

Section 12. Behavioral Measures

This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the web-based behavioral assessments. The behavioral assessments of the MTN-011 protocol will be collected via Computer Assisted Self-Interview (CASI) questionnaires.

12.1 Overview

Behavioral assessments will be captured through web-based Computer Assisted Self-Interview (CASI). CASI computer interviews are source documentation and must be maintained in accordance with the guidelines for other study documentation. Table 1 outlines the timing (by study visit) and mode (by instrument) each behavioral assessment should be completed.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Participants	Questionnaire	Mode of Administration	Group 1 Timing	Group 2 Timing	Content
Males	Baseline Questionnaire (BAQ)*	CASI	Visit 2	Visit 2	Trial acceptability/ motivation to participate
	Exit Acceptability – Men (EAM)*, **	CASI	Visit 7b	Visit 9	Product and trial acceptability
Females	Baseline Questionnaire (BAQ)*	CASI	Visit 2a	Visit 2	Trial acceptability/ motivation to participate
	Behavioral Questionnaire*** (BEH)	CASI	Visits 2a, 3b, 4b, 5b, 6b, & 7b	Visits 2, 3b, 5, 7b, & 9	Key sexual behavior and other behaviors (including prohibited vaginal practices)
	Exit Acceptability – Women(EAW)**	CASI	Visit 7b	Visit 9	Product and trial acceptability

* Includes practice questions.

**Different exit acceptability CASI for male and female participants.

*** Behavioral CASI will only be administered to female participants, and will be identical at baseline (visit 2) and all follow up visits. Time frame will refer to “since last scheduled visit.”

12.2 Troubleshooting

For any problems with the computerized (CASI) questionnaires, either accessing them or completing them, or with the CASI study computer, please notify the team immediately by sending an email to the alias list mtn011casi@mtnstopshiv.org.

A group of staff members will be available to assist and troubleshoot any problems with the behavioral assessments. They include the following:

RTI International: Helen Cheng, Andrea Hanson, and Ariane van der Straten

12.3 Equipment Requirements and Set-up

The operations manual of the PC or laptop used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-011 CASI Instrument Troubleshooting email alias.

Each study site must have a desktop or laptop computer connected to the internet that is for use by the MTN-011 study participants. Select a location for the CASI study computer that is private (i.e. the screen should be out of sight of staff members, but its location should allow study staff to be nearby to answer questions or assess whether the participant is having technical problems). Also, the location should be out of sight and of hearing of other participants while answers are being entered. The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The CASI study computer should be plugged into an AC power source. An external mouse should be connected to the computer. Each site is responsible for addressing issues of security, privacy, background noise, lighting, ergonomics, and overall participant comfort in its site specific procedures. Staff members should be familiar with the use of the computer and the content of the questionnaires, in case participants raise any questions.

12.3.1 Keyboard and Mouse Use

The CASI study computer will require a keyboard and an external mouse. To use the mouse, the following instructions are provided:

- Move the cursor, move mouse.
- To select an object, tap left button once. To unselect an object, tap left button again once.
- References in this SSP to ‘clicking’ on icons or other items displayed on the screen are meant to direct the user to press the left button.

12.4 Data Collection Instruments

12.4.1 Baseline Questionnaire

The Baseline Questionnaire will be administered at the Enrollment Visit. Male and female participants will answer the same questionnaire separately. A staff member will access the following web page for the CASI Baseline Questionnaire: www.scharp.org/MTN011_BAQ. The staff member will select the participant’s ID (PTID) to log in. On the next screen, the staff member will re-enter the participant’s ID (PTID), select the participant’s study group number and visit code, and double enter the date.

The staff member should provide instructions to participants for using both the keyboard and mouse, as well as moving from page to page to answer questions using the ‘NEXT’ and ‘PREVIOUS’ buttons (not the browser arrows). Initially, the participants will be presented with simple practice questions (e.g., “choose all that apply,” “select one response”). The staff member should verify that participants are comfortable with using the mouse and keyboard, and navigating through the questionnaire. The participants should be given time to complete the practice questions, with assistance as needed. Staff should ensure that the participants understand how to answer questions by ticking boxes or entering

numbers, and how to change invalid entries. Invalid entries are those that are not accepted by the program, either because they contradict information that a participant previously entered or because they are not permitted (e.g., numbers that are out of the possible range). Staff should inform the participants that they can refuse to answer any question by ticking the “**refuse to answer**” button in the bottom corner of the screen. If participants are unsure of an answer, they should be encouraged to make their best guess rather than to refuse. Participants should be informed that they may go back and change answers at any time, using the back arrow. Staff should then remind participants that the staff is available to answer any questions or assist with administration of the computer.

Following the practice questions, participants should be left alone to complete the Baseline Questionnaire. This questionnaire will measure study participants’ motivation to participate in this study. At the end of the questionnaire, a message will appear instructing the participants to click ‘NEXT’ if they want to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

12.4.2 Behavioral Questionnaire

At enrollment and follow-up visits, female participants will complete a Web-based Behavioral Questionnaire and following procedures similar to those utilized for the Baseline Questionnaire. Female participants in Cohort 1 will complete the Behavioral Questionnaire at Visits 2a, 3b, 4b, 5b, 6b, and 7b, or at early product discontinuation and early termination visit, Female participants in Cohort 2 will complete the Behavioral Questionnaire at Visits 2, 3b, 5, 7b, and 9, or at early product discontinuation and early termination visit, At the appropriate time, a staff member will access the Web page for the Behavioral Questionnaire: www.ssharp.org/MTN011_BEH. The staff member will double enter the PTID, select the participant’s study group number and visit code, and double enter the date. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

The Behavioral Questionnaire will explore sexual behavior and vaginal practices (including prohibited vaginal practices) the participant has engaged in since the previous CASI questionnaire (or previous study visit for Enrollment visit). The participant will answer questions about current sexual activity and about items inserted in the vagina for contraception, personal hygiene, menstrual control or other reasons. At the end of the questionnaire (penultimate screen), a message will appear instructing the participant to click ‘NEXT’ if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

12.4.3 Exit Acceptability Questionnaire

At the Exit visit (Visit 7b for Cohort 1, and Visit 9 for Cohort 2) or at early termination (if not completed before), the participants will complete a Web-based Exit Acceptability Questionnaire following procedures similar to those utilized for the Baseline Questionnaire. There will be separate questionnaires specifically for male and female participants. The male participants will be presented with a repeat of the practice questions presented before the Baseline Questionnaire to refresh the male participants on the use of the CASI. The male participants should be given time to complete the practice questions, with assistance as needed, and a staff member should verify that the participants are comfortable navigating through the questionnaire, as before the Baseline Questionnaire. At the appropriate time, a staff member will access the Web page for the Exit Acceptability Questionnaire for female participants: www.ssharp.org/MTN011_EAW or for male participants: www.ssharp.org/MTN011_EAM. The staff

member will double enter the PTID, select the participant's study group number and visit code, and double enter the date. Next, the participant will be left to answer the questionnaire on his/her own.

The Exit Acceptability Questionnaire will investigate the participants' experiences with the study product and trial procedures, their likes and dislikes, as well as their willingness and likelihood of participating in a similar study in the future. At the end of the questionnaire (penultimate screen), a message will appear instructing the participants to click 'NEXT' if they want to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

12.5 Managing Data and Data Quality Control

12.5.1 Question-by-Question Instructions

A question-by-question guide that explains the purpose and intention of each question, has been developed as reference for the CASI questionnaires. These guides are available on the MTN-011 Study Implementation Materials webpage: <http://www.mtnstopshiv.org/node/4525>. Staff should become familiar with the question-by-question guides, and ensure that they are reviewed prior to the enrollment of the first participant. The guides should be consulted if participants request assistance in the interpretation of a CASI question, or if staff members are unclear with the meaning of a CASI question.

12.5.2 Special cases and Technical issues

12.5.2.1 Hard Copy Back-up

Hard copy versions of only the Baseline Questionnaires (BAQ), Exit Acceptability – Men (EAM), and Exit Acceptability – Women (EAW) will be distributed to study sites. In the event of technical problems (i.e. server or power outage) that would preclude a participant's ability to complete these questionnaires online, the participant will be asked to complete the hard copy version in a private setting. Following the visit, a staff member will transcribe the data from the hard copy into CASI, assuming the system is functioning.

A hard copy version of the Behavioral Questionnaire (BEH) will not be used in this study. In the event of technical problems (i.e. server or power outage) that would preclude a participant's ability to complete the BEH online, the participant will not be able to complete the questionnaire for that visit, and these data will be considered missing.

In all cases of technical problems, whether the questionnaire is completed by paper and then later transcribed into CASI, or if the questionnaire is missed completely, the circumstances should be documented in the chart notes and a brief description recorded on the applicable CRF (i.e. Enrollment, Visit Summary, or Study Exit CASI Tracking).

12.5.2.2 Interrupted visits

Split visits will not be allowed in this study. If participants miss part of a visit, they cannot come back and complete it. As such, site staff should ensure that CASI questionnaires are always completed at the appropriate scheduled visit, and that all CASI data from a given questionnaire is collected on that day. If a participant is interrupted and does not complete a CASI questionnaire in one sitting, based on site staff

judgment and length of interruption, she/he can complete the CASI questionnaire later as long as it is **during the same visit**.

If participants need to briefly interrupt their computer sessions (i.e. attend to a call, go to the bathroom), at the discretion of the site staff, they can do so, and resume the CASI where they left it, as long as the survey window remains open. However if the computer window is closed before the CASI is completed, participants will need to start a **new** CASI survey from the beginning. If participants need to leave the clinic, resulting in an incomplete visit, they must close the interview window.

If duplicate CASI questionnaires are present for the same PTID and date, the fully-completed CASI questionnaire will be the one used in study analyses. These unique circumstances should be documented in the chart notes and a brief description recorded on the applicable CRF (i.e. Enrollment, Visit Summary, or Study Exit CASI Tracking).

Sites should contact 'mtn011casi@mtncstopshiv.org' if there is ever a situation where the participants were not able to complete CASI, or the hard copy back-up, during the appropriate visit.

12.5.2.3 Management of errors on CASI

Once a CASI questionnaire is completed, no one can change the responses or administrative fields, including site staff. If errors are noted by site staff for the administrative section (or by participants to the site staff on the questionnaire section), notify the CASI troubleshooting team via email at mtn011casi@mtncstopshiv.org. Please include the following information in the message text: PTID, date, visit code, the name of the CASI questionnaire and a description of the error. Also, to facilitate the troubleshooting process, please indicate in your email a description of the problem, including a copy of the error message(s), if any, and date and time of when the problem occurred. The CASI troubleshooting team will assess the problem and communicate with site staff about resolutions. If this occurs, it should be documented by keeping a record in the participant's file.

12.6 Staff Training

Site staff that will be assisting participants with CASI is required to complete at least 2 practice sessions for each instrument.

For testing, please access questionnaires through the websites indicated above. The following test PTIDs should be used:

UPMC TEST PTIDs		Cleveland TEST PTIDs	
Female	Male	Female	Male
999-9080-9-0	999-9080-9-1	999-9090-0-0	999-9090-0-1
999-9081-7-0	999-9081-7-1	999-9091-6-0	999-9091-6-1
999-9082-2-0	999-9082-2-1	999-9092-1-0	999-9092-1-1
999-9083-0-0	999-9083-0-1	999-9093-3-0	999-9093-3-1
999-9084-6-0	999-9084-6-1	999-9094-2-0	999-9094-2-1
999-9085-8-0	999-9085-8-1	999-9095-4-0	999-9095-4-1
999-9086-5-0	999-9086-5-1	999-9096-7-0	999-9096-7-1
999-9087-3-0	999-9087-3-1	999-9097-8-0	999-9097-8-1
999-9088-4-0	999-9088-4-1	999-9098-9-0	999-9098-9-1
999-9089-1-0	999-9089-1-1	999-9099-5-0	999-9099-5-1

Upon completion of testing at each given site, an email should be sent to the MTN-011 CASI alias mtn011casi@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

Section Appendix 12-1
QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS

- Prior to starting a questionnaire, make sure that the computer, internet connection, keyboard and mouse are connected and working properly.
- Make sure that the participant is comfortable and has privacy to ensure the confidentiality of her responses.
- Start the questionnaire by typing the Web address to the corresponding Questionnaire:
 - Baseline Questionnaire (Enrollment Visit) www.ssharp.org/MTN011_BAQ
 - Behavioral Questionnaire (Female Cohort 1 participants: Visits 2a, 3b, 4b, 5b, 6b, & 7b; Female Cohort 2 participants: Visits 2, 3b, 5, 7b, & 9): www.ssharp.org/MTN011_BEH
 - Exit Acceptability Questionnaire (Cohort 1 participants: Visit 7b; Cohort 2 participants: Visit 9): Female participants: www.ssharp.org/MTN011_EAW and Male participants: www.ssharp.org/MTN011_EAM
- Make sure that the participant is comfortable with using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's ID to enter the questionnaire.
- Enter or select: participant's ID, participant's study group number, visit code, and double enter the date. Additionally, double enter the date of the last computer interview (or study visit for enrollment CASI) on the Behavioral Questionnaire.
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire for all participants, Exit Acceptability Questionnaire for male participants only).
- Assist the participant as needed with the practice questions.
- Instruct the participants that when they reach the end of the survey, they will see a screen that says "Thank you for completing this questionnaire!" The participants are not finished until they reach this end screen and click on the NEXT button. At that point the participants should leave the computer as it is and notify a staff member.
- If a participant is interrupted and does not complete a CASI questionnaire in one sitting, based on site staff judgment and length of interruption, she/he can complete the CASI questionnaire later as long as it is **during the same visit**. However if the computer window is closed before the CASI is completed, she/he will need to start a **new** CASI survey from the beginning.

Section Appendix 12-2
MTN-011 CASI Questionnaires

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NOTE: All titles and variable names bolded and highlighted in gray are *not* shown on screen.

Practice Questions

PRACINTRO1

Thank you for agreeing to complete this questionnaire for the MTN-011 Study.

Before you begin, there are a few practice questions for you to get used to how the system works. You may wish to experiment with your responses (try to leave certain fields blank, change your answers, etc.) to become more comfortable with the system. If you have any questions on how to use the computer, the clinic staff can assist you.

Click the "NEXT" button to go to the next screen.

PRACINTRO2

Good! You can always move to the next screen by clicking "NEXT," or to go to the previous screen, click the "PREVIOUS" button. If you refuse to answer the question, click on the grey box in the bottom corner. You will be asked to confirm that you wish to skip the question and go on to the next page.

Click the "NEXT" button to go to the practice questions.

1. **PRAC1** (*note: example of a radio button question*)

This is an example of a question where one answer is allowed. It shows how to answer questions with buttons. Try answering the question below by moving the mouse arrow and clicking on the button that matches your answer. If you want to change your answer, simply click the new answer you want.

Example question:

Do you like summer?

- Yes
 No

2. **PRAC2** (*note: example of a radio table question*)

You will also be asked to answer questions listed in a table. For each row, click on one of the columns. For example, in the question below, for each season, mark 'Yes' or 'No'.

Example question:

Please indicate whether or not you like the following seasons.

	Yes	No
a. Winter	<input type="radio"/>	<input type="radio"/>
b. Spring	<input type="radio"/>	<input type="radio"/>
c. Summer	<input type="radio"/>	<input type="radio"/>
d. Fall	<input type="radio"/>	<input type="radio"/>

3. **PRAC3** (note: example of a drop-down menu question, only in prac questions for BAQ, not EAM)
You will be asked questions which involve selecting one answer from a drop-down menu. In order to answer these questions, click on the down arrow and select the appropriate answer.

Example question:

When was the last time you ate ice cream?

(drop-down menu will display these eight options)

- Today
- Yesterday
- 2 days ago
- 3 days ago
- 4 days ago
- 5 days ago
- 6 days ago
- 7 or more days ago

4. **PRAC4**(note: example of a check-all-that-apply question)

Several questions will involve checking one or more boxes. You will be asked to mark **all** the boxes that are appropriate and you may mark several boxes. If you would like to select a response, click on the box beside the response. If you change your mind, you can de-select the response by clicking again on the checked box to remove the check.

Example question:

What type(s) of ice cream do you like to eat? Choose all that apply.

- Vanilla
- Strawberry
- Chocolate
- Other (Please specify:-----)
- None of the above**

A few notes about this type of question:

1. If you select 'Other', be sure to fill in the box beside the response with the specific flavor of ice cream that you like. If you forget to fill this in, you will receive an error message.
2. If you select **None of the above**, you may not select any of the other boxes. If you select **None of the above** after checking any of the other boxes, the checks in the other boxes will disappear. Be sure to only check the last option if none of the other options are appropriate.

(Logic: At least one must be marked.)

PRACEND

Thank you for completing the practice questions. If you had any problem answering any of them, let the study staff know about it. Otherwise, click "NEXT" to proceed to the questionnaire.

Baseline Questionnaire (BAQ)

BAQINTRO

Thank you for coming to the clinic today for the MTN-011 study. As part of the study, you will be asked questions about your experience participating in the study.

There are no right or wrong answers to the questions and every answer is important. Please feel free to be completely honest. We are using the computer to give you the most privacy possible. The site staff at this clinic will not have access to your answers and none of your answers will prevent you from participating in the study. All of your answers will be kept confidential. If at any time you have a question or a problem, please ask the study staff to help you. Let's begin.

[PREVIOUS]

[NEXT]

1. Have you ever participated in a clinical trial or any other research study?
 - Yes
 - No

2. Please indicate all the reason(s) you joined this research study. Choose **all** that apply.
 - To receive the financial reimbursement
 - To be provided with free health care during the study, or to get higher quality health care
 - To be tested for HIV
 - To get educated or find out more about HIV
 - To help test a product that may prevent women from getting HIV
 - To contribute to scientific knowledge
 - To satisfy my curiosity about participating in a study
 - A friend/family member recommended that I join the study
 - Other (Please specify: _____)

((Logic: At least one must be marked. If less than 2 "yes" answers provided in Q2, SKIP to BAQCOMPLETE.))

3. Of the reasons you selected, which one is the **main** reason you joined this research study?
 - To receive the financial reimbursement
 - To be provided with free health care during the study, or to get higher quality health care
 - To be tested for HIV

- To get educated or find out more about HIV
- To help test a product that may prevent women from getting HIV
- To contribute to scientific knowledge
- To satisfy my curiosity about participating in a study
- A friend/family member recommended that I join the study
- Other [specified answer]

(Range: Answers listed should correspond to "YES" answers from Q2)

BAQCOMPLETE

Thank you for completing this questionnaire! Please click on 'Next' if you would like to save your responses. After you do so, you will not be able to change your answers.

[PREVIOUS]

[NEXT]

LASTSCREEN

Please inform the research staff member that you are finished.

Behavioral Questionnaire (BEH)

BEHINTRO

As part of the study, you will now be asked questions about your sexual behavior and reproductive health. There are no right or wrong answers to the questions and every answer is important. Please feel free to be completely honest.

Some of the questions may seem personal. We are using the computer to give you the most privacy possible. The site staff at this clinic will not have access to your answers and none of your answers will prevent you from participating in the study. All of your answers will be kept confidential. If at any time you have a question or a problem, please ask the study staff to help you. Let's begin.

(the text and table below will appear at the top of Questions 1 and 2 of this section)

(Q1 screen) There are different types of sexual activities we will ask you about.

(Q2 screens) As a reminder, we have listed below all the different types of sexual activities that we may ask you about.

<u>When we say:</u>	<u>We mean:</u>
Vaginal sex	When a man inserts his penis into your vagina
Anal sex	When a man puts his penis into your anus (or butt)
Receiving oral sex	When a partner puts his or her mouth or tongue on your vagina, or anus (or butt)
Performing oral sex	When you put your mouth or tongue on your partner's penis, vagina or anus (or butt)
Finger sex	When you or a partner inserts finger(s) into your vagina
Non-penetrative sex	When you have any kind of sex with yourself or with a partner, without inserting something into your vagina or anus (e.g. rubbing each other, mutual masturbation or self masturbation)

1. Since your last scheduled visit on **[Date of last visit]**, what type(s) of sexual activity have you had? Choose **all** that apply.

- Vaginal sex with a condom
- Vaginal sex without a condom
- Anal sex with a condom
- Anal sex without a condom
- Receiving oral sex
- Performing oral sex
- Finger sex
- Non-penetrative sex

- Inserting a sex toy (i.e. dildo, vibrator) in your vagina
- Other sexual activity (Please specify: _____)
- None of the above**

(Logic: If k—None of the above, SKIP to BEHIVPINTRO. For each activity X that is marked, ask Q2.)

2. When was the last time you engaged in X?

- Today
- Yesterday
- 2 days ago
- 3 days ago
- 4 days ago
- 5 days ago
- 6 days ago
- 7 or more days ago

(Range: For Group 1, Visit 3, range will be reduced to # of days since last visit)

BEHIVPINTRO

For the next questions, we will ask you about items that women sometimes insert in their vaginas. This may be for contraception, personal hygiene, menstrual control or other reasons, and some women may not insert any of these items. Please note that these questions are about putting items **inside your vagina** and not about using them outside your vagina. You should feel free to tell us anything you have used. Your answers will not affect your participation in the study.

3. Since your last scheduled visit on **[Date of last visit]**, have you used any of the following?

Choose **all** that apply.

- Male or female condom
- Contraceptive vaginal ring
- Spermicidal sponge, cream or jelly
- Cervical barrier (diaphragm, cervical cup, etc.) or menstrual cup
- Douche or other personal hygiene products that are inserted inside the vagina
- Tampon
- Personal or sexual lubricant
- Vaginal medication
- Other product (Please specify: _____)
- None of the above**

(Logic: If j, none of the above, SKIP to BEHCOMPLETE. For each IVP Y that is marked, ask question 4.)

4. When did you last use a Y?

- Today
- Yesterday
- 2 days ago
- 3 days ago
- 4 days ago
- 5 days ago
- 6 days ago
- 7 or more days ago

(Range: For Group 1, Visit 3, range will be reduced to # of days since last visit)

(Logic: If answer is a or b, ask Q5; else SKIP to BEHCOMPLETE)

5. Please indicate the time [today/yesterday] that you last used a Y, rounding to the nearest hour. If you are unsure, just give your best estimate.

	<u>Y</u>
Time Used:	<input type="checkbox"/> <input type="checkbox"/> am/pm

(Range: Time in is a drop-down menu. choice for time in is: 1 AM, 2 AM..., 12 Noon, 1 PM,... 12 Midnight.)

BEHCOMPLETE

Thank you for completing this questionnaire! Please click on 'Next' if you would like to save your responses. After you do so, you will not be able to change your answers.

LASTSCREEN

Please inform the research staff member that you are finished.

Exit Acceptability Questionnaire – Men (EAM)

PRACTICE QUESTIONS

Thank you for agreeing to complete this questionnaire for the MTN-011 Study.

Before you begin, there are a few practice questions for you to get used to how the system works. You may wish to experiment with your responses (try to leave certain fields blank, change your answers, etc.) to become more comfortable with the system. If you have any questions on how to use the computer, the clinic staff can assist you.

Click the "NEXT" button to go to the next screen

[PREVIOUS]

[NEXT]

Good! You can always move to the next screen by clicking "NEXT," or to go to the previous screen, click the "PREVIOUS" button. If you refuse to answer the question, click on the grey box in the bottom corner. You will be asked to confirm that you wish to skip the question and go on to the next page.

Click the "NEXT" button to go to the practice questions.

PRAC1 (note: example of a radio button question)

This is an example of a question where one answer is allowed. It shows how to answer questions with buttons. Try answering the question below by moving the mouse arrow and clicking on the button that matches your answer. If you want to change your answer, simply click the new answer you want.

Example question:

Do you like summer?

- Yes
- No

PRAC2 (note: example of a radio table question)

You will also be asked to answer questions listed in a table. For each row, click on one of the columns. For example, in the question below, for each season, mark 'Yes' or 'No'.

Example question:

Please indicate whether or not you like the following seasons.

	Yes	No
a. Winter	<input type="radio"/>	<input type="radio"/>
b. Spring	<input type="radio"/>	<input type="radio"/>
c. Summer	<input type="radio"/>	<input type="radio"/>

d. Fall	<input type="radio"/>	<input type="radio"/>
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PRAC3 (note: example of a check-all-that-apply question)

Several questions will involve checking one or more boxes. You will be asked to mark **all** the boxes that are appropriate and you may mark several boxes. If you would like to select a response, click on the box beside the response. If you change your mind, you can de-select the response by clicking again on the checked box to remove the check.

Example question:

What type(s) of ice cream do you like to eat? Choose all that apply.

- Vanilla
- Strawberry
- Chocolate
- Other (Please specify:-----)
- None of the above**

A few notes about this type of question:

1. If you select 'Other', be sure to fill in the box beside the response with the specific flavor of ice cream that you like. If you forget to fill this in, you will receive an error message.
2. If you select **None of the above**, you may not select any of the other boxes. If you select **None of the above** after checking any of the other boxes, the checks in the other boxes will disappear. Be sure to only check the last option if none of the other options are appropriate.

(Logic: At least one must be marked.)

PRACEND

Thank you for completing the practice questions. If you had any problem answering any of them, let the study staff know about it. Otherwise, click "NEXT" to proceed to the questionnaire.

1.1. Part A: Product Acceptability

EAMINTRO1

Thank you for coming to the clinic today for the MTN-011 study. The questions in this survey are about your experience with the gel and this study.

EAMINTRO2

The following questions are about your experience with the gel since you started the study, including today.

1. Overall, how comfortable were you with your partner using the study gel?

- Very uncomfortable
- Uncomfortable
- Comfortable
- Very comfortable

2. Overall, how much did you like the study gel?

- Disliked very much
- Disliked
- Liked
- Liked very much

2a. Please specify why you liked or disliked the study gel: _____

1.2. Part B: Trial Acceptability**EAMTRIALINTRO**

The following questions are about your experience with this study.

3. How would you rate your overall experience of participating in this study?

- Very negative
- Negative
- Neutral
- Positive
- Very positive

4. Overall, how bothered were you by the following study procedures:

	Very bothered	A little bothered	Not at all bothered
4a. Having to be sexually abstinent during specified times	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4b. Computer-administered questionnaires	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4c. Physical examination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4d. Genital examination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4e. Semen collection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4f. Having blood drawn	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4g. Being tested for HIV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4h. Being tested for other sexually transmitted infections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4i. Your partner's gel use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4j. Having sex at specified times and location	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4k. Having your partner participate in the study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. In the future, would you be willing to join a research study similar to this one?

- Yes, I would be willing to join a similar study
- No, I would not be willing to join a similar study

(Logic: If No - unwilling - skip to Q8)

6. Please indicate the reasons why you are **willing** to join a similar study in the future. Choose **all** that apply.

- To receive the financial reimbursement
- To be provided with free health care during the study, or to get faster or better quality health care
- To be tested for HIV
- To get educated or find out more about HIV
- To help test a product that may prevent women from getting HIV
- To contribute to scientific knowledge
- To satisfy my curiosity about participating in a study
- A friend/family member recommended that I join the study
- Other *(Please specify: _____)*

(Logic: At least one must be marked. If only one marked, go to EAMCOMPLETE)

7. Please indicate the **main** reason you are willing to join a similar study in the future.
- To receive the financial reimbursement
 - To be provided with free health care during the study, or to get faster or better quality health care
 - To be tested for HIV
 - To get educated or find out more about HIV
 - To help test a product that may prevent women from getting HIV
 - To contribute to scientific knowledge
 - To satisfy my curiosity about participating in a study
 - A friend/family member recommended that I join the study
 - Other [specific answer]

[drop-down menu populated with all reasons marked in Q6]

(Logic: Go to EAMCOMPLETE)

8. Please indicate the reasons why you are **not willing** to join a similar study in the future. Choose **all** that apply.
- The study participation was too time-consuming
 - The financial compensation was not sufficient
 - I did not like the study product
 - I did not like having to be sexually abstinent during specified times
 - I did not like completing the computer-administered questionnaires
 - I did not like the study staff, or I had a bad interaction with study staff
 - I did not like being tested for HIV
 - I did not feel the information I provided was kept confidential
 - I did not like having sex at specified times and location
 - I did not like some of the study procedures (*Please specify:* _____)
 - Other (*Please specify:* _____)

(Logic: At least one must be marked. If only one marked, go to EAMCOMPLETE)

9. Please indicate the **main** reason you are not willing to join a similar study in the future.
- The study participation was too time-consuming

- The financial compensation was not sufficient
- I did not like the study product
- I did not like having to be sexually abstinent during specified times
- I did not like completing the computer-administered questionnaires
- I did not like the study staff, or I had a bad interaction with study staff
- I did not like being tested for HIV
- I did not feel the information I provided was kept confidential
- I did not like having sex at specified times and location
- I did not like some of the study procedures [specific answer]
- Other [specific answer]

[drop-down menu populated with all reasons marked in Q8]

EAMCOMPLETE

Thank you for completing this questionnaire! Please click on 'Next' if you would like to save your responses. After you do so, you will not be able to change your answers.

LASTSCREEN

Please inform the research staff member that you are finished.

Exit Acceptability Questionnaire – Women (EAW)

1.3. Part A: Product Acceptability

EAWINTRO1

Thank you for coming to the clinic today for the MTN-011 study. The questions in this survey are about your experience with the gel and this study.

EAWINTRO2

The following questions are about your experience with the gel since you started the study, including today.

1. Overall, how comfortable were you with using the study gel?

- Very uncomfortable
- Uncomfortable
- Comfortable
- Very comfortable

2. Overall, how much did you like the study gel?

- Disliked very much
- Disliked
- Liked
- Liked very much

2a. Please specify why you liked or disliked the study gel: _____

1.4. Part B: Trial Acceptability

EAWTRIALINTRO

The following questions are about your experience with this study.

3. How would you rate your overall experience of participating in this study?

- Very negative
- Negative
- Neutral
- Positive
- Very positive

4. Overall, how bothered were you by the following study procedures:

	Very bothered	A little bothered	Not at all bothered
4a. Having to be sexually abstinent during specified times	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4b. Computer-administered questionnaires	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4c. Physical examination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4d. Pelvic examination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4e. Genital swab specimen collection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4f. Rinsing the vagina and cervix with fluids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4g. Genital tissue biopsy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4h. Rectal sponge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4i. Having blood drawn	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4j. Being tested for HIV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4k. Being tested for other sexually transmitted infections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4l. Providing a urine sample	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4m. Using the study gel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4n. Having sex at specified times and location	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4o. Having your partner participate in the study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. In the future, would you be willing to join a research study similar to this one?

- Yes, I would be willing to join a similar study
- No, I would not be willing to join a similar study

(Logic: If No - unwilling - skip to Q8)

6. Please indicate the reasons you are **willing** to join a similar study in the future. Choose **all** that apply.

- To receive the financial reimbursement
- To be provided with free health care during the study, or to get faster or better quality health care
- To be tested for HIV
- To get educated or find out more about HIV
- To help test a product that may prevent women from getting HIV
- To contribute to scientific knowledge
- To satisfy my curiosity about participating in a study
- A friend/family member recommended that I join the study
- Other (*Please specify:* _____)

(Logic: At least one must be marked. If only one marked, go to EAWCOMPLETE)

7. Please indicate the **main** reason you are willing to join a similar study in the future.

- To receive the financial reimbursement
- To be provided with free health care during the study, or to get faster or better quality health care
- To be tested for HIV
- To get educated or find out more about HIV
- To help test a product that may prevent women from getting HIV
- To contribute to scientific knowledge
- To satisfy my curiosity about participating in a study
- A friend/family member recommended that I join the study
- Other [specific answer]

[drop-down menu populated with all reasons marked in Q6]

(Logic: Go to EAWCOMPLETE)

8. Please indicate the reasons why you are **not willing** to join a similar study in the future. Choose **all** that apply.

- The study participation was too time-consuming
- The financial compensation was not sufficient
- I did not like the study product

- I did not like having to be sexually abstinent during specified times
- I did not like completing the computer-administered questionnaires
- I did not like the study staff, or I had a bad interaction with study staff
- I did not like being tested for HIV
- I did not feel the information I provided was kept confidential
- I did not like having sex at specified times and location
- I did not like some of the study procedures (*Please specify:*_____)
- Other (*Please specify:*_____)

(Logic: At least one must be marked. If only one marked, go to EAWCOMPLETE)

9. Please indicate the **main** reason you are not willing to join a similar study in the future.

- The study participation was too time-consuming
- The financial compensation was not sufficient
- I did not like the study product
- I did not like having to be sexually abstinent during specified times
- I did not like completing the computer-administered questionnaires
- I did not like the study staff, or I had a bad interaction with study staff
- I did not like being tested for HIV
- I did not feel the information I provided was kept confidential
- I did not like having sex at specified times and location
- I did not like some of the study procedures [specific answer]
- Other [specific answer]

[drop-down menu populated with all reasons marked in Q8]

EAWCOMPLETE

Thank you for completing this questionnaire! Please click on 'Next' if you would like to save your responses. After you do so, you will not be able to change your answers.

LASTSCREEN

Please inform the research staff member that you are finished.

Section Appendix 12-3
Question by Question (QxQ) Instructions for MTN-011 CASI Questionnaires

QxQ Table of Contents

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Baseline Questionnaire (BAQ)

Beginning a Questionnaire: Entering Participant Information

At the beginning of each Baseline Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

Practice Questions

Note: while in the actual questionnaires participants are allowed to refuse to answer and skip a question, this option is NOT allowed during the practice questions. All participants will be required to give an answer to each of the practice questions. However these data will not be kept or analyzed, in case the participant has concerns. Also, as we want to keep the “refuse to answer” at a minimum, staff will explain this option to participants, but they will not be practicing it.

Introduction The first two screens of the Practice section introduce the participants to the practice and teach participants how to navigate between screens by pressing the “NEXT” and “PREVIOUS” buttons.

PRAC1. This question gives an example of a question where only one answer is allowed. The participant should answer the question by clicking on the button next to the answer he/she wishes to select. If the participant wants to change his/her answer after selecting a response, he/she should select another answer by clicking the button next to the new answer he/she wants to select.

PRAC2. This question gives an example of choosing answers in a table and teaches participants how to answer a question where only one answer is allowed per question. It also shows how to answer questions with buttons and shows the participant how to change an answer once a choice is selected. The tables in the questionnaire will include one question per row and answer choices in columns. Participants should select one answer per question by clicking on the button. If the participant wants to change his/her answer after selecting a response, he/she should select another answer by clicking the button next to the new answer he/she wants to select.

PRAC3. This question gives an example of choosing an answer in a drop-down menu. Participants will click on the down arrow to display the available options in the menu and select one answer. To change an answer, the participant may click on the down arrow again and select a different answer.

PRAC4. This question teaches participants how to answer a question where more than one answer is allowed, and shows the participant how to change an answer once it is selected by clicking again to de-select the response. This question also introduces the answer category of 'Other.' If a participant selects 'Other,' she/he should be instructed to fill in the box beside the response with a specific description of what 'Other' means. If the participant selects the last **bolded** option in a list, all other responses that have been selected will be removed because this option is incompatible with the other responses. Instruct the participant to make sure to only select the last bolded option when all of the other choices do not apply.

At the end of the practice questions, a screen will appear to let the participant know he/she has finished the practice. The Baseline questionnaire begins after this screen and the participant must click "Next" to proceed to the Baseline questionnaire.

Baseline Questionnaire (BAQ)

The first screen of the Baseline Questionnaire explains to the participants that all answers are confidential and will not affect their participation in the study. Participants should be encouraged to ask questions of the study staff if they do not understand any part of the questionnaire. When the participants clicks "Next" on this screen, they will be taken to the first question.

Q1. This question refers to any research studies the participant has volunteered for and participated in before this one.

Q2. This question asks the participant to identify all reasons for deciding to participate in this study. Participants should mark all choices they feel are applicable. If the "Other" option is selected, participants must fill in the box beside the response with a description of another reason for joining the study that is not already on the list.

Q3. This question will only be asked if participants marked more than one reason for participating in the study in the previous question. If participants marked more than one reason, this question will ask the participant to identify the main reason he/she decided to participate in the study. Participants will be offered a list of choices that corresponds to all the options they marked in the previous question. One answer may be selected. If the participant only marked one reason in the previous question, Q3 will not appear.

At the end of the Baseline Questionnaire, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

Behavioral Questionnaire (BEH)

This questionnaire will be completed by female participants only.

Beginning a Questionnaire: Entering Participant Information

At the beginning of each Behavioral Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

Under “Select date of participant’s last computer interview”, select the date from the calendar that appears when clicking on the date box that corresponds to the participant’s last clinic visit where she completed a questionnaire on the computer. When this is entered at the enrollment visit, this will refer to the date of her screening visit. Use the arrows on either side of the month to view a different month. Confirm the date of the last computer interview by selecting the correct date.

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

Behavioral Questionnaire (BEH)

The first screen of the Behavioral Questionnaire explains to the participants that all answers are confidential and will not affect their participation in the study. Participants should be encouraged to ask questions of the study staff if they do not understand any part of the questionnaire. When the participants click the “Next” button on this screen, they will be taken to the first question.

Current Sexual Activity

In these questions we ask about female participants’ current sex lives. The section begins with a list of sexual terms and definitions of sexual behavior. If at any time a participant has questions about a specific term, refer her to the list of sexual terms and help her to understand the meaning of what is being asked.

Note: “Finger sex” refers to masturbation with finger insertion, as well as a partner inserting finger(s) in the participant’s vagina.

Q1. This question asks about the different kinds of sexual activity the participant has engaged in **since her last study visit**. The date of her last study visit will appear in the question as it is entered on the log-in screen by the study staff. When the question is answered at the baseline visit, this will refer to time since her screening visit. If the participant has questions about the sexual terms used, please refer her back to the list of terms and definitions and clarify the meaning of the question. Be sure to tell the participant that none of her answers will affect her participation in the study. More than one answer may be selected. If there is another sexual activity she has engaged in that is not listed, the participant should choose “other” and describe that sexual activity in the space provided.

Q2. This sub-question refers to the last time the participant engaged in each type of sexual activity recorded in question 1. The question will be repeated for each type of sexual activity that the participant recorded in Q1. The participant should select one answer for each activity. If the participant selected “None of the above,” in Q1, this question will be skipped.

Recent Intravaginal Practices

The next questions ask about items that women sometimes insert into their vaginas for a variety of reasons (contraception, personal hygiene, menstrual control or other reasons). Please note that these questions are about putting items **inside** the vagina and not about using them outside the vagina, on the external genitalia. Some participants may not have inserted any of the items into their vaginas. The participant is reassured that none of her answers will affect her participation in the study.

Q3. This question asks about all the items that a participant has inserted into her vagina **since her last study visit**. The date of her last study visit will appear in the question as it is entered on the log-in screen by the study staff. When the question is answered at the baseline visit, this will refer to time since her screening visit. More than one answer may be selected. If there is an item she has used that is not listed, the participant should choose “Other product” and describe that item in the space provided.

Q4. This sub-question refers to the last day the participant inserted each item she recorded in Q3. The question will be repeated for each item that the participant recorded in Q3. The participant should select one answer for each item. If the participant selected “None of the above,” in Q3, this question will be skipped.

Examples of recording the day of product use:

- If today is Monday, and a participant last inserted a product at 11:57PM on Saturday night, the day will be recorded as: 2 days ago.
- If today is Monday, and a participant last inserted a product at 12:05AM, just after Midnight on Sunday morning, the day will be recorded as: Yesterday.

Q5. This sub-question refers to the last time the participant inserted each item she recorded in Q3 if she reported that she inserted it either “today” or “yesterday”. If the product was inserted 2 or more days ago, this question will be skipped. Times are listed in a drop-down menu by hour starting with morning hours through midnight: 1 AM, 2 AM, ... 12 Noon, 1 PM,... 12 Midnight. The participant should select one answer from the drop-down menu that corresponds to the last time she used the product today or yesterday, rounding to the nearest hour. If she is unsure of the exact time she used the product, she should give her best estimate of the time.

Examples of rounding to the nearest hour:

- If a participant last inserted a product at 11:57PM, last night, the time should be recorded as: Yesterday at 12 Midnight.
- If today is Monday, and a participant last inserted a product at 12:05AM, just after Midnight on Sunday morning, the time will be recorded as: Yesterday at 1AM.

At the end of the Behavioral Questionnaire, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

Exit Acceptability Questionnaire – Men (EAM)

This questionnaire will be completed by male participants only.

Beginning a Questionnaire: Entering Participant Information

At the beginning of the Exit Acceptability Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

Practice Questions

Note: while in the actual questionnaires participants are allowed to refuse to answer and skip a question, this option is NOT allowed during the practice questions. All participants will be required to give an answer to each of the practice questions. However these data will not be kept or analyzed, in case the participant has concerns. Also, as we want to keep the “refuse to answer” at a minimum, staff will explain this option to participants, but they will not be practicing it.

Intro. The first two screens of the Practice section introduce the participants to the practice and teach participants how to navigate between screens by pressing the “NEXT” and “PREVIOUS” buttons.

PRAC1. This question gives an example of a question where only one answer is allowed. The participant should answer the question by clicking on the button next to the answer he wishes to select. If the participant wants to change his answer after selecting a response, he should select another answer by clicking the button next to the new answer they want to select.

PRAC2. This question gives an example of choosing answers in a table and teaches participants how to answer a question where only one answer is allowed per question. It also shows how to answer questions with buttons and shows the participant how to change an answer once a choice is selected. The tables in the questionnaire will include one question per row and answer choices in columns. Participants should select one answer per question by clicking on the button. If the participant wants to change his answer after selecting a response, he should select another answer by clicking the button next to the new answer they want to select.

PRAC3. This question teaches participants how to answer a question where more than one answer is allowed, and shows the participant how to change an answer once it is selected by clicking again to de-select the response. This question also introduces the answer category of 'Other.' If a participant selects 'Other,' she/he should be instructed to fill in the box beside the response with a specific description of what 'Other' means. If the participant selects the last **bolded** option in a list, all other responses that have been selected will be removed because this option is incompatible with the other responses. Instruct the participant to make sure to only select the last bolded option when all of the other choices do not apply.

Part A: Product Acceptability

After the practice questions, the next two screens introduce the male participants to the topic of questions in the survey about their experience with the gel and this study. The first set of questions is about their experience with the gel since starting the study, up through and including today.

Q1. This question asks about the participant's level of comfort with his partner using the gel during the study, including today. One answer may be selected.

Q2. This question asks for the participant's opinion of the study gel and whether he liked or disliked the gel during the study, up through and including today. One answer may be selected.

Q2a. This sub-question asks participants to explain why they liked or disliked the study gel. They may answer by typing in their response.

Part B: Trial Acceptability

The questions in this section ask the male participants about their experiences participating in the study.

Q3. This question asks the participant to rate his overall experience participating in the study. One answer may be selected.

Q4. This question asks the participant to rate several study procedures on how bothered or not bothered the participant felt by each procedure during the study. One answer per item in each row may be selected.

- 4a. Sexually abstinent means not having penetrative sex or ejaculating during a specific time.
- 4b. Computer-administered questionnaires refers to all the surveys like this one that the participant completed on the computer at study visits.
- 4c. Physical examination means having vital signs, general appearance, and any symptoms checked by the clinic staff/physician.
- 4d. Genital examination means having the penis, scrotum, and lymph nodes checked by the clinic staff/physician.

- 4e. Semen collection means collecting semen in a cup at the screening visit.
- 4f. Having blood drawn means having a needle inserted in a vein in the arm to collect blood in a tube for lab tests.
- 4g. Being tested for HIV means having a blood sample taken at screening and final visit.
- 4h. Being tested for other sexually transmitted infections means taking a urine sample to check for gonorrhea and chlamydia; and a blood sample for Hepatitis B and HIV.
- 4i. Your partner's gel use means having your partner use the study product.
- 4j. Having sex at specified times and location means following the study schedule for sex.
- 4k. Having your partner participant in the study means having your partner come to the clinic and study visits and follow the study procedures.

Q5. This question asks if the participant would be willing to participate in another study like this one sometime in the future. One answer may be selected.

If the participant selects "Yes", the questionnaire will continue with Q6-7. If the participant selects, "No", the questionnaire will skip to Q8-9.

Q6. This sub-question refers to Q5 and asks the participant for any reasons why he would be willing to participate in a study like this in the future. More than one answer may be selected. If the "Other" option is selected, the participant should type a response in the box next to "please specify".

Q7. This question will be asked if the participant marked more than one reason he would be willing to participate in future studies in Q6. If only one reason was selected in Q6, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q6.

Q8. This sub-question refers to Q5 and asks the participant for any reasons why he would not be willing to participate in a study like this in the future. More than one answer may be selected. If the "Other" option is selected, the participant should type a response in the box next to "please specify".

Q9. This question will be asked if the participant marked more than one reason he would not be willing to participate in future studies in Q8. If only one reason was selected in Q8, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q8.

At the end of the Exit Acceptability Questionnaire - Men, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the "Next" button. After clicking the "Next" button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

Exit Acceptability Questionnaire – Women (EAW)

This questionnaire will be completed by female participants only.

Beginning a Questionnaire: Entering Participant Information

At the beginning of the Behavioral Questionnaire, a screen will appear asking for the participant's ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the "Next" button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant's ID. Below the PTID, select the participant's appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today's date, click on the box below "Select today's date". A calendar will appear with today's date highlighted. Click on today's date, and the date will be entered in the box. Repeat these steps to confirm today's date in the box below "Select today's date to confirm."

When all the participant's information is entered correctly, click on the "Next" button to begin the questionnaire.

Part A: Product Acceptability

The first two screens introduce the female participants to the topic of the questions in the survey about their experience with the gel and this study. The first set of questions is about their experience with the gel since starting the study, including today.

Q1. This question asks about the participant's level of comfort using the gel during the study, up through and including today. One answer may be selected.

Q2. This question asks for the participant's opinion of the study gel and whether she liked or disliked the gel during the study, up through and including today. One answer may be selected.

Q2a. This sub-question asks the participant to explain why she liked or disliked the study gel. She may answer by typing in her response.

Part B: Trial Acceptability

The questions in this section ask the participant about her experience participating in the study.

Q3. This question asks the participant to rate her overall experience participating in the study. One answer may be selected.

Q4 This question asks the participant to rate several study procedures on how bothered or not bothered the participant felt by each procedure during the study. One answer per item in each row may be selected.

4a. Sexually abstinent means not having penetrative sex or ejaculating during a specific time.

- 4b. Computer-administered questionnaires refers to all the surveys like this one that the participant completed on the computer at study visits.
- 4c. Physical examination means having vital signs, general appearance, and any symptoms checked by the clinic staff/physician.
- 4d. Pelvic examination means collecting samples for research purposes and also having clinic staff/physician check on health of vagina
- 4e. Genital swab specimen collection is for research purposes and to check for STIs
- 4f. Rinsing the vagina and cervix with fluids is part of the pelvic exam.
- 4g. Genital tissue biopsy means taking a small tissue sample from the vagina and cervix
- 4h. Rectal sponge means placing a small sponge in the rectum for about 5 minutes
- 4i. Having blood drawn means having a needle inserted in a vein in the arm to collect blood in a tube for lab tests.
- 4j. Being tested for HIV means having a blood sample taken at screening and final visit.
- 4k. Being tested for other sexually transmitted infections means taking a urine sample to check for gonorrhea and chlamydia; a blood sample for Hepatitis B and HIV; and a vaginal swab for trichomonas.
- 4l. Providing a urine sample means collecting urine in a cup
- 4m. Using the study gel means using the study product.
- 4n. Having sex at specified times and location means following the study schedule for sex.
- 4o. Having your partner participate in the study means having your partner come to the clinic and study visits and follow the study procedures.

Q5. This question asks if the participant would be willing to participate in another study like this one sometime in the future. One answer may be selected.

If the participant selects “Yes”, the questionnaire will continue with Q6-7. If the participant selects, “No”, the questionnaire will skip to Q8-9.

Q6. This sub-question refers to Q5 and asks the participant for any reasons why she would be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

Q7. This question will be asked if the participant marked more than one reason she would be willing to participate in future studies in Q6. If only one reason was selected in Q6, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q6.

Q8. This sub-question refers to Q5 and asks the participant for any reasons why she would not be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

Q9. This question will be asked if the participant marked more than one reason she would not be willing to participate in future studies in Q8. If only one reason was selected in Q8, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q8.

At the end of the Exit Acceptability Questionnaire - Women, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the "Next" button. After clicking the "Next" button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.