SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) 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? ..... dd MMM yy → If unknown, record age: years

2. What is your gender? ..... male [ ] female [X]

NOT APPLICABLE FOR THIS PROTOCOL.

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

4. Do you currently have a male sex partner? By sex partner, I mean someone with whom you have vaginal or anal sex. ..... yes [ ] no [ ]

5. What is your household's average monthly income? This includes income from all sources, even income from people who may not live in the household. .....

6. What is your race or ethnic group? *Read aloud. Mark all that apply.*

U.S.

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] White
- [ ] other, specify: _____

SOUTH AFRICA

- [ ] Zulu
- [ ] Xhosa
- [ ] Indian
- [ ] Colored
- [ ] White
- [ ] other, specify: _____

→ ***Go to item 8 on page 2.***

UGANDA

- [ ] Bantu
- [ ] Nilotics
- [ ] other, specify: _____

→ ***Go to item 8 on page 2.***

7. **U.S. only:** Do you consider yourself to be Latina or Hispanic? ..... yes [ ] no [ ]

Demographics (DEM-1)

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

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

***Note**: If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. Refer to the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

***If the participant refuses or is unable to give a response to any item(s),** draw a line through the response boxes, write "refused" or "don't know," and initial and date the note in the white space next to the item.*

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. ***Note:** Participant must be between the ages of 18 and 45 years at the time of screening, as verified per site standard operating procedures (SOP), to be eligible for study participation.*
- **Item 5:** Record the **average** monthly income for the household (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	2	1	4	5

  If the household's average monthly income is greater than 99,999,999 write "99999999" in the boxes provided, and record the actual value in the white space near the item.
- **Item 6:** This item must be self-identified by the participant. This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "other, specify" box and record her response on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) DEM-2 (002)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

8. 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

Demographics (DEM-2)

No instructions necessary.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code . 0 1

MTN 001 (146) RPA-1 (068)

Participant ID

Site Number – Participant Number – Chk

Rectal PK Acceptability and Anal Gel Use

Visit Date

dd MMM yy

Interviewer: *Complete item 1 before the interview.*

1. *Did the participant provide a rectal PK specimen at this visit?* ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

2. How did you find the rectal specimen procedure? ***Read categories aloud.***

very uncomfortable	*a little uncomfortable*	*comfortable/ not a problem*
☐	☐	☐

3. Did you insert study gel into your anus today or yesterday? ..... *yes* ☐ *no* ☐

4. In the **past 6 weeks**, did you ever insert study gel into your anus and into your vagina on the same day? ..... *yes* ☐ *no* ☐

Comments: _____

☐ ☐ ☐ ☒ 22-JAN-10

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0 1 Language

Staff Initials / Date

Rectal PK Acceptability and Anal Gel Use (RPA-1)

Purpose: This form is designed to capture participant acceptability of rectal PK sampling. It also serves to capture anal gel use near the time of rectal PK sampling, as anal gel use may affect the concentration of tenofovir detected in the rectal fluid.

General Information/Instructions: This form is completed at each End-of-study Period Visit (Weeks 6, 13, and 20) for all participants enrolled at the Bronx-Lebanon Hospital site, regardless of whether or not rectal PK sampling is done at the visit. It is a mixed form. Item 1 is completed by a member of site staff, and items 2–4 are interviewer-administered.

Item-specific Instructions:

- **Visit Code:** Record the visit code associated with the End-of-study Period Visit when this form is completed [Week 6 (04.0), Week 13 (07.0), or Week 20 (10.0).]
- **Items 3–4:** These items ask about anal gel use. Please complete these items at each End-of-study Period Visit, including the visit at the end of the oral period. The reason is that the participant may still have access to study gel (either unreturned or from another study participant), even though she is in the oral period.

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) EBA-1 (072)

Participant ID

Site Number – Participant Number – Chk

Enrollment Behavior Assessment

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Your honest answers will be very helpful to us. There is no right or wrong answer to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions are about vaginal sex, and some are about anal sex. Vaginal sex means when a man puts his penis inside your vagina. Anal sex means when a man puts his penis inside your anus.

1. In the **past 3 months**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.

# of partners ☐☐☐ → ***If 0, participant is ineligible. Go to statement above item 9 on page 3.***

1a. Were any of these sex partners casual partners? By casual partner, I mean someone whom you do not consider to be your main partner. .....

yes ☐ *no* ☐

2. In the **past 3 weeks**, did you have vaginal sex? .....

yes ☐ *no* ☐ → ***If no, go to statement above item 5 on page 2.***

2a. In the **past 3 weeks**, how often did you have vaginal sex? ***Showcard #2.***

less than once a week	*1–3 times a week*	*4–6 times a week*	*once a day*	*more than once a day*
☐	☐	☐	☐	☐

I know that you have been counseled to use male condoms for each act of vaginal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with vaginal sex, so your honest and accurate answers are very important to us.

2b. In the **past 3 weeks**, how often did your partner(s) use a male condom during vaginal sex? ***Showcard #3.***

never	*rarely*	*sometimes*	*most of the time*	*always*
☐	☐	☐	☐	☐

Enrollment Behavior Assessment (EBA-1)

This form is used to collect baseline information about the participant's sexual behaviors. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Enrollment visit.

Interview tips:

See Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Note: *Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made during the Enrollment Visit interview only, unless requested otherwise by SCHARP. Once the participant has completed the Enrollment Visit interview in which this form is administered, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) EBA-2 (073)

Participant ID

Site Number – Participant Number – Chk

Enrollment Behavior Assessment

☐ No data recorded on this page

3. In the **past 7 days**, how many times did you have vaginal sex? ..... *# of times* ☐☐ → ***If 0, go to item 4.***

3a. In the **past 7 days**, how many times did your partner(s) use a male condom during vaginal sex? ..... *# of times* ☐☐

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

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

5. Have you ever had anal sex?..... *yes* ☐ *no* ☐ → *If no, go to statement above item 9 on page 3.*

6. In the **past 3 weeks**, did you have anal sex? ..... *yes* ☐ *no* ☐ → *If no, go to statement above item 9 on page 3.*

6a. In the **past 3 weeks**, how often did you have anal sex?
Showcard #2

less than once a week	*1–3 times a week*	*4–6 times a week*	*once a day*	*more than once a day*
☐	☐	☐	☐	☐

I know that you have been counseled to use male condoms for each act of anal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with anal sex, so your honest and accurate answers are very important to us.

6b. In the **past 3 weeks**, how often did your partner(s) use a male condom during anal sex?
Showcard #3

never	*rarely*	*sometimes*	*most of the time*	*always*
☐	☐	☐	☐	☐

Enrollment Behavior Assessment (EBA-2)

Item-specific Instructions:

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

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) EBA-3 (074)

Participant ID

Site Number – Participant Number – Chk

Enrollment Behavior Assessment

7. In the **past 7 days**, how many times did you have anal sex? ..... *# of times* ☐☐ → ***If 0, go to item 8.***

   7a. In the **past 7 days**, how many times did your partner(s) use a male condom during anal sex? ..... *# of times* ☐☐

8. The **last time** you had anal sex, did your partner use a male condom? ..... *yes* ☐ *no* ☐

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

9. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.

		yes	*no*	*# of times in **past week***
9a.	water?	☐	☐	☐☐
9b.	water with vinegar? ***Note for U.S. sites:*** *This includes all commercial douching products.*	☐	☐	☐☐
9c.	water with soap?	☐	☐	☐☐
9d.	paper, cloth, cotton, or cotton wool?	☐	☐	☐☐
9e.	tampons?	☐	☐	☐☐
9f.	fingers without anything else?	☐	☐	☐☐
9g.	anything else? Specify below.	☐	☐	☐☐

Local Language: _____

English: _____

☐ ☐ ☐ ☒ 21-APR-08

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Staff Initials / Date

Enrollment Behavior Assessment (EBA-3)

Item-specific Instructions:

- **Item 9:** Read each item 9a–9g aloud and mark the participant's response. For each item to which she replies "yes," ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the "# of times in **past week**" boxes. If "yes" is marked for item 9g, record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN 001 (146) SPA-1 (180)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Instructions: Complete items 1–3c before the interview. Also, prior to the interview, circle the correct study product (tenofovir gel, tenofovir tablets, tenofovir gel and tablets together) in the statement above item 4 to read aloud.

	vaginal tenofovir	*oral tenofovir*	*dual use (vaginal and oral tenofovir)*
1. *Participant's current study regimen period: .....*	☐	☐	☐

→ ***If oral tenofovir, go to item 3.***

2. *Date and time of last three applications of vaginal tenofovir gel prior to this visit starting with the most recent:*

Not done/ Not collected		*dd*	*MMM*	*yy*	*hr*	*min*
☐	2a.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐
☐	2b.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐
☐	2c.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐

→ ***If participant is in the vaginal study period, go to statement above item 4.***

3. *Date and time of last three doses of oral tenofovir tablets prior to this visit starting with the most recent:*

Not done/ Not collected		*dd*	*MMM*	*yy*	*hr*	*min*
☐	3a.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐
☐	3b.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐
☐	3c.	☐☐	☐☐☐	☐☐	☐☐ :	☐☐

I would like to ask you some questions about the way you have been using the study product during this study period. By study product, I mean [tenofovir gel tenofovir tablets tenofovir gel and tablets together]. We need to understand what people really are doing and why, so please report your experience as it happened. Do not worry if you did not use your study product every day. It is common for people to miss some days, and while some people use their study product every day, others may not be able to do so. We would like to know what is really happening for you.

4. In the **past 3 weeks**, how often did you use the study product?
Showcard #4.

never	*less than once a week*	*1–3 times a week*	*4–6 times a week*	*once a day*
☐	☐	☐	☐	☐

Study Product Adherence and Behavior Assessment (SPA-1)

This form is used to collect information about the participant's study product use (both vaginal and oral) and sexual behavior during her study follow-up. This is an interviewer-administered form (with the exception of items 1–3c), and is administered at the Week 3, 6, 10, 13, 17, and 20 Visits.

Note: *Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the interview in which this form is completed, unless requested otherwise by SCHARP. Once the interview is finished, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 4:** Read each response category aloud, using the appropriate showcard to help the participant respond.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

5. In the **past 3 weeks**, what was the longest number of days in a row that you missed using the study product? This does not include doses that you missed, but were able to make up prior to your next scheduled dose. .....

# of days

☐☐ → ***If 00, go to item 8 on page 3.***

6. For the days you did not use the study product, what were the reasons? *Mark all that apply.*

- ☐ 6a. away from home
- ☐ 6b. feeling sick because of using study product
- ☐ 6c. had other health problems not related to study product
- ☐ 6d. instructed by study staff to stop using study product
- ☐ 6e. tired of using study product daily
- ☐ 6f. busy/interfered with daily activities
- ☐ 6g. forgot
- ☐ 6h. gave study products(s) away
- ☐ 6i. sold study product
- ☐ 6j. someone took study product
- ☐ 6k. menses
- ☐ 6l. lack of privacy
- ☐ 6m. participant thought it interfered with sex
- ☐ 6n. partner thought it interfered with sex
- ☐ 6o. partner did not approve
- ☐ 6p. lost study product
- ☐ 6q. ran out of study product
- ☐ 6r. other, specify:

Local Language: _____

English: _____

Study Product Adherence and Behavior Assessment (SPA-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.
- **Item 6: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the "other, specify" box and record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

7. In the **past 3 weeks**, how many days did you not use the study product? This does not include doses that you missed but were able to make up prior to your next scheduled dose. ..... *# of days* ☐☐ → ***If 00, go to item 8.***

   7a. In the **past 7 days**, how many days did you not use the study product? This does not include doses that you missed but were able to make up prior to your next scheduled dose. *# of days* ☐

8. In the **past 3 weeks**, did you ever insert study gel into your anus?..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 9.***

   8a. In the **past 3 weeks**, how many times did you insert study gel into your anus? ..... *# of times* ☐☐

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Your honest answers will be very helpful to us. There are no right or wrong answers to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions are about vaginal sex, and some are about anal sex. Vaginal sex means when a man puts his penis inside your vagina. Anal sex means when a man puts his penis inside your anus.

9. In the **past 3 weeks**, have you had a new sex partner? By sex partner, I mean someone with whom you have had vaginal or anal sex. ..... *yes* ☐ *no* ☐

Now I am going to ask you some questions about vaginal sex only.

10. In the **past 3 weeks**, did you have vaginal sex? ..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 14 on page 6.***

    10a. In the **past 3 weeks**, how often did you have vaginal sex? ***Showcard #2.***

less than once a week	*1–3 times a week*	*4–6 times a week*	*once a day*	*more than once a day*
☐	☐	☐	☐	☐

Study Product Adherence and Behavior Assessment (SPA-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.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

☐ No data recorded on this page

I know that you have been counseled to use male condoms for each act of vaginal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with vaginal sex, so your honest and accurate answers are very important to us.

10b. In the **past 3 weeks**, how often did your partner(s) use a male condom during vaginal sex? ***Showcard #3.***

never	*rarely*	*sometimes*	*most of the time*	*always*
☐	☐	☐	☐	☐

11. In the **past 7 days**, how many times did you have vaginal sex? ..... *# of times* ☐☐ → ***If 00, go to item 12.***

11a. In the **past 7 days**, how many times did your partner(s) use a male condom during vaginal sex? ..... *# of times* ☐☐

12. The **last time** you had vaginal sex:

12a. did your partner use a male condom? ..... *yes* ☐ *no* ☐ → ***If participant is in the oral tenofovir period, go to item 12f on page 5.***

12b. did you use the tenofovir gel that same day? ..... ☐ ☐

If no, and participant is in the vaginal tenofovir period, go to statement above item 14 on page 6.
If no and participant is in the dual use period, go to item 12f on page 5.

12c. did you use the tenofovir gel **before** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 12d.***

12c1. How long before? .....
*Mark only one measurement of time (e.g., minutes **or** hours).*
☐☐☐ ☐ *minutes* ☐ *hours*

12d. did you use the tenofovir gel **after** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 12e on page 5.***

12d1. How long after? .....
*Mark only one measurement of time (e.g., minutes **or** hours).*
☐☐☐ ☐ *minutes* ☐ *hours*

Study Product Adherence and Behavior Assessment (SPA-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 no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

☐ No data recorded on this page

12e. did you use the tenofovir gel at a different time than usual because you had sex? ..... *yes* ☐ *no* ☐ → ***If participant is in the vaginal tenofovir period, go to statement above item 14 on page 6.***

12f. did you use the tenofovir tablets that same day? ..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 14 on page 6.***

12g. did you use the tenofovir tablets **before** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 12h.***

12g1. How long before? ..... *Mark only one measurement of time (e.g., minutes **or** hours).* # ☐☐☐ ☐ *minutes* ☐ *hours*

12h. did you use the tenofovir tablets **after** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 12i.***

12h1. How long after? ..... *Mark only one measurement of time (e.g., minutes **or** hours).* # ☐☐☐ ☐ *minutes* ☐ *hours*

12i. did you use the tenofovir tablets at a different time than usual because you had sex? ..... *yes* ☐ *no* ☐

13. Did you have vaginal sex today or yesterday? ..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 14 on page 6.***

13a. Thinking about when you had vaginal sex today and yesterday, did you have any vaginal sex **without** using a male condom? ..... *yes* ☐ *no* ☐ → ***If yes, go to statement above item 14 on page 6.***

Study Product Adherence and Behavior Assessment (SPA-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 no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

13b. When you had vaginal sex today and yesterday, did you and your partner experience any of the following:

		yes	no
13b1.	the male condom burst, broke or had a tear during sex or during removal of the penis from your vagina?	☐	☐
13b2.	the male condom slipped off completely during sex or during removal of the penis from your vagina?	☐	☐
13b3.	semen or fluid spilled from the male condom into your vagina?	☐	☐

13c. When you had vaginal sex today and yesterday, did your partner ever:

		yes	no
13c1.	insert his penis inside your vagina before putting a male condom on?	☐	☐
13c2.	remove the male condom and continue having vaginal sex?	☐	☐

I am now going to ask you some questions about another way that people have sex. This way is anal sex, which is when a man puts his penis inside his partner's anus. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

	yes	no	
14. In the **past 3 weeks**, did you have anal sex?	☐	☐ →	***If no, go to instructions above item 18 on page 10.***

14a. In the **past 3 weeks**, how often did you have anal sex? ***Showcard #2.***

less than once a week	*1–3 times a week*	*4–6 times a week*	*once a day*	*more than once a day*
☐	☐	☐	☐	☐

Study Product Adherence and Behavior Assessment (SPA-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.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

☐ No data recorded on this page

I know that you have been counseled to use male condoms for each act of anal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with anal sex, so your honest and accurate answers are very important to us.

14b. In the **past 3 weeks**, how often did your partner(s) use a male condom during anal sex?
Showcard #3.

never	*rarely*	*sometimes*	*most of the time*	*always*
☐	☐	☐	☐	☐

15. In the **past 7 days**, how many times did you have anal sex? ..... *# of times* ☐☐ → ***If 00, go to item 16.***

15a. In the **past 7 days**, how many times did your partner(s) use a male condom during anal sex? ..... *# of times* ☐☐

16. The **last time** you had anal sex:

16a. did your partner use a male condom? ..... *yes* ☐ *no* ☐ → ***If participant is in the oral tenofovir period, go to item 16f on page 8.***

16b. did you insert the tenofovir gel into your vagina that same day? ..... *yes* ☐ *no* ☐

If no, and participant is in the vaginal tenofovir period, go to statement above item 18 on page 10.
If no and participant is in the dual use period, go to item 16f on page 8.

16c. did you use the tenofovir gel **before** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 16d.***

16c1. How long before? .....
*Mark only one measurement of time (e.g., minutes **or** hours).*
☐☐☐ ☐ *minutes* ☐ *hours*

16d. did you use the tenofovir gel **after** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 16e on page 8.***

16d1. How long after? .....
*Mark only one measurement of time (e.g., minutes **or** hours).*
☐☐☐ ☐ *minutes* ☐ *hours*

Study Product Adherence and Behavior Assessment (SPA-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 no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

☐ No data recorded on this page

16e. did you use the tenofovir gel at a different time than usual because you had sex? ..... *yes* ☐ *no* ☐ → ***If participant is in the vaginal tenofovir period, go to statement above item 18 on page 10.***

16f. did you use the tenofovir tablets that same day? ..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 18 on page 10.***

16g. did you use the tenofovir tablets **before** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 16h.***

16g1. How long before? ..... *Mark only one measurement of time (e.g., minutes **or** hours).*

\# ☐☐☐ ☐ *minutes* ☐ *hours*

16h. did you use the tenofovir tablets **after** sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 16i.***

16h1. How long after? ..... *Mark only one measurement of time (e.g., minutes **or** hours).*

\# ☐☐☐ ☐ *minutes* ☐ *hours*

16i. did you use the tenofovir tablets at a different time than usual because you had sex? ..... *yes* ☐ *no* ☐

17. Did you have anal sex today or yesterday? ..... *yes* ☐ *no* ☐ → ***If no, go to statement above item 18 on page 10.***

17a. Thinking about when you had anal sex today and yesterday, did you have any anal sex **without** using a male condom? ..... *yes* ☐ *no* ☐ → ***If yes, go to statement above item 18 on page 10.***

Study Product Adherence and Behavior Assessment (SPA-8)

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 no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

☐ No data recorded on this page

17b. When you had anal sex today and yesterday, did you and your partner experience any of the following:

		yes	no
17b1.	the male condom burst, broke or had a tear during sex or during removal of the penis from your anus?	☐	☐
17b2.	the male condom slipped off completely during sex or during removal of the penis from your anus?	☐	☐
17b3.	semen or fluid spilled from the male condom into your anus?	☐	☐

17c. When you had anal sex today and yesterday, did your partner ever:

		yes	no
17c1.	insert his penis inside your anus before putting a male condom on?	☐	☐
17c2.	remove the male condom and continue having anal sex?	☐	☐

Study Product Adherence and Behavior Assessment (SPA-9)

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 no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

18. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.

		yes	*no*	*# of times in **past week***
18a.	water?	☐	☐	☐☐
18b.	water with vinegar? ***Note for U.S. sites:*** *This includes all commercial douching products.*	☐	☐	☐☐
18c.	water with soap?	☐	☐	☐☐
18d.	paper, cloth, cotton, or cotton wool?	☐	☐	☐☐
18e.	tampons?	☐	☐	☐☐
18f.	fingers without anything else?	☐	☐	☐☐
18g.	anything else? Specify below:	☐	☐	☐☐

Local Language: _____

English: _____

Study Product Adherence and Behavior Assessment (SPA-10)

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–18g aloud and mark the participant's response. For each item to which she replies "yes," ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the "# of times in **past week**" boxes. If "yes" is marked for item 18g, be sure to record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN 001 (146) PSA-1 (201)

Participant ID

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

Product Sharing Assessment

Visit Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Instructions: Before the interview, circle the correct study product (tenofovir gel, tenofovir tablets, tenofovir gel and tablets together) in the statement above item 1 to read aloud. Complete items 1–3h at the end-of-study period visits (Weeks 6, 13, and 20) only.

I am now going to ask you some questions about sharing of study product during this study period. By study product, I mean [tenofovir gel tenofovir tablets tenofovir gel and tablets together]. I know that you are counseled to **not** share your study product with other people, but I also know that this is not always possible.

1. Since you started using the study product, has anyone asked you for your study product?..... *yes* ☐ *no* ☐ → ***If no, go to item 2 on page 2.***

Who asked you for your study product:

		yes	*no*	*n/a*	*# of tablets shared*	*# of applicators shared*
1a.	husband or primary male sex partner?	☐	☐	☐	☐☐	☐☐
1b.	other sex partner(s)?	☐	☐	☐	☐☐	☐☐
1c.	your children?	☐	☐	☐	☐☐	☐☐
1d.	other relative(s)?	☐	☐	☐	☐☐	☐☐
1e.	friend(s) who you do not have sex with?	☐	☐	☐	☐☐	☐☐
1f.	neighbor(s)?	☐	☐	☐	☐☐	☐☐
1g.	other study participants?	☐	☐	☐	☐☐	☐☐
1h.	other, specify:	☐	☐	☐	☐☐	☐☐

Local Language: _____

English: _____

☐ ☐ ☐ ☒ 21-APR-08

0 1
Language

_____
Staff Initials / Date

Product Sharing Assessment (PSA-1)

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Items 1a–1h:** Read each item aloud and mark the participant's response. For each item to which she replies "yes," ask how many study tablets and applicators were shared. Record the responses in the "#of tablets shared" and "# of applicators shared" boxes. For each "yes," response, both the "# of tablets shared" and the "# of applicators shared" boxes should be completed. Use leading zeros when needed so that all boxes are filled. If "yes" is marked for "other, specify," record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Product Sharing Assessment

2. Since you started using the study product, have you ever sold, traded, or given away your study product? ..... *yes* ☐ *no* ☐ → ***If no, go to item 3 on page 3.***

Who did you sell, trade, or give your study product to:

		yes	*no*	*n/a*	*# of tablets sold/traded/given*	*# of applicators sold/traded/given*
2a.	husband or primary male sex partner?	☐	☐	☐	☐☐	☐☐
2b.	other sex partner(s)?	☐	☐	☐	☐☐	☐☐
2c.	your children?	☐	☐	☐	☐☐	☐☐
2d.	other relative(s)?	☐	☐	☐	☐☐	☐☐
2e.	friend(s) who you do not have sex with?	☐	☐	☐	☐☐	☐☐
2f.	neighbor(s)?	☐	☐	☐	☐☐	☐☐
2g.	other study participants?	☐	☐	☐	☐☐	☐☐
2h.	other, specify:	☐	☐	☐	☐☐	☐☐

Local Language: _____

English: _____

Product Sharing Assessment (PSA-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 2a–2h:** Read each item aloud and mark the participant's response. For each item to which she replies "yes," ask how many study tablets and applicators were sold/traded/given. Record the responses in the "#of tablets sold/traded/given" and "# of applicators sold/traded/given" boxes. For each "yes," response, both the "# of tablets sold/traded/given" and the "# of applicators sold/traded/given" boxes should be completed. Use leading zeros when needed so that all boxes are filled. If "yes" is marked for "other, specify," record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Product Sharing Assessment

3. Since you started using the study product, has anyone taken your study product without your permission? ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

Who do you think took your study product:

		yes	*no*	*n/a*	*# of tablets taken*	*# of applicators taken*
3a.	husband or primary male sex partner?	☐	☐	☐	☐☐	☐☐
3b.	other sex partner(s)?	☐	☐	☐	☐☐	☐☐
3c.	your children?	☐	☐	☐	☐☐	☐☐
3d.	other relative(s)?	☐	☐	☐	☐☐	☐☐
3e.	friend(s) who you do not have sex with?	☐	☐	☐	☐☐	☐☐
3f.	neighbor(s)?	☐	☐	☐	☐☐	☐☐
3g.	other study participants?	☐	☐	☐	☐☐	☐☐
3h.	other, specify:	☐	☐	☐	☐☐	☐☐

Local Language: _____

English: _____

Product Sharing Assessment (PSA-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.
- **Items 3a–3h:** Read each item aloud and mark the participant's response. For each item to which she replies "yes," ask how many study tablets and applicators were taken. Record the responses in the "#of tablets taken" and "# of applicators taken" boxes. For each "yes," response, both the "# of tablets taken" and the "# of applicators taken" boxes should be completed. Use leading zeros when needed so that all boxes are filled. If "yes" is marked for "other, specify," record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), *draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) AA-1 (272)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Acceptability Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Instructions: Complete item 1 before the interview.

1. Which study regimen period is the participant in?

☐ vaginal tenofovir → ***If vaginal tenofovir, go to item 2.***

☐ oral tenofovir → ***If oral tenofovir, go to item 3.***

☐ dual use (both vaginal and oral tenofovir) → ***If dual use, go to item 4.***

2. One goal of this study is to understand how acceptable daily use of the vaginal tenofovir gel is to women and their partners. I would like to ask you about your experience using the tenofovir gel. Your honest answer will be very helpful to us. If daily use of tenofovir gel is found to protect people from HIV, how likely would you be to use it? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*	
☐	☐	☐	☐	→ ***Go to item 5.***

3. One goal of this study is to understand how acceptable daily use of oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using oral tenofovir. Your honest answer will be very helpful to us. If daily use of oral tenofovir is found to protect people from HIV, how likely would you be to use it? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*	
☐	☐	☐	☐	→ ***Go to item 5.***

4. One goal of this study is to understand how acceptable daily use of vaginal tenofovir gel and oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using vaginal and oral tenofovir. Your honest answer will be very helpful to us. If daily use of vaginal tenofovir gel and oral tenofovir is found to protect people from HIV, how likely would you be to use them? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*
☐	☐	☐	☐

5. How worried are you that you will become HIV-positive in the next year? ***Showcard #5***

very worried	*somewhat worried*	*not very worried*	*not at all worried*
☐	☐	☐	☐

Acceptability Assessment (AA-1)

This form is used to collect study product acceptability information from study participants. This is an interviewer-administered form except for item 1, which should be completed by study staff before starting the interview. This form is administered at each 6-Week and 13-Week visit.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN 001 (146) AA-2 (273)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Acceptability Assessment

6. Are you currently married? ..... *yes* ☐ *no* ☐
   → ***If yes, go to item 8.***

7. Do you currently have a primary male sex partner? By primary partner, I mean someone you have sex with on a regular basis, and who you consider to be your main partner. ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

8. Is he HIV-positive? ..... *yes* ☐ *no* ☐ *don't know* ☐
   → ***If yes, go to item 10.***

9. How worried are you that he will become HIV-positive in the next year?
   Showcard # 5

very worried	*somewhat worried*	*not very worried*	*not at all worried*
☐	☐	☐	☐

10. Did he accompany you here to the clinic during this study period? ..... *yes* ☐ *no* ☐

11. Did he know that you were using the study product? ..... *yes* ☐ *no* ☐ *don't know* ☐
    → ***If no or don't know, end of form.***

12. What was his reaction to your use of the study product? *Mark all that apply.*

- ☐ 12a. he liked it
- ☐ 12b. he did not like it
- ☐ 12c. he thought it improved sex
- ☐ 12d. he thought it worsened sex
- ☐ 12e. he thought it interfered with sex
- ☐ 12f. he had no reaction
- ☐ 12g. don't know
- ☐ 12h. other, specify:

Local Language: _____

English: _____

Acceptability Assessment (AA-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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN 001 (146) FAA-1 (372)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Final Acceptability Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Instructions: Complete item 1 before the interview.

1. Which study regimen period is the participant in?

☐ vaginal tenofovir → ***If vaginal tenofovir, go to item 2.***

☐ oral tenofovir → ***If oral tenofovir, go to item 3.***

☐ dual use (both vaginal and oral tenofovir) → ***If dual use, go to item 4.***

2. One goal of this study is to understand how acceptable daily use of the vaginal tenofovir gel is to women and their partners. I would like to ask you about your experience using the tenofovir gel. Your honest answer will be very helpful to us. If daily use of tenofovir gel is found to protect people from HIV, how likely would you be to use it? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*	
☐	☐	☐	☐	→ ***Go to item 5.***

3. One goal of this study is to understand how acceptable daily use of oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using oral tenofovir. Your honest answer will be very helpful to us. If daily use of oral tenofovir is found to protect people from HIV, how likely would you be to use it? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*	
☐	☐	☐	☐	→ ***Go to item 5.***

4. One goal of this study is to understand how acceptable daily use of vaginal tenofovir gel and oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using vaginal and oral tenofovir. Your honest answer will be very helpful to us. If daily use of vaginal tenofovir gel and oral tenofovir is found to protect people from HIV, how likely would you be to use them? ***Showcard #1***

very likely	*likely*	*unlikely*	*very unlikely*
☐	☐	☐	☐

5. How worried are you that you will become HIV-positive in the next year? ***Showcard #5***

very worried	*somewhat worried*	*not very worried*	*not at all worried*
☐	☐	☐	☐

Final Acceptability Assessment (FAA-1)

This form is used to collect study product acceptability information from study participants. This is an interviewer-administered form except for item 1, which should be completed by study staff before starting the interview. This form is administered at the 20-Week visit.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN 001 (146) FAA-2 (373)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Final Acceptability Assessment

6. Are you currently married? ..... yes ☐ no ☐
   → ***If yes, go to item 8.***

7. Do you currently have a primary male sex partner? By primary partner, I mean someone you have sex with on a regular basis, and who you consider to be your main partner. ..... yes ☐ no ☐
   → ***If no, go to item 16 on page 3.***

8. Is he HIV-positive? ..... yes ☐ no ☐ don't know ☐
   → ***If yes, go to item 10.***

9. How worried are you that he will become HIV-positive in the next year? ***Showcard #5***

very worried	*somewhat worried*	*not very worried*	*not at all worried*
☐	☐	☐	☐

10. Did he accompany you here to the clinic during this study period? ..... yes ☐ no ☐

11. Did he know that you were using the study product? ..... yes ☐ no ☐ don't know ☐
    → ***If no or don't know, go to item 16 on page 3.***

12. What was his reaction to your use of the study product?
    Mark all that apply.

- ☐ 12a. he liked it
- ☐ 12b. he did not like it
- ☐ 12c. he thought it improved sex
- ☐ 12d. he thought it worsened sex
- ☐ 12e. he thought it interfered with sex
- ☐ 12f. he had no reaction
- ☐ 12g. don't know
- ☐ 12h. other, specify:

Local Language: _____

English: _____

☐☐☐☒ 21-APR-08

0 1 Language

Staff Initials / Date

Final Acceptability Assessment (FAA-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.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN 001 (146) FAA-3 (374)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Final Acceptability Assessment

13. Since you joined the study, how supportive was he about your use of the study gel?
Showcard #6

very supportive	*somewhat supportive*	*not very supportive*	*not at all supportive*
☐	☐	☐	☐

14. Since you joined the study, how supportive was he about your use of the study tablets?
Showcard #6

very supportive	*somewhat supportive*	*not very supportive*	*not at all supportive*
☐	☐	☐	☐

15. What did he prefer that you use—using the study gel or the study tablets?

- ☐ study gel
- ☐ study tablets
- ☐ neither—disliked both study products
- ☐ both—liked both study products equally

16. What did you prefer—using the study gel or taking the study tablets?

- ☐ study gel
- ☐ study tablets
- ☐ neither—disliked both study products
- ☐ both—liked both study products equally

Comments: _____

Final Acceptability Assessment (FAA-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.

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

MTN 001 (146)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Eligibility

Form Completion Date

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

dd *MMM* *yy*

Complete items 1–4 before the interview.

		yes	no	
1.	*Was the participant willing and able to provide a written informed consent for screening?*	☐	☐	
2.	*Was the participant willing and able to provide adequate locator information?*	☐	☐	***If no to either, participant is ineligible. End of form.***
3.	*Was the participant previously enrolled in this study?*	☐	☐	***If yes, participant is ineligible. End of form.***
4.	*Is documentation of a normal Pap test result in the last 12 calendar months available?*	☐	☐	***If no, perform Pap test as necessary.***

I am now going to ask you some more questions about yourself. Some of these questions are personal and sensitive, but remember that we do not have your name on these papers and all of your answers will be kept confidential.

		yes	no	
5.	Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐	
6.	Do you have any current male sex partner(s) who have had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐	
7.	Have you ever had an adverse or bad reaction to either of the study products (Tenofovir (Viread) oral tablet or Tenofovir 1% vaginal gel and/or applicator)?	☐	☐	
8.	Have you ever been diagnosed with a pathologic bone fracture not related to trauma?	☐	☐	
9.	Are you breastfeeding?	☐	☐	
10.	Do you plan to become pregnant during the 21 weeks of study participation?	☐	☐	
11.	Do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation?	☐	☐	
12.	Do you plan to use acyclovir, valacyclovir, post-exposure prophylaxis for HIV exposure, Truvada, or non-study vaginal products (other than tampons) at any time during your study participation?	☐	☐	
13.	Have you had more than three male sex partners in the past month (30 days)?	☐	☐	***If yes to any, participant is ineligible.***

Screening Eligibility – Page 1 of 4 (nonDF)

This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 5–25), while other items are not (items 1–4 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 25. Do not inform her that she is ineligible for the study until the form has been administered. Also, avoid letting the participant know the reason why she is ineligible, to prevent socially desirable reporting.*

Item-specific Instructions:

- **Items 1–4:** These items are NOT interviewer-administered and should not be read aloud to the participant.
- **Item 2:** Adequate locator information is defined in site standard operating procedures (SOP).
- **Item 3:** Review the Screening and Enrollment Log to verify that the participant has not previously enrolled in the study.
- **Item 4:** Per protocol, a participant must have either a normal Pap test result at screening or documentation of a normal Pap test result in the 12 calendar months prior to screening in order to be eligible to enroll in the study. If the participant does not provide documentation of a normal Pap test result in the 12 calendar months prior to screening, conduct a Pap Smear test for this participant as part of the Screening Visit pelvic exam.

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

MTN 001 (146)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Eligibility

14. In the past 4 weeks, how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina..... [ ][ ] → ***If < 4, participant is ineligible. Go to item 16.***

15. Do you anticipate having vaginal sex at least once per week during your study participation? ..... *yes* [ ] *no* [ ] → ***If no, participant is ineligible.***

16. Do you have a regular menstrual cycle that is 21 days or longer? ..... *yes* [ ] *no* [ ]

If yes, go to item 17.

16a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? ..... *yes* [ ] *no* [ ] → ***If no, participant is ineligible.***

17. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? ..... *yes* [ ] *no* [ ] → ***If no, go to item 18.***

17a. When did you last give birth, have a miscarriage or abortion? ..... [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

If date is within the last 60 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.

18. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C), surgery of the uterus, ovaries, or fallopian tubes (including tubal ligation), biopsy, or cryotherapy (freezing) of the cervix? ..... *yes* [ ] *no* [ ] → ***If no, go to item 19.***

18a. When did you last have gynecological surgery? ..... [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

If date is within the last 60 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.

Screening Eligibility – Page 2 of 4 (nonDF)

No additional instructions needed.

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Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Screening Eligibility

19. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ..... *yes* ☐ *no* ☐ → ***If yes, participant is ineligible.***

20. In the past month (30 days), have you participated in any other research study that involves drugs, medical devices, or vaginal products? ..... *yes* ☐ *no* ☐ → ***If no, go to item 21.***

20a. When did you last participate in one of these studies? ..... ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

If participant is currently participating in another investigational drug, device, or vaginal product research study, participant is ineligible. Otherwise, schedule enrollment when participant is no longer within 30 days of other study participation.

Screening Eligibility – Page 3 of 4 (nonDF)

No additional instructions needed.

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

MTN 001 (146)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Screening Eligibility

	yes	no
21. Do you agree to not participate in any other research study that involves drugs, medical devices, or vaginal products?	☐	☐
22. From the day of your study enrollment, through one month after you finish your study participation, do you agree to use one of the following types of birth control: Depo-Provera (“the shot”), hormonal contraceptives (“the pill”), Ortho-Evra (“the patch”), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy?	☐	☐
23. Are you willing to use the study products, which are tenofovir oral tablets and tenofovir 1% vaginal gel, once a day as directed by study staff?	☐	☐
24. Are you willing to attend all scheduled study visits?	☐	☐
25. Are you willing to undergo all study evaluations, including a pelvic exam, urine testing, and blood draws?	☐	☐

If no to any, participant is ineligible.

Complete item 26 when Screening urine hCG result is available.

	yes	no
26. *Is the participant pregnant?*	☐	☐

If yes, participant is ineligible.

	yes	no
27. *Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives?*	☐	☐

If yes, participant is ineligible.

Screening Eligibility – Page 4 of 4 (nonDF)

Item-specific Instructions:

- **Item 22:** If the participant's chosen effective method of contraception is sterilization (of participant or her sexual partner(s)), participant self-report is acceptable and sufficient documentation in order to enroll the participant.
- **Item 26:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening Visit urine hCG result here.
- **Item 27:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the "yes" box, record the reason in the participant's chart notes, and do not enroll the participant in the study.

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MTN 001 (146)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Summary

- ☐ 2t. has a history of pathologic bone fracture, not related to trauma
- ☐ 2u. has a history of adverse reaction to either study product (tenofovir oral tablets, tenofovir 1% vaginal gel and/or applicator)
- ☐ 2v. has a history of prior participation in the study
- ☐ 2w. has a laboratory value or abnormality at screening that is exclusionary per protocol
- ☐ 2x. had a gynecological surgical procedure within 90 days of enrollment
- ☐ 2y. is pregnant or plans to become pregnant during the study period
- ☐ 2z. is within 90 days of last pregnancy outcome at enrollment
- ☐ 2aa. has an abnormal physical or pelvic exam finding that is exclusionary, per investigator or designee
- ☐ 2ab. is diagnosed with a current UTI, or an STI and/or other RTI requiring treatment according to WHO guidelines
- ☐ 2ac. has a significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory immunologic disorder or infectious disease, including active TB, or any other medical condition that is exclusionary, per site investigator
- ☐ 2ad. has a history of non-therapeutic injection drug use in the 12 months prior to screening
- ☐ 2ae. has participated in another study that involves drugs, medical devices or vaginal products in the 30 days prior to enrollment
- ☐ 2af. does not intend to have vaginal intercourse at least once per week during study participation
- ☐ 2ag. is breastfeeding
- ☐ 2ah. exceeded the 30-day screening window
- ☐ 2ai. has any other condition that, in the opinion of the Investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives

Screening Summary – Page 2 of 2 (nonDF)

Item-specific Instructions:

- **Item 2t–2v:** Review **Screening Eligibility** form.
- **Item 2w:** Review **Safety Laboratory Results** form from the Screening Visit.
- **Item 2x–2z:** Review **Screening Eligibility** *and* **Enrollment Eligibility** forms.
- **Item 2aa:** Review **Screening and Enrollment Pelvic Exam** forms from both the Screening and Enrollment Visits; **and** the **Physical Exam** form; **and** the **Clinical Eligibility** form from both the Screening and Enrollment Visits.
- **Item 2ab–2ac:** Review **Clinical Eligibility** forms from both the Screening and Enrollment Visits.
- **Item 2ad:** Review **Screening Eligibility** form.
- **Item 2ae–2ag:** Review **Screening Eligibility** *and* **Enrollment Eligibility** forms.
- **Item 2ah:** Review **Screening Consent** form *and* date of enrollment as recorded on the **Enrollment** form.
- **Item 2ai:** Review **Screening Eligibility** *and* **Enrollment Eligibility** forms.

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MTN 001 (146)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Enrollment Eligibility

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Complete item 1 before the interview.

		yes	no	
1.	*Was the participant willing and able to provide a written informed consent for enrollment?*	☐	☐	→ *If no, participant is ineligible. End of form.*

To confirm your eligibility for the study, I need to ask you a few more questions.

		yes	no
2.	In the past month (30 days), have you participated in any other research study that involves drugs, medical devices, or vaginal products?	☐	☐
3.	Are you breastfeeding?	☐	☐
4.	Do you plan to become pregnant during the 21 weeks of study participation?	☐	☐
5.	In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C), surgery of the uterus, ovaries, or fallopian tubes (including tubal ligation), biopsy, or cryotherapy (freezing) of the cervix?	☐	☐
6.	Are you currently using, or do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation?	☐	☐
7.	Are you currently using, or do you plan to use acyclovir, valacyclovir, post-exposure prophylaxis for HIV exposure, Truvada, or non-study vaginal products (other than tampons) at any time during your study participation?	☐	☐
8.	In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?	☐	☐
9.	Have you had an intrauterine device (IUD) inserted in the past 29 days?	☐	☐

If yes to any, participant is ineligible.

Enrollment Eligibility – Page 1 of 2 (nonDF)

This form is used to document the participant's eligibility for the study at enrollment. This is a mixed form—some of the items are interviewer-administered (items 2–15), while other items are not (items 1, 16–17). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Interviewer Tips:

Refer to the Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

- **Items 2–15:** These items were also asked during the Screening 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 15. 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.**

MTN 001 (146)

Participant ID

			–						–	

Site Number Participant Number Chk

Enrollment Eligibility

Visit Date

dd *MMM* *yy*

	yes	no
10. Do you agree to not participate in any other research study that involves drugs, medical devices, or vaginal products while participating in this study?	☐	☐
11. Do you anticipate having vaginal sex at least once per week during your study participation?	☐	☐
12. From today through one month after you finish your study participation, do you agree to use one of the following types of birth control: Depo-Provera (“the shot”), hormonal contraceptives (“the pill”), Ortho-Evra (“the patch”), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy?	☐	☐
13. Are you willing to use the study products, which are tenofovir oral tablets and tenofovir 1% vaginal gel, once a day as directed by study staff?	☐	☐
14. Are you willing to attend all scheduled study visits?	☐	☐
15. Are you willing to undergo all study evaluations, including a pelvic exam, urine testing, and blood draws?	☐	☐

If no to any, participant is ineligible.

Complete item 16 when Enrollment urine hCG result is available.

	yes	no
16. *Is the participant pregnant?*	☐	☐

If yes, participant is ineligible.

Complete item 17 after reviewing all Screening and Enrollment forms.

	yes	no
17. *Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives?*	☐	☐

If yes, participant is ineligible.

Enrollment Eligibility – Page 2 of 2 (nonDF)

Item-specific Instructions:

- **Item 12:** If the participant's chosen effective method of contraception is female sterilization or sexual activity with a vasectomized partner, participant self-report is sufficient documentation, per protocol, that this eligibility criterion has been met.
- **Item 16:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Enrollment Visit urine hCG result here.
- **Item 17:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Enrollment Visit procedures have been completed, but prior to study randomization. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the "yes" box, record the reason in the participant's chart notes, and do not enroll the participant in the study.