18 on page 6.

Truvada/Placebo Adherence and Behavior Assessment (OPA-1)

Purpose: This form is used to collect information about the participant's oral product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 3a, items 4–17 should be left blank for participants who were not exposed to study product in the past 4 or more weeks. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

☐ No data recorded on this page.

I will now ask some questions about taking the study tablet. We need to understand how women in the study are taking their tablets. We know that some women take a tablet every day, while others miss some days or stop taking the tablet for some time. Do not worry about telling me if there were times when you were not able to take your tablet every day. I would like to know what is really happening for you.

4. In the **past 4 weeks**, at what time of day did you typically take your tablet?
Read response categories aloud. Use visual aid.

☐ morning

☐ afternoon

☐ evening

☐ other, specify: *Local Language:* _____ *English:* _____

5. In the **past 4 weeks**, how often did you take your tablet at about the same time each day? .....
Read response categories aloud. Showcard #1

always	*sometimes*	*never*
☐	☐	☐

6. Different women have different ways of remembering to take their tablet. In the **past 4 weeks**, what has helped you remember to take your tablet? ***Do <u>not</u> read response categories aloud. Mark all that apply.***

☐ 6a. nothing → ***If nothing, go to item 7 on page 3.***

☐ 6b. calendar

☐ 6c. alarm/bell/cell phone ringer/pager

☐ 6d. pill box

☐ 6e. husband/primary sex partner

☐ 6f. family member or friend

☐ 6g. association with a daily activity

☐ 6h. association with having sex

☐ 6i. association with taking Oral Contraceptives

☐ 6j. association with taking other pills or medications

☐ 6k. other, specify: *Local Language:* _____ *English:* _____

Truvada/Placebo Adherence and Behavior Assessment (OPA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–17:** If the site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study product use for the past 4 weeks, leave items 4–17 blank. Mark the "No data recorded on this page" box in the upper-right corner of pages 2–5, then proceed to the statement above item 18 on page 6.
- **Items 4 and 5:** Read each response category aloud and mark the participant's answer.
- **Item 6:** Do not read responses 6a–6k aloud. If the participant reports a response other than those listed, mark item 6k and be record the participant's verbatim response. Also provide the English translation in the space provided.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

☐ No data recorded on this page.

7. Different circumstances may prevent women from taking a tablet every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from taking your tablet. ***Do not read response categories aloud. Mark all that apply.***

☐ 7a. not applicable—participant always took a tablet every day → ***Go to item 8 on page 4.***

☐ 7b. participant didn't have the tablet with her

☐ 7c. participant felt sick/was concerned about getting sick from the tablet

☐ 7d. participant ran out of or lost the tablets

☐ 7e. participant got tired of taking the tablet every day

☐ 7f. participant gave/sold/traded the tablets to someone else

☐ 7g. participant had a change in her daily routine

☐ 7h. participant forgot or was too busy

☐ 7i. participant was on menses

☐ 7j. participant did not have sex/was not intending to have sex

☐ 7k. participant had difficulty swallowing the tablet

☐ 7l. participant didn't like the tablet/taste of the tablet

☐ 7m. someone else took/stole some of participant's tablets

☐ 7n. participant's primary sex partner did not approve of her taking the tablet

☐ 7o. family member or friend did not approve of her taking the tablet

☐ 7p. other, specify: *Local Language:* _____ *English:* _____

Truvada/Placebo Adherence and Behavior Assessment (OPA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant missed taking some tablets due to a product hold/discontinuation, mark the "other, specify" box and record the reason in the space provided. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-4 (213)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

☐ No data recorded on this page.

8. In the **past 4 weeks**, how often did you take the tablet? Was it...
Read response categories aloud. Showcard #2

- ☐ every day
- ☐ usually (most days)
- ☐ sometimes (some days)
- ☐ rarely (not many days)
- ☐ never → ***If never, go to item 10.***

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** take the tablet? ..... *# of days* ☐☐

10. Different circumstances may lead women to take **more** than one tablet per day. Thinking about your experience taking the tablet in the **past 4 weeks**, please tell me **all** of the reasons that led you to take **more than one tablet** on any single day. ***Do <u>not</u> read response categories aloud. Mark all that apply.***

- ☐ 10a. not applicable—never took more than 1 tablet per day → ***If not applicable, go to item 13 on page 5.***
- ☐ 10b. participant forgot she had taken her tablet already
- ☐ 10c. participant did not understand the instructions for taking her tablet
- ☐ 10d. participant wanted to have the correct number of tablets in her bottle(s) at her next study visit
- ☐ 10e. participant had sex without a condom/had risky sex
- ☐ 10f. participant had a new partner
- ☐ 10g. participant wanted to make up for not taking the tablet on earlier days
- ☐ 10h. participant thought it would protect her more
- ☐ 10i. participant's husband/primary sex partner asked her to take more tablets
- ☐ 10j. participant vomited after taking the tablet
- ☐ 10k. other, specify: *Local Language:* _____ *English:* _____

Truvada/Placebo Adherence and Behavior Assessment (OPA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she took the tablet every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

☐ No data recorded on this page.

11. In the **past 4 weeks**, on how many days did you take the **lighter** tablet **more** than once per day?

NO LONGER APPLICABLE FOR THIS PROTOCOL.

# of days

12. In the **past 4 weeks**, on how many days did you take the tablet **more** than once per day? ☐☐

13. Please rate your ability, over the **past 4 weeks**, to take the tablet exactly as you were instructed. ***Read response categories aloud. Showcard #3***

- ☐ very poor
- ☐ poor
- ☐ fair
- ☐ good
- ☐ very good
- ☐ excellent

Now I will ask about taking the tablet in the **past 7 days** (not including today).

14. In the **past 7 days** (not including today),...

# of days

14a. on how many days did you take **no** tablets? ..... ☐

14b. on how many days did you take the **lighter** tablet and not the darker tablet?

14c. on how many days did you take the **darker** tablet and not the lighter tablet?

NO LONGER APPLICABLE FOR THIS PROTOCOL.

# of days

14d. on how many days did you take the tablet? ..... ☐

15. In the **past 7 days** (not including today),...

15a. on how many days did you take the **lighter** tablet **more** than once per day?

NO LONGER APPLICABLE FOR THIS PROTOCOL.

# of days

15b. on how many days did you take the tablet **more** than once per day? ..... ☐

Truvada/Placebo Adherence and Behavior Assessment (OPA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 12:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she did not take the tablet more than once per day, record "00."
- **Item 13:** Read each response category aloud and mark the participant's answer.
- **Items 14a and 14d:** If the participant reports "none" or "zero," record "0." The sum of the responses to 14a and 14d should equal "7."
- **Item 15b:** If the participant reports "none" or "zero," record "0."

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

The next questions are about the **last time** you took the tablet.

16. The **last time** you took the tablet, was it in the morning, afternoon, or evening?

- ☐ morning
- ☐ afternoon
- ☐ evening

17. The **last time** you took the **lighter** tablet, was it in the morning, afternoon, or evening?

NO LONGER APPLICABLE FOR THIS PROTOCOL.

- morning
- afternoon
- evening

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

18. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

		yes	*no*	*N/A*
18a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
18b.	people at home/family?	☐	☐	☐
18c.	your friends/personal relationships?	☐	☐	☐
18d.	people at work?	☐	☐	☐
18e.	people at school?	☐	☐	☐
18f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
18g.	your landlord or property owner?	☐	☐	☐
18h.	anyone else? If yes, specify:	☐	☐	☐

*Local Language:*_____ *English:* _____

If no or N/A to all, end of form.

Truvada/Placebo Adherence and Behavior Assessment (OPA-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 18:** Read each item 18a–18h aloud and mark the participant's answer. If "yes" is marked for item 18h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 18a through 18h are all "no" or "N/A," end the form. You must mark the "no data recorded on this page" box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-7 (216)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Truvada/Placebo Adherence and Behavior Assessment

☐ No data recorded on this page.

19. Has this problem/have any of these problems resulted in:

		yes	no
19a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
19b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
19c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
19d.	physical or other harm to your children?	☐	☐

20. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 21–21a after the interview.*

	yes	no
21. Did any of the problem(s) require reporting as an Adverse Event (AE)?	☐	☐ → ***If no, end of form.***

21a. Record AE Log page number(s):

AE Log page # ☐☐☐ *AE Log page #* ☐☐☐ *AE Log page #* ☐☐☐

☐ ☐ ☒ ☐ 06-OCT-11

0 1 Language

Staff Initials / Date

Truvada/Placebo Adherence and Behavior Assessment (OPA-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 20:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any,. Also provide the English translation in the space provided.
- **Items 21 and 21a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) VPA-1 (230)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? ..... *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** ..... *# of acts with condom* ☐☐ → *If 00, go to statement below item 3a.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 4 weeks or more, go to statement above item 15 on page 6.

Vaginal Product Adherence and Behavior Assessment (VPA-1)

Purpose: This form is used to collect information about the participant's vaginal product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 3a, items 4–14 should be left blank for participants who were not exposed to study product in the past 4 or more weeks. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

I will now ask some questions about inserting study gel. We need to understand how women in the study are inserting their gel. We know that some women insert their gel every day while others miss some days or stop inserting gel for some time. Do not worry about telling me if there were times when you were not able to insert your gel every day. I would like to know what is really happening for you.

4. In the **past 4 weeks**, at what time of day did you typically insert gel? ***Read response categories aloud. Use visual aid.***

   ☐ morning

   ☐ afternoon

   ☐ evening

5. In the **past 4 weeks**, how often did you insert your gel at about the same time each day? ***Read response categories aloud. Showcard #1***

always	*sometimes*	*never*
☐	☐	☐

6. Different women have different ways of remembering to insert their gel. In the **past 4 weeks**, what has helped you remember to insert your gel? ***Do <u>not</u> read response categories aloud. Mark all that apply.***

   ☐ 6a. nothing → ***If nothing, go to item 7 on page 3.***

   ☐ 6b. calendar

   ☐ 6c. alarm/bell/cell phone ringer/pager

   ☐ 6d. husband/primary sex partner

   ☐ 6e. family member or friend

   ☐ 6f. association with a daily activity

   ☐ 6g. association with having sex

   ☐ 6h. association with taking Oral Contraceptives

   ☐ 6i. association with taking other pills or medications

   ☐ 6j. other, specify: *Local Language:* _____ *English:* _____

Vaginal Product Adherence and Behavior Assessment (VPA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–14:** If the site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study product use for the past 4 weeks, leave items 4–14 blank. Mark the "No data recorded on this page" box in the upper-right corner of pages 2–5, then proceed to the statement above item 15 on page 6.
- **Item 4:** Read each response category aloud and mark the participant's answer.
- **Item 5:** Read each response category aloud and mark the participant's answer.
- **Item 6:** Do not read responses 6a–6j aloud. If the participant reports a response other than those listed, mark item 6j and record the participant's verbatim response. Also provide the English translation in the space provided.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

7. Different circumstances may prevent women from inserting their gel every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from inserting your gel. ***Do <u>not</u> read response categories aloud. Mark all that apply.***

☐ 7a. not applicable—participant inserted gel every day → ***Go to item 8 on page 4.***

☐ 7b. participant didn't have the gel with her

☐ 7c. participant felt sick/was concerned about getting sick from the gel

☐ 7d. participant ran out of or lost the gel

☐ 7e. participant got tired of inserting the gel every day

☐ 7f. participant gave/sold/traded the gel to someone else

☐ 7g. participant had a change in her daily routine

☐ 7h. participant forgot or was too busy

☐ 7i. participant was on menses

☐ 7j. participant did not have sex/was not intending to have sex

☐ 7k. participant had difficulty inserting the gel

☐ 7l. participant didn't like the smell or feel of the gel

☐ 7m. someone else took/stole some of participant's gel

☐ 7n. participant's primary sex partner did not approve of her inserting the gel

☐ 7o. family member or friend did not approve of her inserting the gel

☐ 7p. other, specify: *Local Language:* _____ *English:* _____

Vaginal Product Adherence and Behavior Assessment (VPA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant did not insert gel due to a product hold/discontinuation, mark the "other, specify" box and record the reason in the space provided. Also provide the English translation in the space provided.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

8. In the **past 4 weeks**, how often did you insert the gel? Was it...
Read response categories aloud. Showcard #2

- ☐ every day
- ☐ usually (most days)
- ☐ sometimes (some days)
- ☐ rarely (not many days)
- ☐ never → ***If never, go to item 10.***

# of days

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** insert the gel? ☐☐

10. Different circumstances may lead women to insert the study gel **more** than once per day. Thinking about your experience inserting gel in the **past 4 weeks**, please tell me **all** of the reasons that led you to insert gel **more** than once on any single day. ***Do <u>not</u> read response categories aloud. Mark all that apply.***

- ☐ 10a. not applicable—never inserted study gel more than once per day → ***If not applicable, go to item 12 on page 5.***
- ☐ 10b. participant forgot she had inserted gel already
- ☐ 10c. participant did not understand the instructions for inserting gel
- ☐ 10d. participant wanted to have the correct number of applicators at her next study visit
- ☐ 10e. participant had sex without a condom/had risky sex
- ☐ 10f. participant had a new partner
- ☐ 10g. participant wanted to make up for not inserting gel on earlier days
- ☐ 10h. participant thought it would protect her more
- ☐ 10i. participant's husband/primary sex partner asked her to insert more gel
- ☐ 10j. participant thought that the gel leaked out
- ☐ 10k. other, specify: *Local Language:* _____ *English:* _____

Vaginal Product Adherence and Behavior Assessment (VPA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she inserted gel every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) VPA-5 (234)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

# of days

11. In the **past 4 weeks**, on how many days did you insert gel **more** than once per day? ..... ☐☐

12. Please rate your ability, over the **past 4 weeks**, to insert gel exactly as you were instructed. ***Read response categories aloud. Showcard #3***

- ☐ very poor
- ☐ poor
- ☐ fair
- ☐ good
- ☐ very good
- ☐ excellent

Now I will ask about inserting gel in the **past 7 days** (not including today).

13. In the **past 7 days** (not including today),...

# of days

13a. on how many days did you **not** insert gel? ..... ☐

# of days

13b. on how many days did you insert gel **once** per day? ..... ☐

# of days

13c. on how many days did you insert gel **more than once per day**? ..... ☐

This next question is about the **last time** you inserted the gel.

14. The **last time** you inserted the gel, was it in the morning, afternoon, or evening?

- ☐ morning
- ☐ afternoon
- ☐ evening

Vaginal Product Adherence and Behavior Assessment (VPA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 11:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she never inserted gel more than once per day, record "00" for this item.
- **Item 12:** Read each response category aloud and mark the participant's answer.
- **Items 13a–13c:** If the participant reports "none" or "zero," record "0." The sum of the responses to 13a–13c should equal "7."

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) VPA-6 (235)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

15. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

		yes	*no*	*N/A*
15a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
15b.	people at home/family?	☐	☐	☐
15c.	your friends/personal relationships?	☐	☐	☐
15d.	people at work?	☐	☐	☐
15e.	people at school?	☐	☐	☐
15f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
15g.	your landlord or property owner?	☐	☐	☐
15h.	anyone else? If yes, specify: ..... *Local Language:*_____ *English:* _____	☐	☐	☐

If no or N/A to all, end of form.

16. Has this problem/have any of these problems resulted in:

		yes	*no*
16a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
16b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
16c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
16d.	physical or other harm to your children?	☐	☐

Vaginal Product Adherence and Behavior Assessment (VPA-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 15:** Read each item 15a–15h aloud and mark the participant's answer. If "yes" is marked for item 15h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 15a through 15h are all "no" or "N/A," end the form. Mark the "No data recorded on this page" box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) VPA-7 (236)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

17. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 18–18a after the interview.*

	yes	*no*	
18. *Did any of the problem(s) require reporting as an Adverse Event (AE)?*	☐	☐ →	***If no, end of form.***

18a. *Record AE Log page number(s):*

AE Log page #	*AE Log page #*	*AE Log page #*
☐☐☐	☐☐☐	☐☐☐

Vaginal Product Adherence and Behavior Assessment (VPA-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 17:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any,. Also provide the English translation in the space provided.
- **Items 18 and 18a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) MPS-1 (240)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

The first questions ask about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

		yes	*no*	
1.	In the **past 3 months**, have you had a menstrual period?	☐	☐ →	*If no, go to statement above item 3.*

2. In the **past 3 months**, what have you used during your menstrual period? You can answer "yes" to more than one item.

		yes	*no*
2a.	Paper or cloth or cotton wool—put inside the vagina?	☐	☐
2b.	Paper or cloth or cotton wool—placed in underwear?	☐	☐
2c.	Tampon?	☐	☐
2d.	Sanitary pad?	☐	☐
2e.	Anything else? If yes, specify:	☐	☐

Local Language: _____

English: _____

The next questions are about people you may have talked to about this study.

3. In the **past year**, have you talked with any of the following people about your participation in this study? You can answer "yes" to more than one item.

		yes	*no*	*N/A*
3a.	Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
3b.	Other sex partners?	☐	☐	☐
3c.	Your mother or father?	☐	☐	☐
3d.	Your sister or brother?	☐	☐	☐
3e.	Other family member?	☐	☐	☐

Menstrual Practices and Study Disclosure Assessment (MPS-1)

Purpose: This form is used to collect information about the participant's menstrual practices and disclosure of study participation. This is an interviewer-administered form, and it is administered at each annual visit, the Product Use End Visit, and the Study Exit Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 2:** Read each item 2a–2e aloud and mark the participant's answer. If "yes" is marked for item 2e, record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 3:** Read each item 3a–3e aloud and mark the participant's answer.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) MPS-2 (241)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

		yes	no	N/A
3f.	A friend or neighbor?	☐	☐	☐
3g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
3h.	An elder or community leader?	☐	☐	☐
3i.	Anyone else? If yes, specify:	☐	☐	

Local Language: _____

English: _____

4. In the **past year**, have you talked with any of the following people about the tablets or gel you are using for this study? You can answer "yes" to more than one item.

		yes	no	N/A
4a.	Your primary sex partner?	☐	☐	☐
4b.	Other sex partners?	☐	☐	☐
4c.	Your mother or father?	☐	☐	☐
4d.	Your sister or brother?	☐	☐	☐
4e.	Other family member?	☐	☐	☐
4f.	A friend or neighbor?	☐	☐	☐
4g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
4h.	An elder or community leader?	☐	☐	☐
4i.	Anyone else? If yes, specify:	☐	☐	☐

Local Language: _____

English: _____

Menstrual Practices and Study Disclosure Assessment (MPS-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 3f–3i:** Read each item aloud and mark the participant's answer. If "yes" is marked for item 3i, record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 4:** Read each item 4a–4i aloud and mark the participant's answer. If "yes" is marked for item 4i, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) MPS-3 (242)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

		yes	*no*	*N/A*
5.	In the **past year**, has your primary sex partner come to the study clinic for any reason?	☐	☐	☐
5a.	Did he attend a study meeting?	☐	☐	
5b.	Did he accompany you to a study visit?	☐	☐	
5c.	Did he receive counseling or other clinical services?	☐	☐	
5d.	Did he come to the study clinic for any other reason?	☐	☐	

If no or N/A, end of form.

If yes, specify:

Local Language: _____

English: _____

☐☐☐☒ 17-MAR-09

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0 1 Language

Staff Initials / Date

Menstrual Practices and Study Disclosure Assessment (MPS-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 5:** Read each item 5a–5d aloud and mark the participant's answer. If "yes" is marked for item 5d, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SBA-1 (260)

Participant ID

Site Number – Participant Number – Chk

Study Exit Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 2 months**, have you had vaginal sex? ..... yes ☐ no ☐ → *If no, go to statement above item 4 on page 2.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... # of acts ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** ..... # of acts with condom ☐☐ → *If 00, go to statement above item 4 on page 2.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** yes ☐ no ☐ → *If no, go to statement above item 4 on page 2.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... male condom ☐ female condom ☐

Study Exit Behavior Assessment (SBA-1)

Purpose: This form is used to collect information about the participant's sexual behavior and possible problems (emotional, physical, social, or other difficulties) experienced while she took part in the study. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Study Exit Visit.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SBA-2 (261)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Study Exit Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

4. In the **past 2 months**, have you had any problems with the following people as a result of being in this study:

		yes	*no*	*N/A*
4a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
4b.	people at home/family?	☐	☐	☐
4c.	your friends/personal relationships?	☐	☐	☐
4d.	people at work?	☐	☐	☐
4e.	people at school?	☐	☐	☐
4f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
4g.	your landlord or property owner?	☐	☐	☐
4h.	anyone else? If yes, specify:	☐	☐	☐

*Local Language:*_____ *English:* _____

If no or N/A to all, end of form.

☐ ☐ ☐ ☒ 17-MAR-09

N:\hivnet\forms\MTN_003\forms\m003_study_exit_beh_assess.fm

0 1 Language

Staff Initials / Date

Study Exit Behavior Assessment (SBA-2)

Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant's answer. If "yes" is marked for item 4h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 4a through 4h are all "no" or "N/A," end the form. Mark the "No data recorded on this page" box in the upper right corner of page 3. Also record the Visit Code, PTID, and staff initials and date on page 3 of this form. Leave all other items on page 3 blank. Fax all 3 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SBA-3 (262)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Study Exit Behavior Assessment

☐ No data recorded on this page.

5. Has this problem/have any of these problems resulted in:

		yes	no
5a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
5b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
5c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
5d.	physical or other harm to your children?	☐	☐

6. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 7–7a after the interview.*

		yes	no
7.	*Did any of the problem(s) require reporting as an Adverse Event (AE)?*	☐	☐ → ***If no, end of form.***

7a. Record AE Log page number(s):

AE Log page # [ ][ ][ ] *AE Log page #* [ ][ ][ ] *AE Log page #* [ ][ ][ ]

Study Exit Behavior Assessment (SBA-3)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 6:** Do not record the participant's verbatim response; describe the problem and outcome, if any, in the local language. Also provide the English translation in the space provided.
- **Items 7 and 7a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) PPA-1 (270)

Participant ID

Site Number – Participant Number – Chk

Perceived Product Assessment

Visit Date

dd MMM yy

Items 1–2 are completed by the site clinician prior to the interview. If participant is in the vaginal group, go to item 2.

1. *As you know, none of the study staff know which participants are taking tenofovir tablets, which participants are taking Truvada tablets, and which are taking placebo tablets. We would like you to say which study tablets you think the participant has been taking: tenofovir, Truvada, or placebo?*

tenofovir ☐ *Truvada* ☐ *placebo* ☐ →

If participant completed a Product Use End Visit, go to item 3. If participant did not complete a Product Use End Visit, end of form.

2. *As you know, none of the study staff know which participants are inserting tenofovir gel and which are inserting placebo gel. We would like you to say which gel you think the participant has been inserting: tenofovir or placebo? .....*

tenofovir ☐ *placebo* ☐ →

If participant completed a Product Use End Visit, go to item 4. If participant did not complete a Product Use End Visit, end of form.

3. As you know, none of the women taking tablets in this study know if they were given tenofovir tablets, Truvada tablets, or placebo tablets. Now that you have finished taking the tablets, I would like you to say which study tablets you think you were taking: tenofovir, Truvada, or placebo?

tenofovir ☐ *Truvada* ☐ *placebo* ☐ → ***End of form.***

4. As you know, none of the women inserting gel in this study know if they were given tenofovir gel or placebo gel. Now that you have finished inserting the gel, I would like you to say which gel you think you were inserting: tenofovir or placebo?

tenofovir ☐ *placebo* ☐

Perceived Product Assessment (PPA-1)

Purpose: This form is used to collect information about the site clinician's perception and the participant's perception of which product the participant was given. This a mixed form. Some items are completed by the site clinician (items 1–2) and some items are interviewer-administered (items 3–4). It is administered only once to each enrolled participant as part of her Product Use End Visit. If the participant did not complete a Product Use End Visit (for example, she is lost to follow up), complete this form when the site has determined that she has permanently discontinued study product use.

General Information/Instructions:

- **Visit Date:** If the participant completes a Product Use End Visit (PUEV), record the date when the PUEV is conducted. If the participant terminates from the study and does not complete a PUEV, record the date when this form is completed.

Item-specific Instructions:

- **Item 3:** This item should be answered by all participants taking tablets during the study. The participant should make her best guess, as there is no option for "don't know."
- **Item 4:** This item should be answered by all participants using gel during the study. The participant should make her best guess, as there is no option for "don't know."

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) MBA-1 (275)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Monthly Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first two questions are about vaginal sex.

	yes	*no*
1. In the **past 4 weeks**, have you had vaginal sex?	☐	☐ →

If no, go to statement below item 2.

	yes	*no*
2. Now I would like to ask you about your most recent vaginal sex act, that is the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.***	☐	☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 7 or more days, end of form.
If participant is in the vaginal group, go to statement above item 4.

Now I will ask about taking the tablet in the **past 7 days** (not including today).

3. In the **past 7 days** (not including today),...

	# of days
3a. on how many days did you take **no** tablets?	☐

NO LONGER APPLICABLE FOR THIS PROTOCOL.

3b. on how many days did you take the **lighter** tablet and not the darker tablet?

3c. on how many days did you take the **darker** tablet and not the lighter tablet?

	# of days
3d. on how many days did you take the tablet?	☐ →

End of form.

Now I will ask about inserting gel in the **past 7 days** (not including today).

4. In the **past 7 days** (not including today),...

	# of days
4a. on how many days did you **not** insert gel?	☐
4b. on how many days did you insert gel?	☐

Monthly Product Adherence and Behavior Assessment (MBA-1)

Purpose: This form is used to collect information about the participant's product use while she is taking part in the study. This is an interviewer-administered form, and it is administered at each monthly visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 2, items 3a–4b should be left blank for participants who were not exposed to study product in the past 7 or more days. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Items 3–4:** If site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study drug use for the past 4 weeks, leave items 3–4b blank.
- **Items 3a and 3d:** If the participant reports "none" or "never" record "0." The sum of the responses to 3a and 3d should equal "7."
- **Items 4a–4b:** If the participant reports "none" or "never" record "0." The sum of the responses to 4a–4b should equal "7."

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Part 1 Eligibility

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

I am now going to ask some questions about you, your sexual behaviors and your health. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. Have you ever had a bad reaction to latex (such as latex condoms or gloves)? ..... *yes* ☐ *no* ☐ → *If yes, participant is ineligible.*

2. Have you ever used tenofovir gel, tenofovir tablets, or Truvada tablets? ***Use visual aid.*** ..... ☐ ☐ → *If no, go to item 4.*

3. Have you ever had a bad reaction to tenofovir gel, tenofovir tablets, or Truvada tablets?***Use visual aid.*** ..... ☐ ☐ → *If yes, participant is ineligible.*

4. In the **past year** (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ☐ ☐ → *If yes, participant is ineligible.*

5. In the **past 3 months**, have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. ..... ☐ ☐ → *If no, participant is ineligible. Go to item 9.*

6. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... [ ][ ] *# of vaginal sex acts*
   → *If 00, go to item 8.*

7. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ..... [ ][ ] *# of vaginal sex acts with condom*

8. Now I would like to ask you about your most recent vaginal sex act. That is, the very **last vaginal sex act** that you had, including today. During the last act of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** ..... *yes* ☐ *no* ☐ → *If no, go to item 9.*

   8a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

9. In the **past 6 weeks** (42 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated? ..... *yes* ☐ *no* ☐ → *If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.*

Screening Part 1 Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 1 Visit. This is a mixed form—some of the items are interviewer-administered (items 1–19), while other items are not (items 20–22). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If a participant is being re-screened, a new Screening Part 1 Eligibility form must be completed as part of the subsequent Screening Attempt. See the Data Collection Section of the Study-specific Procedures (SSP) Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Items 1–19:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 19. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 2:** Mark the "no" box if the participant does not recall having ever used tenofovir gel, tenofovir tablets, or Truvada tablets.
- **Item 3:** Mark the "no" box if the participant does not recall having had an adverse reaction to tenofovir gel, tenofovir tablets, or Truvada tablets

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Screening Part 1 Eligibility

10. Are you breastfeeding now? ..... *yes* ☐ *no* ☐ → *If yes, participant is ineligible.*

11. Do you and your partner intend to have a child in the future? ..... *yes* ☐ *no* ☐ *don't know* ☐ → *If no or don't know, go to item 13.*

12. When do you and your partner intend to have your future child? ..... # ☐☐ ☐ *months from now* **OR** ☐ *years from now*

13. If you were to join this research study, would you be willing to use a reliable method of contraception for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo-provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s). ..... *yes* ☐ *no* ☐ → *If no, participant is ineligible.*

14. Do you plan to move away from this area in the next 2 years (24 months)? ..... *yes* ☐ *no* ☐ *don't know* ☐ → *If yes, participant is ineligible.*

15. Do you plan to be away from this area for more than 8 weeks in a row in the next two years (24 months)? This includes seasonal travel, and travel for farming, trade, or other purposes. ..... *yes* ☐ *no* ☐ *don't know* ☐ → *If yes, participant is ineligible.*

16. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products? ..... *yes* ☐ *no* ☐ → *If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.*

17. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)? ..... *yes* ☐ *no* ☐ → *If no, participant is ineligible.*

Screening Part 1 Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 12:** Record in months or years the amount of time expected to pass before the participant gives birth to a future child. For example, if the participant reports that she plans to give birth to a future child in a year and a half, record “18” in the “#” boxes and mark the “months from now” box. Record her best estimate.
- **Item 16:** Mark the “no” box if the participant does not recall having participated in another research study of medicines, medical devices, or vaginal products in the past 30 days.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Screening Part 1 Eligibility

18. Do you currently have tuberculosis, also known as TB? ..... *yes* ☐ *no* ☐ *don't know* ☐

19. Are you currently taking any medication used to treat tuberculosis or TB? *yes* ☐ *no* ☐ *don't know* ☐

If yes, refer participant to site medical officer.

If no or don't know, and participant's response to item 18 is "yes" or "don't know," refer participant to site medical officer. If site medical officer determines that participant has active TB, participant is ineligible.

End of interview. Site staff to complete items 20–22.

20. *Per the site Investigator of Record or designee, does the participant currently have active tuberculosis (TB)?* ..... *yes* ☐ *no* ☐ *If yes, participant is ineligible.*

21. *Based on the urine hCG test result, is the participant pregnant?* ..... *yes* ☐ *no* ☐ *If yes, participant is ineligible.*

22. *Transcribe, in months, the response recorded for item 12 here:* ..... ☐☐ *months from now*

If 33 months or less, participant is ineligible.

Screening Part 1 Eligibility (non-DataFax) - Page 3

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Screening Part 2 Medical Eligibility

Form Completion Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. At Screening Part 1 or Screening Part 2, was the participant diagnosed by study staff with any of the following conditions requiring treatment per protocol:

		yes	*no*
1a.	urinary tract infection (UTI)	☐	☐
1b.	chlamydia	☐	☐
1c.	gonorrhea	☐	☐
1d.	syphilis	☐	☐
1e.	symptomatic BV	☐	☐
1f.	symptomatic vaginal candidiasis	☐	☐
1g.	trichomoniasis	☐	☐
1h.	active herpes lesions	☐	☐
1i.	genital warts requiring treatment per protocol	☐	☐
1j.	pelvic inflammatory disease (PID)	☐	☐
1k.	any other STI or RTI requiring treatment, specify: _____	☐	☐

If yes to any, treat per protocol and SSP Manual. Participant is ineligible until treatment is completed and symptoms (if any) have resolved. Participants found to meet all other eligibility criteria may be enrolled after treatment is completed and symptoms (if any) have resolved within the 56-day screening window.

2. Please answer the following questions based on the participant's Baseline Medical and Menstrual History.

		yes	*no*
2a.	Did the participant report any pathologic bone fracture not related to trauma (ever)?	☐	☐

If yes, participant is ineligible.

		yes	*no*
2b.	Did the participant report taking post-exposure prophylaxis (PEP) for HIV exposure within the past 6 months?	☐	☐

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 6 months after last use of PEP.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 1

This form is completed at the Screening Part 2 Visit and is used to document the participant's medical eligibility for the study. It is completed based on review of all Screening Part 1 and Part 2 clinical and lab test results documentation.

Note: *None of the UTI/STIs/RTIs listed on this form should be documented on the Pre-existing Conditions form, even if the participant tested positive for one or more of these UTI/STIs/RTIs during screening. Because a participant is not eligible for enrollment if she is currently diagnosed with a UTI/ STI/RTI requiring treatment, and because the Pre-existing Conditions form only documents ongoing conditions at the time of enrollment, none of the UTI/STIs/RTIs recorded on this form should be documented on the Pre-existing Conditions form.*

If a participant is being re-screened, a new Screening Part 2 Medical Eligibility form must be completed as part of the subsequent Screening Attempt. See the Study-specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Screening Part 2 Medical Eligibility

2c. Did the participant report any gynecologic or genital procedure (e.g., biopsy, tubal ligation, dilation and curettage, piercing) in the past six weeks (42 days)?

yes ☐ no ☐

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after procedure.

2d. Did the participant report that she is currently using spermicide; interferon or interleukin therapy; medication(s) with significant nephrotoxic potential, including but not limited to amphotericin B, aminoglycosides, cidofovir, foscarnet and systemic chemotherapy; medication(s) that may inhibit or compete for elimination via active renal tubular secretion (including but not limited to probenecid)?

yes ☐ no ☐

If yes, participant is ineligible for as long as she uses the reported medication(s).

2e. Did the participant report, as determined by the IoR/ designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis?.....

yes ☐ no ☐

If yes, participant is ineligible.

3. Does the participant have a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)?.....
Note: Cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the IoR/ designee is considered expected non-menstrual bleeding and is not exclusionary.

yes ☐ no ☐

If yes, participant is currently ineligible. Provide treatment if clinically indicated. Participants with exclusionary pelvic exam findings who are found to meet all other eligibility criteria may be enrolled after the exclusionary pelvic exam findings have improved to a non-exclusionary severity grade or have resolved.

4. Does the participant have documentation of a normal Pap result from a Pap Smear done during this visit, or in the last 12 months? .....

yes ☐ no ☐ N/A ☐ → ***If N/A, go to item 5 on page 3.***

If yes and participant meets all other eligibility criteria, schedule Enrollment Visit to occur within 12 months of normal Pap result. Go to item 5 on page 3.

4a. Does participant have a Grade 2 or higher Pap result?

yes ☐ no ☐

If yes, participant may be ineligible. Participants with abnormal Pap results who are found to meet all other eligibility criteria may be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated. If grade 2 or higher Pap result, specify evaluation and treatment plan in the space provided, clearly noting whether treatment is currently indicated.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 4:** Mark the “yes” box if the participant has documentation of a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is negative for intraepithelial lesion or cancer (malignancy). Mark the “no” box if the participant has a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is anything other than negative for intraepithelial lesion or cancer (malignancy). Mark the “N/A” box if a Pap result is not required per protocol to determine the participant’s eligibility.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Screening Part 2 Medical Eligibility

5. Please answer the following questions based on the participant's laboratory results from the Screening Part 1 and Screening Part 2 Visits.

		yes	*no*
5a.	Is the participant pregnant?	☐	☐
5b.	Is the participant HIV-infected per the screening algorithm in protocol Appendix II?	☐	☐
5c.	Is the participant's AST or ALT greater than 1.5 times the site lab upper limit of normal (ULN)?	☐	☐
5d.	Is the participant's calculated creatinine clearance < 60 mL/min?	☐	☐
5e.	Is the participant's serum creatinine greater than the site lab ULN for women? ***Note**: If the serum creatinine is less than the site LLN, creatinine testing must be repeated during the screening period.*	☐	☐
5f.	Is the participant's hemoglobin less than 10.0g/dl?	☐	☐
5g.	Is the participant's platelet count less than 100,000/mm^3?	☐	☐
5h.	Is the participant's serum phosphate level below the site lab lower limit of normal (LLN)?	☐	☐
5i.	Did the participant test positive for Hepatitis B surface antigen (HBsAg)?	☐	☐
5j.	Is the participant's dipstick urinalysis for protein 2+ or greater from a single visit?	☐	☐
5k.	Does the participant have at least two dipstick urinalysis protein results of 1+ or greater at separate visits?	☐	☐
5l.	Is the participant's dipstick urinalysis result for glucose 2+ or greater from a single visit?	☐	☐
5m.	Does the participant have at least two dipstick urinalysis glucose results of 1+ or greater at separate visits?	☐	☐

If yes to any, participant is ineligible. For all exclusionary test results, except HIV infection and Hepatitis B infection, participant may be retested and enrolled (or have another screening attempt) if the retest result is not exclusionary per protocol. Dipstick urinalysis should only be retested if abnormal results are attributable to urinary tract infection or menses, according to the judgment of the IoR/designee.

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

yes	*no*
☐	☐

If yes, participant is ineligible.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 3

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Screening Part 2/Enrollment Behavioral Eligibility

Form Completion Date

dd MMM yy

I am now going to ask some questions about you, your sexual behaviors and your health. I know that you have been asked these questions before, but I need to ask them again to confirm your eligibility for the study. There are no right or wrong answers, and every answer is important, so we need you to be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. In the **past six weeks** (42 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated?..... ☐ yes ☐ no

   → *If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.*

   If yes at enrollment, participant is ineligible.

2. Are you breastfeeding now?..... ☐ ☐

   → *If yes, participant is ineligible.*

3. What method(s) of contraception or family planning are you currently using? ***Mark all that apply.***

   ☐ Oral contraceptive pills

   ☐ Contraceptive injections

   ☐ Contraceptive implants

   ☐ Contraceptive ring → *If "Contraceptive ring" is reported at enrollment, participant is ineligible.*

   ☐ Contraceptive patch

   ☐ Intrauterine contraceptive device

   ☐ Surgical sterilization of participant (as verified per site SOP)

   ☐ Surgical sterilization of partner(s) (as verified per site SOP)

   ☐ Other, specify: _____ → *If "Other" is reported at enrollment, evaluate for eligibility.*

   ☐ None → *If "None" is reported at enrollment, participant is ineligible.*

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 2 and Enrollment Visits. It is completed once at the Screening Part 2 Visit, and again at the Enrollment Visit. This is a mixed form—some of the items are interviewer-administered (items 1–6), while other items are not (item 7). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *If a participant is being re-screened, a new Screening Part 2/Enrollment Behavioral Eligibility form must be completed as part of the subsequent screening attempt. See the Study-specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 Visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 6. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]

Site Number Participant Number Chk

Screening Part 2/Enrollment Behavioral Eligibility

4. If you were to join this study, would you be willing to use a reliable method for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s).

yes ☐ *no* ☐ → *If no, participant is ineligible.*

5. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products? .....

☐ ☐ → *If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.*

If yes at Enrollment, participant is ineligible.

6. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)? .....

yes ☐ *no* ☐ → *If no, participant is ineligible.*

End of interview. Complete item 7 after the interview.

7. *Was the participant willing and able to provide adequate locator information as defined in site SOPs? .....*

yes ☐ *no* ☐ → *If no at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, and only needs more time to provide adequate locator information, schedule Enrollment Visit (or another screening attempt) to occur when adequate locator information is available.*

If no at Enrollment, participant is ineligible.

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 Visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 6. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 7:** This item is NOT interviewer-administered and should not be read aloud to the participant.