

Question by Question (Q x Q) Instructions for MTN 001 Behavioral and Adherence Assessment Case Report Forms

Introduction

This guide provides instruction for site staff in the use of the behavioral and adherence assessment CRFs (including the Enrollment Behavior Assessment, Study Product Adherence and Behavior Assessment, Product Sharing Assessment, Acceptability Assessment, and the Final Acceptability Assessment) and presents general guidelines for administering these forms. It supplements the training sessions conducted by FHI and SCHARP. The overall objective of this document is to help study interviewers be consistent when administering these CRFs. Consistency is crucial for the data to be meaningful. By administering the behavioral and adherence assessments the same way from site to site, you will avoid biasing the participants' responses.

The assessment CRFs consist of a list of questions that you will read aloud to the participant. If you deviate from asking the questions properly (for example, by making it into a conversation of sorts), the investigators of the study will not be able to interpret the data appropriately. It is important that you do not inject your personality and try hard to limit your influence (i.e., you have worked with the participant throughout the trial, she has received continuous counseling on protocol requirements, and now we're asking her to answer honestly about how she use the product, her sexual behaviors, etc.), because you might unintentionally influence a participant to answer the way you want her to, or the way the participant *thinks* you want her to answer. For this reason, it is crucial that the participant receives risk-reduction and product adherence counseling after the forms are administered, and from a different site staff member than the one who administers the forms to her.

Before the trial begins, it is suggested that each staff person who will administer these assessments conduct several role-play scenarios with other staff in-house. Conduct enough role-plays until you are comfortable with the assessments before administering them to the participants. By familiarizing yourself with the questions, wording and skip

patterns, you will ultimately help the participants feel more comfortable as they answer the questions and will ensure that the assessments are administered smoothly and clearly.

General Information

Privacy: The behavioral and adherence assessments need to be conducted in private (and only in locations and situations approved by the site supervisors). Otherwise, the participant may not report behaviors that she does not want overheard. If a participant asks for others to be present, respond with, “Because this is a research study, we need to administer these forms in the same way for every participant. Bringing other people into the situation would make this different, even if the other people didn’t say anything.” This response can also address other deviations that a participant may request, such as being allowed to complete one particular assessment at several time points.

Administration: The behavioral and adherence assessments are administered by reading each item aloud to the participant at a relaxed pace. Inform the participant that is okay to tell you if the pace is too fast or too slow. Your intonation should go up slightly (a raised voice pitch) at the end of each question to indicate that it is a question. Be attentive and respectful during the interview. There are some brief explanations of items that go with certain questions. Avoid adding any extra verbiage between questions other than mild, occasional *general* encouragement such as, “You’re giving this good effort,” or “OK, let’s move on,” or “We’re making good progress.” These statements should be made at “section breaks” in the assessments, for example when you are moving from adherence questions to sexual behavior questions in the Study Product Adherence and Behavior Assessment.

A professional approach in the interview session involves being courteous while moving at a reasonable pace through the assessment. Although the questions involve sensitive topics, the participants are aware of the purpose of the study and its confidential nature. If you are comfortable with the administration and content of the forms, then the participants will be as well. However, do not be disturbed if some participants have negative emotional reactions to question content. This is understandable given the anxiety that sexual topics or adherence questions can evoke. It is important that you not get defensive or judgmental, but take negative reaction in stride with a brief empathic statement (e.g., “I know sometimes these questions can seem very personal.”). If the participant seems unusually uncomfortable, remind her that she does not have to respond

to a particular question. You will usually find that participants are willing to respond if you have established some rapport and ensured their confidentiality.

Feedback: Please do not agree with, disagree with, or correct statements made by participants. If they want to know particular pieces of information about the study products or HIV, for example, you can give them handouts or other information after you finish administering the assessments. If they ask questions about the study itself, you may decide to provide a brief and straightforward answer. If you are uncertain how to answer, you may need to direct participants to the Site/Study Coordinator, the Site Principal Investigator, and/or the site contact number on the informed consent form. It is preferable to politely defer general questions until the end of the interview, at which point you may need to consult a local referral sheet, which lists sources of information. It is important that, in general, you not offer feedback: no inferences or judgments.

Referral needed: The participant may bring up concerns that need to be addressed for ethical reasons. For example, the participant may talk about a particular social harm she has experienced as a result of being in this study, such as domestic violence. There are local referrals available to you for people in crisis. Although we will be providing important services in the course of the study, you cannot try to solve the participants' problems yourself in the interview situation via counseling or practical assistance such as money, goods, or transportation. This is inappropriate for your role as interviewer and could compromise the study. This does not mean that you cannot listen to comments the participant makes about her problems. State that it sounds like she has some important concerns, and that you would like to address them at the end of the interview. If she is emotionally upset, however, the interview may need to be postponed in light of that distress. You should always try to administer the behavioral and adherence assessments according to the visit checklists in the Study-specific Procedures Manual (SSP). If this is not possible, contact FHI and SCHARP, and they will advise you how to manage these instances. If you are in a situation that you are not sure how to handle, call your supervisor. If a participant talks about incorrect facts regarding HIV/STD transmission, use a brochure or other site resource to go over the facts with the participant **after** administering the assessments.

Question Order: Questions must be read in the order they appear on each assessment. Read each question verbatim, that is, word-for-word as written. If the participant wants the question repeated, read it again verbatim. If the participant does not understand, ask her to give it her best answer, based on her current interpretation. The exception is if a participant asks about a term that is defined in the QxQ. If the participant asks, “Do you mean _____?” respond “yes” or “no.” You should be clear on all definitions prior to administering these assessments. Looking items up in the QxQ takes time away from the interview and could affect your rapport with the participant.

Participants may, of course, refuse to answer specific questions. However, you should encourage them to respond by reminding them of the confidential nature of the interview and the importance of the information. In addition, you should remind the participant that there is no right or wrong answer. If, after reminding them of this, they still wish to refuse a question, that is okay; record the refusal and move on. If the participant offers an “I don’t know” answer, respond with, “Well, let me repeat the question...” If the participant is wavering back and forth between two responses reply, “Which do you think is the answer that best applies for you?”

Showcards: Some questions have accompanying showcards with the answer choices listed, which the participant can look at, refer to, and study. Provide the cards at the time the question is read. In addition, read the answer choices aloud to the participant while indicating with your finger which response you are reading. Read all possible answers on the showcard to the participant before recording an answer; if a participant interrupts while you are reading the showcard, wait until she is done and continue with the list. Although some categories are very close in meaning, the participant must select the one (and only one) that best applies. When you have finished reading all the response options, remove your fingers/hands so as not to inadvertently indicate a response. When the participant responds, remove the showcard.

The Interview

1. Before you administer these assessment CRFs to a participant, record on the form her participant ID, the Visit Date, and, when required, the Visit Code.
2. Welcome the participant and make her feel as comfortable as possible.
3. Begin each interview with a general statement that lets the participant know what to expect in the next few minutes, such as: “I’m now going to administer a behavior questionnaire.” Depending on the participant and the situation, the introductory statement on the assessment itself may be enough to accomplish this goal.
4. For some participants, sitting across the table/desk from them is appropriate and feels to be the best option. For others, it may help them feel more comfortable to sit beside you. Either method is fine. What’s important is making the participant feel as comfortable as possible.
5. Don’t read the CRF titles or question numbers aloud to the participants.
6. As you read the questions, vary your tone of voice, so that you don't sound automated. Emphasize the important words in an item (words or phrases that are **bolded**), so that the meaning of the question comes through.
7. Avoid re-phrasing items because this can change the meaning of the item, making it inconsistent with another participant’s interview.
8. Do not read the ‘N/A (not applicable)’ responses to participants. These are for our coding only.
9. Do NOT read the response categories aloud on questions that give that specific instruction (for example, Q6 on the Study Product Adherence and Behavior Assessment).
10. If a question has an “other, specify” option, but you are not allowed to read response categories aloud, wait for the participant to answer the question. If she does not answer the question with a response that is listed, ask the participant to be specific or use one of the following: “give me an example”, or “such as...” or “tell me the specifics.”

11. If a participant gives a response that fits in the “other, specify” option, record the response in the local language and, *after* the interview, translate the response into English (if it wasn’t given in English during the interview) on the line provided in the CRF.
12. If a participant interrupts you, let her know you need to finish the question.
13. If a question has multiple yes/no responses, pause following each question to allow a response. For example, in the Product Sharing Assessment, Q1, a participant is offered the chance to answer yes or no to each item in Q1a-Q1h. Read each sub-question and pause while waiting for the participant to answer “yes” or “no” before moving on to the next sub-question.
14. Sometimes participants get uncomfortable if you look up at them, especially with certain questions. Use your social judgment and monitor the participant’s responses (verbal and nonverbal) to gauge the most comfortable posture for a given participant.
15. If the participant looks confused, unsure, uncomfortable, say, “Let me re-read the question,” and re-read it *verbatim*. Pause again and wait for a response.
16. When asking for a participant’s best guess, be sure to ask, “What is your best guess?” rather than “Could you give me your best guess?”
17. Remember that silence is a probe. Sometimes, when giving the participant time to think, the silence alone will prompt a response – or a question.
18. Always proceed to the next sub-question or question unless an appropriate skip pattern is indicated by an arrow (→) and instructions on the form.
19. Before you end the assessment session, be sure to take a moment to review all pages for any errors, skipped questions, or inconsistencies. Be sure to correct any errors, skipped items that should have been answered, or reconcile inconsistencies before the participant leaves.
20. When the interview has finished, thank the participant for her time and effort in answering the questions.

Question by Question (Q x Q) Instructions MTN 001

Enrollment Behavioral Assessment

Prior to the interview: For general guidance on interviewing techniques and completion of the interviewer-administered case report forms (CRFs), please refer to the Study-specific Procedures Manual Section 13.5.

Read the introductory statement. Say that when questions ask “how often” or “how many times” the participant “had sex”, that this refers to “rounds” of sex. If further clarification is needed, say “for example, if you had sex twice yesterday and once today, that would mean that you had sex three ‘times’ in the past two days.”

Proceed to **Q1**.

Q1: If further clarification is needed say: “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]).” For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.”

Q1a: The definition of “casual partner” in the text of the question uses the term “main partner”. Define “main partner”. “By ‘main partner’, I mean a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.”

Q2: Emphasize “**in the past three weeks.**” State that the next few questions will ask about “the past three weeks.” If further clarification is needed, state: “in the past 21 days.” If further clarification is needed for the term “vaginal sex”, say: “Vaginal sex means when a man puts his penis inside your vagina.”

Q2a: Emphasize “**in the past three weeks.**”

Use showcard #2. Read the question, present the showcard, and read the possible responses on the showcard, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant's response.

Note: If the participant's vaginal sex frequency varied over the past three weeks, help her think about the number of times she had vaginal sex during the past three weeks and then ask her to choose the answer that most closely matches her average frequency of vaginal sex.

Read statement before **Q2b**. If clarification is needed about "act of vaginal sex", say "by 'act of vaginal sex', I mean 'round of vaginal sex'." You can also say: "if you had sex twice yesterday and once today, that would mean that you had sex three 'times' in the past two days."

Q2b: Emphasize "**in the past three weeks.**"

Use showcard #3. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant's response.

Note: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if condoms were used incompletely, say: "your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex."

Q3: Emphasize "**past 7 days.**" If clarification is needed, say "now we are asking about the past seven days" or "in the last week, from last X [insert today's day of week] to today." If clarification is needed about "number of times you had vaginal sex", say: "by number of times you had vaginal sex, I mean the number of rounds of vaginal sex that you had."

Q3a: Clarify that the term "partner(s)" refers to anyone she has had vaginal sex with in the past 7 days.

Note: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if

condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

NOTE: The number entered for Q3a should be less than or equal to the number of times the participant reported having vaginal sex in **Q3**.

Q4: Emphasize “**the last time**” you had vaginal sex. If further clarification is needed, say “the last time you had vaginal sex during the previous three weeks.”

Read the statement before **Q5**.

Q5: This question refers to having anal sex any time during the participant’s lifetime. If further clarification is needed regarding “**anal sex**” say “anal sex means when a man puts his penis inside your anus.”

Q6: Emphasize “**past three weeks.**”

Q6a: Emphasize “**in the past three weeks.**”

Use showcard #2. Read the question, present the showcard and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

Note: If the participant’s sex frequency varied over the past three weeks, help her think about the number of times she had anal sex during this period and then ask her to choose the answer that most closely matches her average frequency of anal sex.

Read statement before **Q6b**. If clarification is needed for “act of anal sex”, say: “by an act of anal sex I mean a round of anal sex.”

Q6b: Emphasize “**in the past three weeks.**”

Use showcard #3. Read the question, present the showcard and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant's response.

Note: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if condoms were used incompletely, say "your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex."

Q7: Emphasize "**past 7 days.**" If clarification is needed, say: "now we are asking about the past seven days" or "in the last week, from last X [insert today's day of week] to today." If clarification is needed about "number of times you had anal sex", say: "by number of times you had anal sex, I mean the number of rounds of anal sex that you had."

Q7a: Emphasize "**past 7 days.**" Use of male condoms during anal sex should be defined by the participant. Clarify that by "Partner(s)" you mean anyone she has had anal sex with in the past 7 days. The number entered here should be less than or equal to the number of times the respondent reported having anal sex in Q7.

Q8: Emphasize "**the last time**" you had anal sex. If further clarification is needed, say "the last time you had anal sex during the previous three weeks."

Read the statement before **Q9**.

Q9: Emphasize "**past month.**" If further clarification is needed, say "in the past 30 (or 31) days" or "from [insert name of previous month and today's date] to today."

Read the lead-in one time then read each item 9a–9g aloud and mark the participant's response. Remind the participant that she can answer "yes" to more than one item.

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.

Q9a: **Note:** This question is meant to assess practices involving the insertion of water **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

Q9b: **Note:** This question is meant to assess practices involving the insertion of water and vinegar **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

***Water with vinegar:** could be commercial or non-commercial product(s) sometimes used to clean or flush out the inside of the vagina.*

Q9c: **Note:** This question is meant to assess practices involving the insertion of water and soap **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

***Soap:** any personal hygiene and/or household products in liquid, gel or bar form, used to clean the body and/or household items.*

Q9d: **Note:** For this question, paper, cloth, etc. must be **inserted** inside the vagina rather than worn outside. For example, a tampon would indicate a YES response. A menstrual pad worn outside the body would indicate a NO response.

***Paper, cloth, cotton, or cotton wool:** these non-commercial items are often used to absorb blood flow during the menstrual period. Only mark YES if inserted inside the vagina, rather than worn outside the vagina.*

Q9e: **Tampon:** cotton or other material some women insert in their vagina during their menstrual period to absorb the blood flow.

Q9f: **Note:** This question relates to the participant's own fingers only and not her partner's fingers.

Q9g: If "anything else" prompts a "yes" response from participant (for example: *lime or lemon juice, herbal/traditional preparations*) ask the participant to specify what it was and then write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation in the space provided. If the

participant reports use of commercial douching products, do not record their use here. Instead, update the response to Q9b as appropriate.

NOTE: body parts (e.g., partner's penis) should NOT be included in this sub-question.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Study Product Adherence and Behavior Assessment

Note for participants on product hold/discontinuation: If the participant was not dispensed any study product at the last regularly scheduled study visit she completed (start-of-study period or mid-study period visit), and was not dispensed any study product at an interim visit after the last regularly scheduled study visit she completed, do not administer this form. Refer to Data Communiqué #4 for specific instructions on form completion and faxing to SCHARP.

Prior to the interview: For general guidance on interviewing techniques and completion of the interviewer-administered case report forms (CRFs), please refer to the Study-specific Procedures Manual Section 13.5.

Q1: Complete this item prior to starting the interview. If the participant is in the oral tenofovir study regimen period then mark the “oral tenofovir” box and skip to Q3, otherwise proceed to Q2.

Q2: Complete this item prior to starting the interview. Ask the participant if she has written documentation of the dates and times of her last three applications of vaginal tenofovir gel. If she provides written documentation, use this information as source documentation to complete Q2a-Q2c with the date (day/month/year) and time (hour: minutes) of her last three applications of vaginal tenofovir gel prior to this visit, *starting* with the *most recent* application. If the participant does not provide written documentation, or only provides written documentation of one or two of her last applications, ask the participant to recall from memory the date and time of the applications for which she does not have written source documentation. Use holidays, weekends, and/or notable events in the participant’s life to narrow down/identify date(s) as needed. Help her to estimate the timing of her latest application(s) by asking what time of day she inserted gel (morning, afternoon, evening) and/or if it was inserted close to a meal time and what her usual meal time is. If the participant is in the vaginal study period (marked in Item 1), skip to the statement above item 4 to begin the interview.

Q3: Complete this item prior to starting the interview. Ask the participant if she has written documentation of the dates and times of her last three applications of oral tenofovir tablets. If she provides written documentation, use this information as source documentation to complete Q3a-Q3c with the date (day/month/year) and time (hour: minutes) of her last three doses of oral tenofovir tablets prior to this visit, *starting* with

the *most recent* dose. If the participant does not provide written documentation, or only provides written documentation of one or two of her last doses, ask the participant to recall from memory the date and time of the doses for which she does not have written source documentation. Use holidays, weekends, and/or notable events in the participant's life to narrow down/identify date(s) as needed. Help her to estimate the timing of her latest dose(s) by asking what time of day she took her dose (morning, afternoon, evening) and/or if it was taken close to a meal time and what her usual meal time is.

Prior to the interview start (**Q4**), in the introductory remarks/instructions, circle the correct study product that reflects the participant's current study regimen: (*tenofovir gel, tenofovir tablets, or tenofovir gel and tablets together*).

Read the introductory remarks/instructions, then proceed to Q4. For clarification of the "study period," you can say, "since your last interview or visit."

Q4: Emphasize "**past 3 weeks.**" If clarification is needed, say: "In the last 21 days." You can also remind the participant that the "study product" is the participant's current study regimen, and name the specific regimen (e.g., tenofovir gel). Use showcard #4. Read each response category aloud, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant's response.

Note: If the participant's use of the study product varied over the past three weeks, help her think about the number of times she used study product during this period and then ask her to choose the answer that most closely matches her average frequency of study product use.

Q5: Emphasize "**past 3 weeks.**" If clarification is needed, say: "In the last 21 days."

For interviewer information:

Missed doses and Make-up period: per protocol, if a participant misses a dose, she must take orally and/or insert vaginally the missed dose as soon as possible, unless the next dose is estimated to be due within 6 hours. If the next dose is estimated to be due within 6

hours, the missed dose must be skipped. The next dose will be taken orally and/or inserted vaginally as originally scheduled.

If the participant asks for clarification on missed doses and making up missed doses, tell her the following example:

Example: *If a participant forgot to take her scheduled dose at 6pm, but remembered at 9pm and took the dose, she has taken her scheduled dose within the make-up period. The dose she remembered to take at 9pm is considered a make-up dose and is not considered missed for purposes of this question. However, if a participant missed her 6pm dose and did not use study product again until her next scheduled dose, then the 6pm dose was missed and should be counted as a missed dose in the response to this question.*

If the participant has not missed any doses, write “00” in the boxes and skip to Q8.

Q6: **Do not** read any of the response categories (6a-6r) aloud. Instead, mark the box(es) that best correspond to each reason reported by the participant. Remind the participant to state all possible reasons. 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 *after* the interview is completed.

Q7: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”

For interviewer information:

Missed doses and Make-up period: *per protocol, if a participant misses a dose, she must take orally and/or insert vaginally the missed dose as soon as possible, unless the next dose is estimated to be due within 6 hours. If the next dose is estimated to be due within 6 hours, the missed dose must be skipped. The next dose will be taken orally and/or inserted vaginally as originally scheduled.*

If the participant asks for clarification on missed doses and making up missed doses, tell her the following example:

Example: *If a participant forgot to take her scheduled dose at 6pm, but remembered at 9pm and took the dose, she has taken her scheduled dose within the make-up period. The dose she remembered to take at 9pm is considered a make-up dose and is not considered missed for purposes of this question. However, if a participant missed her 6pm dose and did not use study product again until her next scheduled dose, then the 6pm dose was missed and should be counted as a missed dose in the response to this question.*

If the participant has not missed any doses, write “00” in the boxes and skip to Q8.

Q7a: Emphasize “**past 7 days.**”

Missed doses and Make-up period: *per protocol, if a participant misses a dose, she must take orally and/or insert vaginally the missed dose as soon as possible, unless the next dose is estimated to be due within 6 hours. If the next dose is estimated to be due within 6 hours, the missed dose must be skipped. The next dose will be taken orally and/or inserted vaginally as originally scheduled.*

If the participant asks for clarification on missed doses and making up missed doses, tell her the following example:

Example: *If a participant forgot to take her scheduled dose at 6pm, but remembered at 9pm and took the dose, she has taken her scheduled dose within the make-up period. The dose she remembered to take at 9pm is considered a make-up dose and is not considered missed for purposes of this question. However, if a participant missed her 6pm dose and did not use study product again until her next scheduled dose, then the 6pm dose was missed and should be counted as a missed dose in the response to this question.*

Q8: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.” **Note:** Q8 may cause some confusion when asked at the Week 3 and Week 6 Visits of participants randomized to the oral period first. To provide further explanation of this question, ask, “Did you have any study gel given to you or in your possession in the past

3 weeks?” If the participant responds “no,” then it can be inferred that she did not insert study gel anally; mark, “no” for Q8, and go to the statement above Q9. This question is designed to capture any insertion of tenofovir gel regardless of the study regimen the participant is in (vaginal, oral or dual), since gel could have been shared or left over from a previous study period (vaginal and/or dual) and inserted anally by a participant.

Q8a: Emphasize “**past 3 weeks.**” If clarification is needed, say: “In the last 21 days.”
If clarification is needed for the term “anal insertion,” say: “by anal insertion I mean inserting the study gel inside your anus.”

Q9: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”
Vaginal sex: When your sex partner puts his penis inside your vagina.
Anal sex: When your sex partner puts his penis inside your anus.
Sex partner: Someone with whom you have had vaginal and/or anal sex. A **new sex partner** is a sex partner that you did not report during your last interview in which an assessment was completed.

Read statement above Q10.

Q10: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”
Vaginal sex: When your sex partner puts his penis inside your vagina.
If the response is “no,” go to statement above Q14.

Q10a: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”
Use showcard #2. Read the question, present the showcard, and read the possible responses on the showcard, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

Note: For the African sites, clarify that “how often” refers to “rounds” of vaginal and/or anal sex. If the participant’s vaginal sex frequency varied over the past three weeks, help her think about the number of times she had vaginal sex during the past three weeks and then ask her to choose the answer that most closely matches her average frequency of vaginal sex.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Go to statement above Q10b.

Q10b: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”

Use showcard #3. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Male condom: a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis prior to his penis entering the vagina or anus for birth control or other purposes.

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q11: Emphasize “**past 7 days.**”

Vaginal sex: When your sex partner puts his penis inside your vagina.

If the response is “zero times,” record “00” in the boxes and skip to Q12.

Q11a: Emphasize “**past 7 days.**”

Vaginal sex: When your sex partner puts his penis inside your vagina.

Male condom: a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if

condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q12: Emphasize “**last time.**” Read the lead-in with each subsequent sub-question (12a-12i).

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12a: *Vaginal sex:* When your sex partner puts his penis inside your vagina.

Male condom: a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q12b: Clarify that “same day” refers to the same period between when the participant wakes up and when she goes to bed (not the past 24 hours).

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12c: Emphasize “**before.**” If “no,” skip to Q12d.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12c1: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes before sex, 2 hours before sex.”

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12d: Emphasize “**after.**” If “no,” skip to Q12e.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12d1: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes after sex, 2 hours after sex.”

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12e: Clarify that you are asking if the participant purposefully changed the time when she inserted tenofovir gel because she had vaginal sex. Provide the participant with the following example: “For example, you usually insert the gel right before you go to bed,

but decided to insert it earlier than usual because you planned to have sex earlier in the evening and wanted to have the gel inserted prior to having sex.” This scenario is an example of a “yes” response to this question.

Note: If the participant inserted the gel earlier because she went to bed earlier (e.g., 10 PM rather than 11:30 PM as usual) than this time difference would NOT be considered a “different time than usual” for this question because the change in dosing time was not made with regard to sexual behavior.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12f: Clarify that “same day” refers to the same period between when the participant wakes up and when she goes to bed (not the past 24 hours). If “no,” go to statement above Q14.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12g: Emphasize “**before.**” If “no,” skip to Q12h.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12g1: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes before sex, 2 hours before sex.”

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12h: Emphasize “**after.**” If “no,” skip to Q12i.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12h1: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes after sex, 2 hours after sex.”

Vaginal sex: When your sex partner puts his penis inside your vagina.

Q12i: Clarify that you are asking if the participant purposefully changed the time when she took tenofovir tablets because she had vaginal sex. Provide the participant with the following example: “For example, you usually take your tenofovir tablets right before you go to bed, but decided to take them earlier than usual because you planned to have sex earlier in the evening and wanted to have taken the tablets prior to having sex.” This scenario is an example of a “yes” response to this question.

Note: If the participant took the tablets earlier because she went to bed earlier (e.g., 10 PM rather than 11:30 PM as usual) than this time difference would NOT be considered a

“different time than usual” for this question because the change in dosing time was not made with regard to sexual behavior.

***Vaginal sex:** When your sex partner puts his penis inside your vagina.*

Q13: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. If “no,” go to statement above Q14.

***Vaginal sex:** When your sex partner puts his penis inside your vagina.*

Q13a: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. Emphasize “**without.**” If “yes,” go to statement above Q14.

***Vaginal sex:** When your sex partner puts his penis inside your vagina.*

***Male condom:** a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q13b: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. Read the lead-in one time only, moving directly to Q13b1 then to the subsequent sub-questions (13b2- 13b3).

***Vaginal sex:** When your sex partner puts his penis inside your vagina.*

***Male condom:** a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during sex.”

Q13c: Read the lead-in one time only, moving directly to Q13c1 then to the subsequent sub-question (13c2). This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview.

Vaginal sex: When your sex partner puts his penis inside your vagina.

Male condom: a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis prior to his penis entering the vagina or anus for birth control or other purposes.

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q14: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”

Anal sex: When your sex partner puts his penis inside your anus.

If “no,” skip to instructions above Q18.

Q14a: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”

Use showcard #2. Read the question, present the showcard and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

Note: If the participant’s sex frequency varied over the past three weeks, help her think about the number of times she had anal sex during this period and then ask her to choose the answer that most closely matches her average frequency of anal sex.

Anal sex: When your sex partner puts his penis inside your anus.

Read statement before **Q14b**. If clarification is needed for “act of anal sex”, say “by an act of anal sex I mean a round of anal sex”.

Q14b: Emphasize “**past 3 weeks.**” If clarification is needed, say “In the last 21 days.”

Use showcard #3. Read the question, present the showcard and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

***Anal sex:** When your sex partner puts his penis inside your anus.*

***Male condom:** a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q15: Emphasize “**past 7 days.**”

***Anal sex:** When your sex partner puts his penis inside your anus.*

If the response is “zero times,” record “00” in the boxes and skip to Q16.

Q15a: Emphasize “**past 7 days.**”

***Anal sex:** When your sex partner puts his penis inside your anus.*

***Male condom:** a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q16: Emphasize “**last time.**” Read the lead-in with each subsequent sub-question (16a-16i).

Anal sex: *When your sex partner puts his penis inside your anus.*

Q16a: Male condom: *a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q16b: Clarify that “same day” refers to the same period between when the participant wakes up and when she goes to bed (not the past 24 hours).

Note: Clarify that the question is asking about **vaginal** insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying: “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16c: Emphasize “**before.**” If “no,” skip to Q16d.

Anal sex: *When your sex partner puts his penis inside your anus.*

Note: Clarify that the question is asking about **vaginal** insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying: “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16c1: Mark **only** minutes **or** hours, but give participant an example of each: “*10 minutes before sex, 2 hours before sex.*”

Anal sex: *When your sex partner puts his penis inside your anus.*

Note: Clarify that the question is asking about **vaginal** insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying: “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16d: Emphasize “**after.**” If “no,” skip to Q16e.

Anal sex: *When your sex partner puts his penis inside your anus.*

Note: Clarify that the question is asking about *vaginal* insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying: “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16d1: Mark **only** minutes **or** hours, but give participant an example of each: “*10 minutes after sex, 2 hours after sex.*”

Anal sex: When your sex partner puts his penis inside your anus.

Note: Clarify that the question is asking about *vaginal* insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying: “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16e: Clarify that you are asking if the participant purposefully changed the time when she inserted tenofovir gel because she had anal sex. Provide the participant with the following example: “For example, you usually insert the gel right before you go to bed, but decided to insert it earlier than usual because you planned to have sex earlier in the evening and wanted to have the gel inserted prior to having sex.” This scenario is an example of a “yes” response to this question.

Note: If the participant inserted the gel earlier because she went to bed earlier (e.g., 10 PM rather than 11:30 PM as usual) than this time difference would **NOT** be considered a “different time than usual” for this question because the change in dosing time was not made with regard to sexual behavior.

Anal sex: When your sex partner puts his penis inside your anus.

Note: Clarify that the question is asking about *vaginal* insertion of tenofovir gel only (**NOT** anal insertion) in relation to anal sex by saying “Even though this series of questions is asking about the last time you had *anal sex*, questions about the study gel only refer to putting or inserting the gel into your *vagina*, not your anus.”

Q16f: Clarify that “same day” refers to the same period between when the participant wakes up and when she goes to bed (not the past 24 hours). If “no,” go to statement above Q18.

Anal sex: When your sex partner puts his penis inside your anus.

Q16g: Emphasize “**before.**” If “no,” skip to Q16h.

Anal sex: When your sex partner puts his penis inside your anus.

Q16g1: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes before sex, 2 hours before sex.”

Anal sex: When your sex partner puts his penis inside your anus.

Q16h: Emphasize “**after.**” If “no,” skip to Q16i.

Anal sex: When your sex partner puts his penis inside your anus.

Q16hi: Mark **only** minutes **or** hours, but give participant an example of each: “10 minutes after sex, 2 hours after sex.”

Anal sex: When your sex partner puts his penis inside your anus.

Q16i: Clarify that you are asking if the participant purposefully changed the time when she took tenofovir tablets because she had anal sex. Provide the participant with the following example: “For example, you usually take your tenofovir tablets right before you go to bed, but decided to take it earlier than usual because you planned to have sex earlier in the evening and wanted to have taken a tablet prior to having sex.” This scenario is an example of a “yes” response to this question.

Note: If the participant took tenofovir tablets earlier because she went to bed earlier (e.g., 10 PM rather than 11:30 PM as usual) than this time difference would NOT be considered a “different time than usual” for this question because the change in dosing time was not made with regard to sexual behavior.

Anal sex: When your sex partner puts his penis inside your anus.

Q17: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. If “no,” go to statement above Q18.

Anal sex: When your sex partner puts his penis inside your anus.

Q17a: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. Emphasize “**without.**” If “yes,” go to statement above Q18.

Anal sex: When your sex partner puts his penis inside your anus.

Male condom: *a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition, rather, it is based on the participant’s current understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q17b: This question refers to the time period since the participant awoke yesterday morning through today when she came in for her interview. Read the lead-in one time only, moving directly to Q17b1 then to the subsequent sub-questions (17b2- 17b3).

Anal sex: *When your sex partner puts his penis inside your anus.*

Male condom: *a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis, prior to his penis entering the vagina or anus, for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q17c: Read the lead-in one time only, moving directly to Q17c1 then to the subsequent subquestion (17c2).

Anal sex: *When your sex partner puts his penis inside your anus.*

Male condom: *a latex or polyurethane sheath, sometimes called a “rubber,” that is put onto a man’s erect penis prior to his penis entering the vagina or anus for birth control or other purposes.*

Note: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during anal sex.”

Q18: Emphasize “**past month.**” If further clarification is needed, say “in the past 30 (or 31) days” or “from [insert name of previous month and today’s date] to today.”

Read the lead-in one time then read each item 18a–18g aloud and mark the participant’s response. Remind the participant that she can answer “yes” to more than one item.

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.

Q18a: Note: This question is meant to assess practices involving the insertion of water **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

Q18b: Note: This question is meant to assess practices involving the insertion of water and vinegar **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

***Water with vinegar:** could be commercial or non-commercial product sometimes used to clean or flush out the inside of the vagina.*

Q18c: Note: This question is meant to assess practices involving the insertion of water and soap **inside** the vagina and does not include any washing or cleansing limited to the external genitalia.

***Soap:** any personal hygiene and/or household products in liquid, gel or bar form, used to clean the body and/or household items.*

Q18d: Note: For this question, paper, cloth, etc. must be **inserted** into the vagina rather than worn outside. For example, a tampon would indicate a YES response. A menstrual pad worn outside the body would indicate a NO response.

***Paper, cloth, cotton, or cotton wool:** these non-commercial items are often used to absorb blood flow during the menstrual period. Only mark YES if inserted inside the vagina, rather than worn outside the vagina.*

Q18e: Tampon: cotton or other material some women insert in their vagina during their menstrual period to absorb the blood flow.

Q18f: Note: This question relates to the participant's own fingers only and not her partner's fingers.

Q18g: If “anything else” prompts a “yes” response from participant (for example: *lime or lemon juice, herbal/traditional preparations*) ask the participant to specify what it was and then write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation in the space provided. If the participant reports use of commercial douching products, do not record their use here. Instead, update the response to Q18b as appropriate.

NOTE: body parts (e.g., partner's penis) should NOT be included in this sub-question.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Product Sharing Assessment

Note for participants on product hold/discontinuation: If the participant was not dispensed any study product during the current study period, do not administer this form. Refer to Data Communiqué #4 for specific instructions on form completion and faxing to SCHARP.

Prior to the interview: For general guidance on interviewing techniques and completion of the interviewer-administered case report forms (CRFs), please refer to the Study-specific Procedures Manual Section 13.5.

Read the introductory remarks/instructions, then proceed to Q1. Clarify that “study period” refers to the study regimen (oral, vaginal, or dual use) the participant has been on for the past 6 weeks. If clarification is needed, say: “since you started using [insert current study product].”

Q1: Emphasize “**since you started using the study product.**” Clarify that study product refers to the study product dispensed during this current study period. Restate what it is (oral tenofovir tablets, vaginal tenofovir gel, or both tenofovir tablets and gel). If “yes”, proceed to Q1a. If “no”, skip to Q2.

Q1a: *Primary Male Sex Partner: a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.* If further clarification is needed, say: “By main partner I mean a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.”

Q1a-h: Mark “yes” for each person who asked the participant for study product, regardless of whether or not the participant actually gave/sold/traded study product to that person. For each “yes” response, record the number of tablets shared and the number of applicators shared. The number recorded may be “00” depending on the participant’s current study regimen and whether she chose to share her study product.

Q1b: If clarification is needed, say “someone else that you have sex with other than your primary male sex partner.”

Q2: Emphasize “**since you started using the study product.**” Clarify that study product refers to the study product dispensed during this current study period. Restate what it is (oral tenofovir tablets, vaginal tenofovir gel, or both tenofovir tablets and gel). If “yes”, proceed to Q2a. If “no”, skip to Q3.

- Q2a-h:** Mark “yes” for each person to whom the participant actually sold, traded, or gave away study product. For each “yes” response, record the number of tablets sold/traded/given away and the number of applicators sold/traded/given away. The number recorded may be “00” depending on the participant’s current study regimen and whether she chose to sell, trade, or give away her study product.
- Q2a:** *Primary Male Sex Partner: a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.* If further clarification is needed, say “By main partner I mean a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.”
- Q2b:** If clarification is needed, say “someone else that you have sex with other than your primary male sex partner”
- Q3:** Emphasize “**since you started using the study product.**” Clarify that study product refers to the study product dispensed during this current study period. Restate what it is (oral tenofovir tablets, vaginal tenofovir gel, or both tenofovir tablets and gel). Clarify for the participant that you understand that she may not know whether or not someone has taken her study product. Ask her to provide her best guess, and record her response on the form. If “yes”, proceed to Q3a. If “no”, skip to end of form.
- Q3a-h:** Clarify for the participant that you understand that she may not know who took her study product. Ask her to provide her best guess of who took it, if anyone, and record her responses on the form. For each “yes” response, record the number of tablets taken and the number of applicators taken from her. If she is unsure of the number ask her to provide her best guess.
- Q3a:** *Primary Male Sex Partner: a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.* If further clarification is needed, say: “By main partner I mean a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.”
- Q3b:** If clarification is needed, say: “someone else that you have sex with other than your primary male sex partner.”

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Acceptability Assessment

Note for participants on product hold/discontinuation: If the participant did not use at least one dose of study product during the current study period, do not administer this form. Refer to Data Communiqué #4 for specific instructions on form completion and faxing to SCHARP.

Prior to the interview: For general guidance on interviewing techniques and completion of the interviewer-administered case report forms (CRFs), please refer to the Study-specific Procedures Manual Section 13.5.

Complete item 1 before the interview

- Q2:** Emphasize “**vaginal tenofovir gel**”. Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q3:** Emphasize “**oral tenofovir tablets**”. Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q4:** Emphasize “**oral tenofovir tablets**” and “**vaginal tenofovir gel**”. If further clarification is needed, say “I mean using oral tenofovir tablets and vaginal tenofovir gel at the same time.” Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q5:** Emphasize “**worried**” and “**you**” and “**within the next year**”. Use showcard #5. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q6:** Clarify that the term “**married**” is based on the participant’s self-perception, and not the legal definition of marriage. If, for example, because she is living with her partner she considers herself to be married, and she answers “**yes**”, mark the “**yes**” box.

- Q7:** *Primary Male Sex Partner: a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.*
- Q8:** If further clarification is needed, say “is your primary male sex partner currently infected with the HIV virus and does he currently have HIV?”
- Q9:** Emphasize “**worried**” and “**he**” and “**within the next year**”. Use showcard #5. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q10:** Emphasize “**study period**”. If clarification is needed, say “since you started using [insert current study product]”.
- Q11:** Clarify that by “study product”, you mean [tenofovir gel tenofovir tablets tenofovir gel and tablets together].
- If further clarification is needed regarding whether her partner knew she was using the study product, say “did you talk to him about your use of the study product, did you tell him, or did he find out another way?”
- Q12:** **Do not** read the response categories 12a-12h aloud. Instead, allow the participant to respond and mark the response(s) that most closely resemble her response(s). If further clarification is needed, use the response categories to prompt her, for example, say “did he like or dislike the study product?” or “did he think it improved or worsened sex?” or “did he have any reaction at all?”

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Final Acceptability Assessment

Note for participants on product hold/discontinuation: If the participant did not use at least one dose of study product during the current study period, do not administer this form. Refer to Data Communiqué #4 for specific instructions on form completion and faxing to SCHARP.

Prior to the interview: For general guidance on interviewing techniques and completion of the interviewer-administered case report forms (CRFs), please refer to the Study-specific Procedures Manual Section 13.5.

Complete item 1 before the interview

- Q2:** Emphasize “**vaginal tenofovir gel**”. Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q3:** Emphasize “**oral tenofovir tablets**”. Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q4:** Emphasize “**oral tenofovir tablets**” and “**vaginal tenofovir gel**”. If further clarification is needed, say “I mean using oral tenofovir tablets and vaginal tenofovir gel at the same time.” Emphasize “**honest answer**”. Use showcard #1. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q5:** Emphasize “**worried**” and “**you**” and “**within the next year**”. Use showcard #5. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q6:** Clarify that the term “**married**” is based on the participant’s self-perception, and not a legal definition of marriage. If, for example, because she is living with her partner she considers herself to be married, and she responds “yes”, then mark the “yes” box.
- Q7:** *Primary Male Sex Partner: a boyfriend, husband, someone with whom you live, or someone you are more serious about than other partners.*

- Q8:** If further clarification is needed, say “is your primary male sex partner currently infected with the HIV virus and does he currently have HIV?”
- Q9:** Emphasize “**worried**” and “**he**” and “**within the next year**”. Use showcard #5. Read the question, present the showcard, and read the possible responses, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.
- Q10:** Emphasize “**study period**”. If clarification is needed, say “since you started using [insert current study product]”.
- Q11:** Clarify that by ‘study product’, you mean [tenofovir gel, tenofovir tablets, or tenofovir gel and tablets together].
- If further clarification is needed regarding whether her partner knew she was using the study product, say “did you talk to him about your use of the study product, did you tell him, or did he find out another way?”
- Q12:** **Do not** read the response categories 12a-12h aloud. Allow participant to respond, mark the response(s) that most closely resemble her response(s). If further clarification is needed, use the response categories to prompt her, for example, say “did he like or dislike the study product?” or “did he think it improved or worsened sex?” or “did he have any reaction at all?”

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.