

Section 12. Behavioral Measures: Web-based Questionnaires

12.1 Types of Behavioral Questionnaires

There will be two sets of behavioral measures collected in MTN-012/IPM 010: the Baseline Behavioral Questionnaire, and the Product Acceptability and Adherence Questionnaire. The Baseline Behavioral Questionnaire will be used to collect information on all participants' sexual behaviors, drug and alcohol use, and knowledge of microbicides, amongst other things. The Product Acceptability and Adherence Questionnaire will be used to collect information on participants' experiences with the gel, their likelihood to use a microbicide in the future and their use of study product. Data collection for the Baseline Behavioral and Product Acceptability and Adherence Questionnaires will be done by means of Web-based technology that is a variation of Computer Assisted Self-Interview (CASI), with the only difference being that the data entered are not stored in a laptop or PC but rather transmitted instantly to a server selected by SCHARP. The questionnaires are not accessible to people who are not participating in the study.

The timing of these questionnaires is listed in Table 12-1.

Table 12-1: Timing of Behavioral Measures

Study Visit	Behavioral Measures
Enrollment Visit	Baseline Behavioral Questionnaire (CASI)
Final Clinic Visit	Product Acceptability and Adherence Questionnaire (CASI)

The purpose of this SSP section is to describe the process for conducting CASI.

12.2 General Computer Use

Each study site will have a PC or laptop connected to the Web for the participants to use. Sites should select a location in the research offices for the PC or laptop that is private (i.e. the screen should be out of sight to staff members and other participants while answers are being entered), but allows study staff to be nearby to answer questions or assess whether the participant is having computer problems. As such, staff members should be familiar with the questionnaires in case participants raise any questions. There should be an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The PC or laptop should be plugged into an AC power source. An external mouse should be connected to the laptop. To minimize problems with computers, keep the laptop plugged into a power source, avoid having food or drink nearby, and keep the area where the computer is used clutter-free. Sites should have an anti-virus program installed on the computer used for questionnaires. It is recommended that each site have a back-up laptop or desktop available for use, in the event that the designated computer does not work. Refer to the operations manual of the PC or laptop for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off).

For questions regarding general computer problems or issues with administering or accessing the questionnaires, please refer to Section 12.5 in this manual for contact information.

12.3 Administering Behavioral Measures

As mentioned in Table 12-1, the Behavioral Measures that will be collected during the course of the study are:

- Enrollment Visit: Baseline Behavioral Questionnaire
- Final Clinic Visit: Product Acceptability and Adherence Questionnaire

If a participant discontinues trial participation early, he will be encouraged to respond to the Product Acceptability and Adherence Questionnaire at the time he exits the study.

12.3.1 Administering the Baseline Behavioral Questionnaire (Enrollment Visit)

To begin, access the Web page for the [Baseline Behavioral Questionnaire](http://www.scharp.org/MTN012bbq/) using Internet Explorer at the following URL:

http://www.scharp.org/MTN012bbq/

Note. If you use browsers other than Internet Explorer, the questions and response choices may not display correctly.

Once the questionnaire is accessed, staff should complete the following:

- 1) Log in by entering the PTID (without spaces), Study Code (MTN012) and re-entering the PTID (without spaces) for confirmation.
- 2) Enter the visit code: 2.0.
- 3) Enter the current date by selecting the month, day and year from the drop down menus.
- 4) Instruct the participant to follow the online instructions for using both the keyboard and mouse, as well as moving from page to page to answer questions (i.e., using the “Next” button).
- 5) Verify the participant's comfort with using the mouse and keyboard, and navigating through the questionnaire.
- 6) Initially, the participant will be presented with simple practice questions (e.g. “choose all that apply”, “indicate how many times”, “choose one of a fixed set of answers”, etc.) The staff member should remain with the participant at this point and allow the participant to complete the practice questions, assisting him if needed, to make sure he understands how to answer and how to change invalid entries.

Note: Invalid entries are those that are not accepted by the program, either because they contradict information that the participant previously entered or because they are not permitted (i.e., numbers that are out of the possible range, e.g. saying he used the gel 100 times).

- 7) Let the participant know that he can refuse to answer any question.

Note: If the participant is unsure of his answer, encourage the participant to make his best guess rather than refuse. Answer any questions that the participant may have and let him know that you are available for help.

- 8) Instruct the participant to notify staff once he sees a message at the end of the questionnaire indicating that he has completed the questionnaire which states: PLEASE STOP HERE AND TELL INTERVIEWER THAT YOU ARE FINISHED, or if he needs/wants to stop the questionnaire before reaching the end.
- 9) Leave the room and allow the participant to proceed to the Baseline Behavioral Questionnaire and respond to the questionnaire on his own. The participant should be the only person in the room at the time he is completing the questionnaire.
- 10) When the participant calls you after he has finished the questionnaire, enter the password: 2011.
- 11) Use the comments field on the following screen to enter information about any deviations from the behavioral measures protocol or any problems with the web-based questionnaire.

Please refer to Section 12.5 below for guidelines and contact information regarding troubleshooting and problems with administering the questionnaire.

12.3.2 Administering the Product Acceptability and Adherence Questionnaire (Final Clinic Visit)

To begin, access the Web page for the Product Acceptability and Adherence Questionnaire at the following URL:

<http://www.scharp.org/MTN012paq/>

Note. If you use other browsers other than Internet Explorer, the questions and response choices may not display correctly.

- 1) Log in by entering the PTID (without spaces) and Study Code (MTN012) and re-entering the PTID (without spaces) for confirmation.
- 2) Enter the Visit Code. The acceptable range for the Product Acceptability Questionnaire is 2.1-3.0.
- 3) Enter the current date by selecting the month, day and year from the drop down menus.
- 4) Instruct the participant to follow the online instructions for using both the keyboard and mouse, as well as moving from page to page to answer questions (i.e., using the “Next” button).
- 5) Verify the participant's comfort with using the mouse and keyboard, and navigating through the questionnaire.
- 6) Initially, the participant will be presented with simple practice questions (e.g. “choose all that apply”, “indicate how many times”, “choose one of a fixed set of answers”, etc.) The staff member should remain with the participant at this point and allow the participant to complete the practice questions, assisting him if needed, to make sure he understands how to answer and how to change invalid entries.

Note: Invalid entries are those that are not accepted by the program, either because they contradict information that the participant previously entered or because they are not permitted (i.e., numbers that are out of the possible range, e.g. saying he used the gel 100 times).

- 7) Let the participant know that he can refuse to answer any question.

Note: If the participant is unsure of his answer, encourage the participant to make his best guess rather than refuse. Answer any questions that the participant may have and let him know that you are available for help.

- 8) Instruct the participant to notify staff once he sees a message at the end of the questionnaire indicating that he has completed the questionnaire which states: PLEASE STOP HERE AND TELL THE INTERVIEWER THAT YOU ARE FINISHED, or if he needs/wants to stop the questionnaire before reaching the end.
- 9) Leave the room and allow the participant to proceed to the Product Acceptability Questionnaire and respond to the questionnaire on his own. The participant should be the only person in the room at the time he is completing the questionnaire.
- 10) When the participant calls you after he has finished the questionnaire, enter the password: 2011.
- 11) Use the comments field on the following screen to enter information about any deviations from the behavioral measures protocol or any problems with the web-based questionnaire.

Please refer to Section 12.5 below for guidelines and contact information regarding troubleshooting and problems with administering the questionnaire.

12.4 Participants Who Discontinue Study Product

Participants who permanently discontinue study product will not be routinely withdrawn from the study and every effort should be made to complete all protocol-specified visits and procedures, including the behavioral measures. Therefore, even if a participant discontinues study product, he should complete the Product Acceptability and Adherence Questionnaire at the Final Clinic Visit.

12.5 Troubleshooting and Contact Information

If you encounter any problems with the questionnaires, either accessing them or completing them, or with the laptop/desktop that you are using, notify the team by sending an email to the alias list mtn012webtrouble@mtnstopshiv.org. The team of staff members (Corey Miller and Lynda McVarish at SCHARP; Craig Hoesley at UAB; Ashley Mayo and Lisa Levy at FHI, Penny Shaw at University of Pittsburgh; and Curtis Dolezal and Marina Mabragaña at the HIV Center) will be available to assist you to troubleshoot and resolve any problems you may have with the Web-based questionnaires.

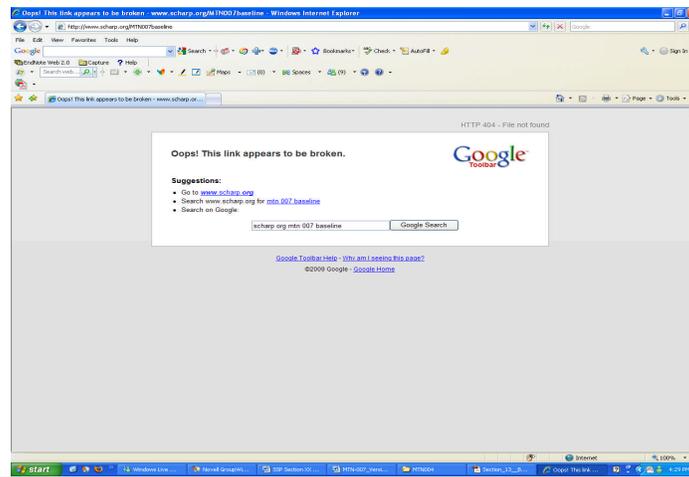
To facilitate the troubleshooting process, please indicate in your email a description of the problem, including a copy of the error message(s), if any, and date and time of when the problem occurred. It is very useful to the MTN-012/IPM 010 Web Trouble team to have an exact copy of error messages. To take a snapshot of an error message presented on the screen, simply maximize the screen containing the error message by clicking on the middle box containing one square located at the top right corner of the screen, and then hit Control (CTRL) and Print Screen (or PRT SC on most laptops) simultaneously on your keyboard to create an image of your screen. Next, open Microsoft Word and paste your image into the Word document (click on Edit and then Paste; or simply hit CTRL and V simultaneously). Save the Word file as [insert date].doc and attach it to your email to the MTN-012/IPM 010 Web Trouble team. An example of an email message to the Web Trouble team is presented in Figure 12-1.

Figure 12-1: Email Error Message

To: mtn012webtrouble@mtnstopshiv.org
 From: XXX
 Date: May 16, 2011, 10:28am EST
 Re: MTN 012 Web Problem

No access to the Baseline Behavioral Questionnaire on May 16, 2011 at 10:20am EST. A participant is expected in for a study visit at 11:00 am and will be ready to complete the questionnaire at 11:30am. HELP!

[Word document containing an image of the error message generated using Ctrl + Print Screen should be attached to the email (example of filename: MTN012WebProblem_5-16-11.doc)]



The following mock PTIDs IDs will be used to troubleshoot any problems and for practice sessions:

MOCK Participant ID's:

Site: Pittsburgh	Site: Alabama
999-30101-7	999-30126-2
999-30102-8	999-30127-3
999-30103-4	999-30128-5
999-30104-2	999-30129-8
999-30105-6	999-30130-1
999-30106-9	999-30131-6
999-30107-5	999-30132-7
999-30108-3	999-30133-0
999-30109-1	999-30134-3
999-30110-9	999-30135-5
999-30111-3	999-30136-8
999-30112-4	999-30137-9
999-30113-8	999-30138-4
999-30114-6	999-30139-2

999-30115-2	999-30140-8
999-30116-0	999-30141-4
999-30117-1	999-30142-0
999-30118-7	999-30143-7
999-30119-5	999-30144-5
999-30120-7	999-30145-3
999-30121-0	999-30146-1
999-30122-1	999-30147-2
999-30123-6	999-30148-6
999-30124-9	999-30149-9
999-30125-4	999-30150-3

Marina Mabragaña will coordinate efforts to quickly resolve any problems. She will keep a record of any problems in a log (MTN-012 Web Troubleshoot Log), track actions taken to correct problems, and inform and follow up with team members, as appropriate. In case a problem occurs when the participant is at the site and actions to resolve the problem need to be taken immediately, you may contact:

- Marina Mabragaña at (212) 568-4237 or mabraga@pi.cpmc.columbia.edu

You may also contact:

- Corey Miller at (206) 667-7672 or corey@scharp.org for questions about accessing the Web-based questionnaires
- SCHARP help desk at (206) 667-2822 or e-mail sc.helpdesk@scharp.org for any technical problems accessing the questionnaires

If a participant is answering the questionnaire and encounters a problem, exit the questionnaire by closing the browser page and then access the appropriate link to the Web page again to log the participant in. The system should return to where the participant left off (i.e., the Web page with the question where a participant left off should be displayed). Then go back using the back arrow until reaching the first question and let the participant start the questionnaire again. If the problem persists, contact mtn012webtrouble@mtnstopshiv.org and call Marina Mabragaña so that actions can be taken immediately. The MTN-012/IPM 010 Web Trouble team will assess the problem and communicate with you about resolutions. If this occurs, you should document it by keeping a record in the participant's file. A record will also be made in the MTN-012/IPM 010 Web Trouble Log.

Refer to Appendix 12-1 for “Quick Tips for Web-Based Behavioral Questionnaires”

Refer to Appendix 12-2 for the Behavioral Measures Questionnaires

Section Appendix 12-1 QUICK TIPS FOR WEB-BASED QUESTIONNAIRES

- Prior to starting a questionnaire, make sure that the external mouse is connected and working properly.
- Make sure that the participant is comfortable and has privacy to assure the confidentiality of his responses.
- Start the questionnaire by typing the Web address to the corresponding Behavioral Measure, using Internet Explorer:
 1. Baseline Behavioral Questionnaire (Enrollment Visit)
<http://www.scharp.org/MTN012bbq/>
 2. Product Acceptability and Adherence Questionnaire (Final Clinic Visit)
<http://www.scharp.org/MTN012paq/>
- Make sure that the participant is comfortable with using the mouse and keyboard.
- Check to confirm that it is the correct questionnaire.
- Enter PTID, Study Code: MTN012, and enter PTID again to confirm.
- Enter the Visit Code. The acceptable visit code for the Baseline Behavioral Questionnaire is 2.0. The acceptable range for the visit code of the Product Acceptability and Adherence Questionnaire is 2.1-3.0.
- Enter the current date.
- Allow participant to complete the practice questions.
- Assist the participant as needed.
- Instruct the participant that when he reaches the end of the survey, he will see a screen that says "PLEASE STOP HERE AND TELL THE INTERVIEWER THAT YOU ARE FINISHED." The participant is not finished until he reaches this end screen. At that point the participant should leave the computer as is and inform the site staff.
- Enter the password: 2011. Enter comments on the following screen if there were any problems with the web-based questionnaires or protocol deviations. Exit the questionnaire by closing the browser screen.
- If, for any reason, the participant cannot complete the questionnaire, you may exit the questionnaire. If the participant is able to return to it, restart the questionnaire by going to the appropriate link for the Web page and logging in with the PTID and study code. Click the back arrow until reaching the first question and let the participant start the questionnaire again.

If you encounter any problems with the questionnaires or with the laptop/desktop that you are using, notify mtn012webtrouble@mtnstopshiv.org.

Section Appendix 12-2

Behavioral Assessments

Participant ID

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Date

<u> </u>	/	<u> </u>	/	<u> </u>
MM		DD		YYYY

MTN-012/IPM 010

Baseline Behavioral Questionnaire

Presentation Version

2-10-11, version 1.3

Ross Cranston, M.D., Protocol Chair

Alex Carballo-Diéguez, Ph.D., Co-Investigator

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TEXT IN CAPITAL LETTERS SHOULD NOT BE PRESENTED TO THE PARTICIPANT.

THE SYSTEM GENERATES AN "X-VALUE" VARIABLE FOR ALL NUMERIC VARIABLES (RESPONSES ARE IDENTICAL TO THE ORIGINAL RESPONSES BUT ALSO INCLUDE VALUES FOR THE REFUSE-TO-ANSWER OPTION). FOR DATA ANALYSIS, WE WILL USE THE ORIGINAL VARIABLE, NOT THE SYSTEM GENERATED X-VALUE VARIABLE.

Thank you for agreeing to complete this questionnaire. Your responses will be kept confidential. To keep the information you provide private, personal information (name, address, phone number) will NOT be collected in this questionnaire. Before you begin, there are a few practice questions for you to get used to how the system works. If you have any questions on how to use the computer, the clinic staff can assist you. [Question 1]

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

Introduction [Question 2]

Good! You can always move to the next screen by clicking "next", or, to go to the previous screen, click on "back" arrow.

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

Practice [Question 3]

This question shows how to answer questions with click boxes. Try answering the question below by moving the mouse arrow and clicking on boxes that match your choices.

PRACTICE QUESTION:

Which items do you like to eat on a salad? *Choose all that apply.*

[Answer options]

- 3.1 Eggs
- 3.2 Cheese
- 3.3 Croutons
- 3.4 Salad Dressing
- 3.5 Carrots
- 3.6 Bacon bits
- 3.7 None of the above

This is an example of a question where more than one answer is allowed:

If you want to change your response, click the response you don't want again to de-select it and then select the answer(s) you do want.

Practice [Question 4]

Do you like summer?

- Yes
- No
- Refuse to answer

This is an example of a single response question:

If you want to change your response, simply click the response you want.

SECTION A. DEMOGRAPHICS

THE REFUSE TO ANSWER VALUE FOR VARIABLES THAT ARE NOT NOMINAL IS **999** IN THIS SECTION.

1 SYSTEM TO RECORD TODAY'S DATE

____/____/____
mm dd yyyy

2 How old are you? _____ (In years)

___ Refuse to answer

3 Please indicate the highest education level you achieved

1. eighth grade or lower
2. partial high school
3. high school graduate/GED
4. partial college
5. college graduate
6. partial graduate school
7. graduate school degree
8. Refuse to answer

4 Do you consider yourself...

- ___ 1 Hispanic or Latino? [SKIP TO Q 5L]
___ 2 Not Hispanic or Latino?
___ 3 Refuse to answer

5 Do you consider yourself... [SKIP TO Q 6]

1. American Indian / Alaska Native
2. Asian
3. Native Hawaiian or other Pacific Islander
4. Black or African American
5. White
6. Other (please specify): _____
7. Refuse to answer

5L As a Hispanic or Latino person, do you also consider yourself...

1. American Indian / Alaska Native
2. Asian
3. Native Hawaiian or other Pacific Islander
4. Black or African American
5. White
6. Other (please specify): _____
7. Refuse to answer

6 Do you consider yourself (check all that apply)...

- ___ 1 Straight/heterosexual?
___ 2 Gay/homosexual?
___ 3 Bisexual?

- _____ 4 Other? (please specify): _____
_____ 5 Refuse to answer
- 7 Please check all that apply to your current occupational status.
- _____ 1 Full time work
_____ 2 Part time work
_____ 3 Full or part time in school
_____ 4 Neither work nor in school
_____ 5 On disability
_____ 6 Other (please specify): _____
_____ 7 Refuse to answer
- 8 Please check what describes who you live with now...
- _____ 1 You live alone
_____ 2 You live with a partner, spouse, or steady girlfriend/boyfriend
_____ 3 You live with family members, friends, or roommates (not spouse)
_____ 5 You are homeless or do not have a regular place to live now
_____ 6 Other (please specify): _____
_____ 7 Refuse to answer
- 9 During the last 12 months, what was your total personal income from all sources?
- _____ 1 \$10,000 or less
_____ 2 \$10,001 to \$20,000
_____ 3 \$20,001 to \$40,000
_____ 4 \$40,001 to \$60,000
_____ 5 \$60,001 to \$80,000
_____ 6 Over \$80,000
_____ 7 Don't know
_____ 8 Refuse to answer

SECTION B. SEXUAL BEHAVIOR

THE REFUSE TO ANSWER VALUE FOR VARIABLES THAT ARE NOT NOMINAL IS **901** IN THIS SECTION.

The following questions refer to your sexual behavior during the past three months that is, from [CASI: INSERT TODAY'S DATE THREE MONTHS AGO] until today.

Sometimes talking about sex can be confusing because people have so many different words to describe body parts and sexual activities. Before we start, we're going to take a minute to review some words so it is clear what we are asking.

[SCREEN TIPS WILL BE GENERATED FOR WORDS IN BOLD TO DISPLAY THEIR MEANINGS AND ALTERNATE PHRASES, AS PER THE FOLLOWING:]

Penis is the male sex organ. Some people call it "dick" or "cock."

Vagina is the female sex organ. Some people call it "pussy."

Rectum and anus are frequently called "butt" or "asshole."

Intercourse is when a man puts his penis into a partner's vagina, rectum, or anus. It includes both anal and vaginal intercourse.

Vaginal intercourse is when a man puts his penis into a woman's vagina; some people call this "fucking" or "screwing" or "having sex."

Anal intercourse is when a man puts his penis in another man's or a woman's rectum or anus; some people call this "butt fucking."

Insertive anal intercourse, or insertive anal sex, is when you put your penis in another man or woman's rectum, or your "dick" in his/her "ass". Some people call this "butt fucking" or "topping".

Receptive anal intercourse, or receptive anal sex, is when a man puts his penis in your rectum, or his "dick" in your "ass". Some people call this being "butt fucked" or "bottoming".

As you go through the following questions, these words will sometimes appear in bold. If you are not sure what a word in bold means, use the mouse to place the arrow or cursor on the bolded word to see its meaning.

Since the focus will be exclusively on anal, vaginal or oral sex, do *NOT* include in your answers references to partners with whom you did not engage in anal, vaginal, or oral sex.

SEXUAL BEHAVIOR WITH WOMEN

First, you will be asked about your sexual behavior with women.

1. During the past three months, how many female sexual partners have you had?

_____ [IF 0, SKIP QUESTIONS ON SEX WITH WOMEN AND GO TO
QUESTIONS ON SEX WITH MEN]
_____ Refuse to answer

- 1x. You responded Refuse to answer for the previous question. Please confirm:
1. I refuse to answer questions about female sexual partners [IF YES, GO TO QUESTIONS ON SEX WITH MEN]
 2. I am willing to answer questions about female sexual partners

Of these women, how many do you consider to be ...(Please put a number in each box. Enter 0 (zero) if none. Your answers must add up to _____ [CASI PROGRAMMER: ENTER NUMBER FROM Q1]):

- 1A.1 a spouse or steady girlfriend (a woman with whom you've felt emotionally involved, in a committed relationship, and with whom you had sex)

- 1A.2 one-night stands (women with whom you had sex only once)

- 1A.3 other female partners (women with whom you had sex who are neither your spouse, steady girlfriends nor one-night stands)

1AX.1 Refuse to answer

Vaginal Intercourse

In the past three months ...

2. How many times did you put your **penis** in a **vagina**?

_____ [IF 0, GO TO Q 9]

_____ Refuse to answer

3. How many times did you put your **penis** in a **vagina** without a condom?

_____ [IF 0, GO TO Q 9]

_____ Refuse to answer

4. Into how many women's **vaginas** did you put your **penis** without a condom?

_____ Refuse to answer

[CASI, IF Q 4 = 1 (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED ONLY ONE WOMAN WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 5; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 6]

You said you put your penis in one woman's vagina without a condom.

5. Regarding this woman (please select one answer).....

___ 1. This woman told you she was HIV negative and you had no reason to doubt it.

___ 2. You knew this woman was HIV positive.

___ 3. You were not completely sure of this woman's HIV status.

___ 4. Refuse to answer

[CASI, IF Q 4 IS 2 OR MORE (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED TWO OR MORE WOMEN WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 6; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 9]

You said you put your penis in ___ women's [CASI CAN INSERT THE NUMBER FROM THE PREVIOUS QUESTION (Q 4)] vaginas without a condom.

6. Of those women, how many had actually told you they were HIV-negative and you had no reasons to doubt it?

7. Of those women, how many do you know to be HIV-positive?

8. How many were you NOT completely sure about their HIV status?

8X.1 Refuse to answer

Anal Intercourse

In the past three months ...

9. How many times did you put your penis in a woman's **rectum**?

_____ [IF 0, GO TO Q 16]

_____ Refuse to answer

10. How many times did you put your penis in a woman's **rectum** without a condom?

_____ [IF 0, GO TO Q 16]

_____ Refuse to answer

11. Into how many women's rectums did you put your penis without a condom?

_____ Refuse to answer

[CASI, IF Q 11 = 1 (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED ONLY ONE WOMAN IN THE RECTUM WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 12; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 13]

You said you put your penis in one woman's rectum without a condom.

12. Regarding this woman (please select one answer).....

___ 1. This woman told you she was HIV negative and you had no reason to doubt it.

___ 2. You knew this woman was HIV positive.

___ 3. You were not completely sure of this woman's HIV status.

___ 4. Refuse to answer

[CASI, IF Q 11 IS 2 OR MORE (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED TWO OR MORE WOMEN IN THE RECTUM WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 13; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 16]

You said you put your penis in _____ women's [CASI CAN INSERT THE NUMBER FROM THE PREVIOUS QUESTION (Q 32)] rectums without a condom.

13. Of those women, how many had actually told you they were HIV-negative and you had no reasons to doubt it?

_____ Refuse to answer

14. Of those women, how many do you know to be HIV-positive?

_____ Refuse to answer

15. How many were you NOT completely sure about their HIV status?

15X.1 Refuse to answer

SEXUAL BEHAVIOR WITH MEN

Now you will be asked questions about your sexual behavior with men.

16. During the past three months, how many male sexual partners have you had?

_____ [IF 0, SKIP QUESTIONS, GO TO QUESTION 31.]
_____ Refuse to answer

- 16x. You responded Refuse to answer for the previous question. Please confirm:
1. I refuse to answer questions about male sexual partners [IF YES, GO TO QUESTION 31]
 2. I am willing to answer questions about male sexual partners

Of these men, how many do you consider to be ...(Please put a number in each box. Enter 0 (zero) if none. Your answers must add up to _____ [CASI PROGRAMMER: ENTER NUMBER FROM Q16]):

16A.1 spouse, lover or boyfriend (men with whom you've felt emotionally involved in a committed relationship and with whom you had sex)

16A.2 one-night stands (men with whom you had sex only once)

16A.3 other male partners (men with whom you had sex who are neither your spouse, lover or boyfriend nor one-night stands)

16AX.1 Refuse to answer

Receptive Anal Intercourse

In the past three months ...

17. How many times did a male partner put his **penis** in your **rectum**?

_____ [IF 0, GO TO Q 923]

_____ Refuse to answer

[CASI PROGRAMMER: IF RESPONSE IS "0", ALSO SKIP QUESTIONS IN SECTION D (LUBRICANT USE), WHICH ARE CONTINGENT ON RAI IN THE PAST 3 MONTHS.]

18. How many times did a male partner put his **penis** in your **rectum** without a condom?

_____ [IF 0, GO TO Q 23.]

_____ Refuse to answer

[CASI PROGRAMMER: IF RESPONSE IS "0", ALSO SKIP QUESTIONS B IN SECTION F (SUBSTANCE USE), WHICH ARE CONTINGENT ON URAI IN THE PAST 3 MONTHS.]

19. How many men put their **penises** in your **rectum** without a condom?

_____ Refuse to answer

[CASI, IF Q 19 = 1 (i.e., THE PARTICIPANT REPORTS THAT ONLY ONE MAN PENETRATED HIM WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 20; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 21]

You said that one man put his penis in your rectum without a condom.

20. Regarding this man (please select one answer).....

___ 1. This man told you he was HIV negative and you had no reason to doubt it.

___ 2. You knew this man was HIV positive.

___ 3. You were not completely sure of this man's HIV status.

___ 4. Refuse to answer

[CASI, IF Q 19 IS 2 OR MORE (I.E., THE PARTICIPANT REPORTS THAT TWO OR MORE MEN PENETRATED HIM WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 21; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 24]

You said ___ men [CASI CAN INSERT THE NUMBER FROM THE PREVIOUS QUESTION (Q 19)] put their penises in your rectum without a condom.

21. Of those men, how many had actually told you they were HIV-negative and you had no reasons to doubt it?

22. Of those men, how many do you know to be HIV-positive?

23. How many were you NOT completely sure about their HIV status?

23X.1 Refuse to answer

Insertive Anal Intercourse

In the past three months ...

24. How many times did you put your penis in a man's rectum?

[IF 0, GO TO Q 16]

_____ Refuse to answer

25. How many times did you put your penis in a man's rectum without a condom?

_____ [IF 0, GO TO Q 16]

_____ Refuse to answer

26. Into how many men's rectums did you put your penis without a condom?

_____ Refuse to answer

[CASI, IF Q 26 = 1 (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED ONLY ONE MAN WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 27; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 28]

You said you put your penis in one man's rectum without a condom.

27. Regarding this man (please select one answer) ...

___ 1. This man told you he was HIV negative and you had no reason to doubt it.

___ 2. You knew this man was HIV positive.

___ 3. You were not completely sure of this man's HIV status.

___ 4. Refuse to answer

[CASI, IF Q 26 IS 2 OR MORE (I.E., THE PARTICIPANT REPORTS THAT HE PENETRATED TWO OR MORE MEN WITHOUT A CONDOM), GO TO INSTRUCTIONS ABOVE Q 28; OTHERWISE SKIP TO INSTRUCTIONS ABOVE Q 31]

You said you put your penis in ___ men's [CASI CAN INSERT THE NUMBER FROM THE PREVIOUS QUESTION (Q 11)] rectums without a condom.

28. Of those men, how many had actually told you they were HIV-negative and you had no reasons to doubt it?

29. Of those men, how many do you know to be HIV-positive?

30. How many were you NOT completely sure about their HIV status?

30X.1 Refuse to answer

31. Are you circumcised?

1. No [SKIP TO NEXT SECTION]

2. Yes
3. Refuse to answer

32. Were you circumcised ...
1. At birth
 2. In childhood or during adolescence
 3. During adulthood
 4. Refuse to answer

SECTION C. LUBRICANT AND SPERMICIDE USE

The following questions refer to commercial sexual lubricants. This does not include saliva or the lubricant that comes with condoms.

Remember, if you are not sure what a word in bold means, use the mouse to place the arrow or cursor on the word to see its meaning.

- 1 Have you ever used a commercial sexual lubricant (e.g, Femglide[®], ID[®], or KY[®])?
- 1 Yes
 - 2 No [SKIP TO NEXT SECTION]
 - 3 I don't know [SKIP TO NEXT SECTION]
 - 4 Refuse to answer

Vaginal Intercourse [IF Q B2 > 0]

- 2 During the past three months, how frequently have you had **vaginal intercourse** using a commercial sexual lubricant?

- 1 Never [ASK Q 3 AND SKIP TO Q 10]
- 2 Sometimes [ASK Q 3 AND CONTINUE WITH THIS SECTION]
- 3 Always [SKIP Q 3 AND GO TO Q 4]
- 4 Refuse to answer

- 3 During the past three months, when you did NOT use a lubricant for **vaginal intercourse**, why was that the case? [Indicate all that apply] [IF Q 2 = 1, ASK THIS QUESTION AND SKIP TO NEXT SECTION; OTHERWISE GO TO Q 4]

- 1 I did not feel it was needed
- 2 Sometimes I prefer dry sex
- 3 I disliked the lubricant
- 4 I used saliva
- 5 I used condoms with lubricant
- 6 Lubricant was not available
- 7 I was in a rush
- 8 I couldn't afford to buy it
- 9 My partner refused
- 10 Other (please specify): _____
- 11 Refuse to answer

- 4 During **vaginal intercourse**, how much commercial lubricant do you use on average?

- 1 5 ml or less (1 teaspoon)
- 2 About 10 ml (2 teaspoons)
- 3 About 15 ml (3 teaspoons)
- 4 About 30 ml (6 teaspoons)
- 5 About 50 ml (10 teaspoons)
- 6 Refuse to answer

- 5 In terms of commercial lubricant consistency, what do you prefer for vaginal intercourse?
- _____ 1 Very liquid
 _____ 2 Somewhat liquid
 _____ 3 Neither
 _____ 4 Somewhat thick
 _____ 5 Very thick
 _____ 6 Refuse to answer
- 6 In general when you have vaginal intercourse, is the lubricant applied...[Indicate all that apply]
- _____ 1 Directly on your penis?
 _____ 2 On the outside of your partner's vagina?
 _____ 3 Inside your partner's vagina?
 _____ 4 Inside the condom?
 _____ 5 On the outside of the condom?
 _____ 6 Other (please specify): _____
 _____ 7 Refuse to answer
- 7 When you are having vaginal intercourse, who applies the lubricant?
- _____ 1 Self
 _____ 2 Partner
 _____ 3 Both
 _____ 4 Refuse to answer
- 8 When is the lubricant first applied?
- _____ 1 Before there is any sexual contact
 _____ 2 During sex but before you penetrate her
 _____ 3 After you first penetrate her if you feel the need for it
 _____ 4 Refuse to answer
- 9 How frequently do you usually reapply the commercial lubricant during vaginal intercourse?
- _____ 1 Never
 _____ 2 Once
 _____ 3 Twice
 _____ 4 3 times or more
 _____ 5 Refuse to answer

[IF Q B9 OR Q B24 > 0] The following questions refer to **insertive anal intercourse** only.

- 10 During the past three months, how frequently have you used a commercial lubricant during **insertive anal intercourse**?
- _____ 1 Never [ASK Q 11 AND SKIP TO Q 18]
 _____ 2 Sometimes [ASK Q 11 AND CONTINUE WITH THIS SECTION]
 _____ 3 Always [SKIP Q 11 AND GO TO Q 12]

- _____ 4 Refuse to answer
- 11 During the past three months, when you did NOT use a lubricant for **insertive anal intercourse**, why was that the case? [Indicate all that apply] [IF Q 10 = 1, ASK THIS QUESTION AND SKIP TO NEXT SECTION; OTHERWISE GO TO Q 12]
- _____ 1 I did not feel it was needed
- _____ 2 Sometimes I prefer dry sex
- _____ 3 I disliked the lubricant
- _____ 4 I used saliva
- _____ 5 I used condoms with lubricant
- _____ 6 Lubricant was not available
- _____ 7 I was in a rush
- _____ 8 I couldn't afford to buy it
- _____ 9 My partner refused
- _____ 10 Other (please specify): _____
- _____ 11 Refuse to answer
- 12 During insertive anal intercourse, how much commercial lubricant do you use on average?
- _____ 1 5 ml or less (1 teaspoon)
- _____ 2 About 10 ml (2 teaspoons)
- _____ 3 About 15 ml (3 teaspoons)
- _____ 4 About 30 ml (6 teaspoons)
- _____ 5 About 50 ml (10 teaspoons)
- _____ 6 Refuse to answer
- 13 In terms of commercial lubricant consistency, what do you prefer for insertive anal intercourse?
- _____ 1 Very liquid
- _____ 2 Somewhat liquid
- _____ 3 Neither
- _____ 4 Somewhat thick
- _____ 5 Very thick
- _____ 6 Refuse to answer
- 14 In general when you have insertive anal intercourse, is the lubricant applied...[Indicate all that apply]
- _____ 1 Directly on your penis?
- _____ 2 On the outside of your partner's anus (rim)?
- _____ 3 Inside your partner's anus?
- _____ 4 Inside the condom?
- _____ 5 On the outside of the condom?
- _____ 6 Other (please specify): _____
- _____ 7 Refuse to answer

- 15 When you are having insertive anal intercourse, who applies the lubricant?
- _____ 1 Self
 _____ 2 Partner
 _____ 3 Both
 _____ 4 Refuse to answer
- 16 When is the lubricant first applied?
- _____ 1 Before there is any sexual contact
 _____ 2 During sex but before penetration
 _____ 3 After penetration if you feel the need for it
 _____ 4 Refuse to answer
- 17 How frequently do you usually reapply the commercial lubricant during insertive anal intercourse?
- _____ 1 Never
 _____ 2 Once
 _____ 3 Twice
 _____ 4 3 times or more
 _____ 5 Refuse to answer

Lubricant Preferences

- 18 From your past experience, does the application of the lubricant interrupt sex?
- _____ 1 It does not interrupt sex
 _____ 2 It interrupts sex but does not bother me
 _____ 3 It interrupts sex and bothers me
 _____ 4 Refuse to answer
- 19 What types of lubricant do you use? [Indicate all that apply]
- _____ 1 Silicon-based (e.g., Eros)
 _____ 2 Water-based (e.g., KY, Wet)
 _____ 3 Oil-based (e.g., Crisco)
 _____ 4 Refuse to answer
- 20 Where do you usually get your lubricant from?
- _____ 1 Sex shop
 _____ 2 Pharmacy/drug store
 _____ 3 AIDS Agency
 _____ 4 Bar, disco, sex club
 _____ 5 Online
 _____ 6 Other (please specify): _____
 _____ 7 Refuse to answer
- 21 Do you prefer a lubricant with ...
- _____ 1 No flavor

- _____ 2 Flavor
_____ 3 It doesn't matter
_____ 4 Refuse to answer
- 22 Do you prefer a lubricant with ...
_____ 1 No color/transparent
_____ 2 Color
_____ 3 It doesn't matter
_____ 4 Refuse to answer
- 23 Do you prefer a lubricant with ...
_____ 1 Unscented/ No scent
_____ 2 Scented
_____ 3 It doesn't matter
_____ 4 Refuse to answer
- 24 Describe the ideal type of dispenser for a lubricant.
_____ 1 Tube (like toothpaste or KY®)
_____ 2 Pump (like in Vaseline Intensive Care® or Wet®)
_____ 3 Containers with pop-up lid
_____ 4 Can or jar
_____ 5 Single use, like a plastic pouch containing lubricant
_____ 6 Disposable tube
_____ 7 Other (please specify): _____
_____ 8 Refuse to answer

SECTION D. SUBSTANCE USE

THE REFUSE TO ANSWER VALUE FOR VARIABLES THAT ARE NOT NOMINAL IS **999** IN THIS SECTION.

The following questions refer to alcohol and drug use. Have you ever used...^[R1]

	EVER USED?			[A] FREQUENCY PAST 3 MONTHS	[B] FREQUENCY WITH UI PAST 3 MONTHS
	No	Yes	Refuse to answer		
1. Alcohol?	1	2	3		
2. Marijuana/hashish?	1	2	3		
3. Ecstasy/MDMA?	1	2	3		
4. "Meth" (Crystal Meth/Amphetamines/ Methamphetamines/Speed/Crank)?	1	2	3		
5. Ketamine/Special K?	1	2	3		
6. GHB (Gamma Hydroxybutyrate)?	1	2	3		
7. Other Hallucinogens (LSD/ Mushrooms)?	1	2	3		
8. Poppers (Amyl Nitrite/Butyl Nitrite)?	1	2	3		
9. Crack?	1	2	3		
10. Cocaine (not Crack)?	1	2	3		
11. Heroin?	1	2	3		
12. Viagra, Cialis, or Levitra?	1	2	3		
13. Other pharmaceutical drugs not prescribed to you by a physician (Percocet or similar drugs)?	1	2	3		

Now using the following response choices, please indicate:

- | | |
|--------------------------|--------------------------|
| 1 = Never | 5 = 2-6 times a week |
| 2 = Once a month or less | 6 = About once a day |
| 3 = 2-3 times a month | 7 = More than once a day |
| 4 = About once a week | 8 = Refuse to answer |

^[R1] This does not show up as a table on the screen but as individual questions.

[PRESENT ONE SUBSTANCE AT A TIME. QUESTIONS C, D AND E APPLY ONLY TO ALCOHOL USE]

A. How often have you used _____ during the past three months? [IF "1" FOR ALCOHOL USE, SKIP B, C, D AND E; IF "1" FOR ALL OTHER SUBSTANCES, SKIP B]

_____ Refuse to answer

B. In the past three months, how often have you used _____ immediately before or during vaginal or anal intercourse?

_____ Refuse to answer

[QUESTIONS C, D AND E APPLY ONLY TO ALCOHOL USE; INSERT QUESTIONS C, D AND E IMMEDIATELY AFTER ALCOHOL QUESTIONS]

C. During the past three months, about how many glasses of beer or wine did you usually have on the days that you drank?

_____ glasses of beer or wine/day

_____ Refuse to answer

D. During the past three months, about how many shots of liquor did you usually have on the days that you drank?

_____ shots of liquor/day

_____ Refuse to answer

E. Thinking about the times you used alcohol during the last three months, how much did you typically use?

- ___ 1. Too little to feel any effect
- ___ 2. Enough to feel it a little
- ___ 3. Enough to feel it a lot
- ___ 4. Enough to get drunk
- ___ 5. Enough to feel like you might pass out
- ___ 6. Refuse to answer

ASK Q 14 AFTER ALL SUBSTANCE QUESTIONS.

14. In the past three months, how many times did you inject any non-prescribed drugs into your veins or under your skin?

_____ Refuse to answer

SECTION E. HIV TESTING

THE REFUSE TO ANSWER VALUE FOR VARIABLES THAT ARE NOT NOMINAL IS **999** IN THIS SECTION, UNLESS OTHERWISE NOTED.

Now you will be asked a few questions about your HIV status. Remember that this information is completely confidential.

1. Including the test you received to join this study, how many times in total have you been tested for HIV?

_____ Refuse to answer [101]

2. When were you first tested for HIV?

___/____ mm yyyy

_____ Don't know / Refuse to answer

3. Before you joined this study, when were you last tested for HIV?

___/____
mm yyyy

_____ Don't know / Refuse to answer

4. How many times, of those you have been tested for HIV, have you been notified of the test results?

[0] None

_____ [IF "0" OR LESS THAN THE # OF TIMES REPORTED IN Q 1, ASK Q 5;
OTHERWISE SKIP TO NEXT SECTION]

_____ Refuse to answer

5. When you did not receive the test results, why was that the case? [Indicate all that apply]

___ 1 Fear of finding out the results

___ 2 Fear that Immigration and Naturalization Services (INS) will find out the results

___ 3 Required for work (e.g., the military)

___ 4 Concern that my sexual partners may be contacted

___ 5 I just assumed I was negative

___ 6 I would have been called if my test result was positive

___ 7 Other: _____

___ 8 Refuse to answer

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

_____ Refuse to answer

7. Why? _____

SECTION G. LIKELIHOOD OF MICROBICIDE USE (BASELINE)

THE REFUSE TO ANSWER VALUE FOR VARIABLES THAT ARE NOT NOMINAL IS **98** IN THIS SECTION.

Scientists are trying to develop alternatives to condoms for the prevention of HIV transmission during intercourse. Microbicides could be one such alternative.

1. Before joining this study, how much did you know about microbicides?
 1. I had never heard about microbicides
 2. I knew a little about microbicides but not in detail
 3. I was quite well informed about microbicides
 4. Refuse to answer

Remember, if you are not sure what a word in bold means, use the mouse to place the arrow or cursor on the word to see its meaning.

2. If a microbicide were available that provided some protection against HIV, and it came in the form of a gel (microbicidal gel), how likely would you be to use it every time you have **intercourse**?
 1. Very unlikely
 2. Unlikely
 3. Likely
 4. Very likely
 5. Refuse to answer
3. If a microbicide were available that provided some protection against HIV, and it came in the form of a gel (microbicidal gel), how likely would you be to use it every time you have **intercourse**, on a scale of 1 to 10?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

4. How likely would you be to use it every time you have **intercourse** with a **spouse or steady girlfriend/boyfriend**?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

5. How likely would you be to use a microbicidal gel every time you have **intercourse** with a **one-night stand**?

1—2—3—4—5—6—7—8—9—10

Very
Unlikely

Very
Likely

Refuse to answer

6. How likely would you be to use a microbicidal gel every time you have **intercourse** with other partners who were neither your **spouse or steady boyfriend/girlfriends** nor **one-night stands**?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

7. How likely would you be to use a microbicidal gel for intercourse if you were using alcohol or drugs?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

That completes the questionnaire. Thank you for your participation.

Participant ID

--	--	--	--

Date

/	/	
MM	DD	YYYY

MTN-012/IPM 010

Product Acceptability and Adherence Questionnaire

Presentation Version

2-10-11 version 1.3

Ross Cranston, M.D., Protocol Chair

Alex Carballo-Diéguez, Ph.D., Co-Investigator

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TEXT IN CAPITAL LETTERS SHOULD NOT BE PRESENTED TO THE PARTICIPANT.

PRESENT PRACTICE QUESTIONS USED IN THE BASELINE QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire. Your responses will be kept confidential. To keep the information you provide private, personal information (name, address, phone number) will NOT be collected in this questionnaire. Before you begin, there are a few practice questions for you to get used to how the system works. If you have any questions on how to use the computer, the clinic staff can assist you. [Question 1]

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

Introduction [Question 2]

Good! You can always move to the next screen by clicking "next", or, to go to the previous screen, click on the "back" arrow.

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

Practice [Question 3]

This question shows how to answer questions with click boxes. Try answering the question below by moving the mouse arrow and clicking on boxes that match your choices.

PRACTICE QUESTION:

Which items do you like to eat on a salad? *Choose all that apply.*

[Answer options]

- 3.1 Eggs
- 3.2 Cheese
- 3.3 Croutons
- 3.4 Salad Dressing
- 3.5 Carrots
- 3.6 Bacon bits
- 3.7 None of the above

This is an example of a question where more than one answer is allowed:

If you want to change your response, click the response you don't want again to de-select it and then select the answer(s) you do want.

Practice [Question 4]

Do you like summer?

- Yes
- No
- Refuse to answer

This is an example of a single response question:

If you want to change your response, simply click the response you want.

SECTION H. PRODUCT ACCEPTABILITY

1. Overall, how much did you like the gel?

- 1. Disliked very much
- 2. Disliked a little
- 3. Liked a little
- 4. Liked very much
- 5. Refuse to answer

2. Overall how much did you like the gel on a scale of 1 to 10?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

3. What did you like most about the gel? _____

4. What did you like least about the gel? _____

5. How much did you like the appearance of the gel?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

6. How much did you like the color of the gel?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

7. How much did you like the taste of the gel?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

Don't know, I did not taste the gel

8. How much did you like the scent of the gel?

1—2—3—4—5—6—7—8—9—10

Disliked
very much

Liked
very much

Refuse to answer
Don't know, I did not smell the gel

9. How much did you like the consistency of the gel (how thick or thin it was)?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

10. How much did you like how the gel felt on your fingers as it came out of the container?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

11. How much did you like how the gel felt on your penis immediately after applying it?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

12. How much did you like how the gel felt on your penis 30 minutes after applying it?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

13. How much did you like how the gel felt after it dried out?

1—2—3—4—5—6—7—8—9—10
Disliked Liked
very much very much

Refuse to answer

SECTION I. APPLICATION PROCESS

Now you will be asked some questions about applying the gel.

1. On average, after you applied the gel, how long did you wait before putting your clothes back on or going to bed?

_____ (minutes)

Refuse to answer

2. Was the product completely dry at the time you put your clothes back on or went to bed?

1. Never
2. Some of the time
3. Most of the time
4. All of the time
5. Refuse to answer

3. Did you have any problem applying the gel?

1. No [SKIP TO NEXT SECTION]
2. Yes. Please describe the problem that you had applying the gel: _____
3. Refuse to answer [SKIP TO NEXT SECTION]

SECTION J. ADHERENCE AND CHANGES IN PRODUCT USE

Now we would like to ask you some questions about how you used the gel.

1. How many times did you apply the gel on your penis during the days of the trial? ____
Refuse to answer
[DO NOT ALLOW RESPONSE GREATER THAN 8]
[IF RESPONSE IS LESS THAN 7 ASK QUESTION 2. IF RESPONSE IS 7 OR 8 SKIP TO Q 3]
2. What prevented you from applying the gel every day during the trial period? _____
3. Did you ever use less than the specified amount of gel on the times you used the gel?
 1. No [SKIP TO QUESTION 7]
 2. Yes
 3. Refuse to answer
4. How many times did you use less than the specified amount of gel? _____ times
[DO NOT ALLOW RESPONSE GREATER THAN 8]
5. When you used less than indicated, about how much did you use?
 1. Three quarters of the dose
 2. Half of the dose
 3. One quarter of the dose
 4. Refuse to answer
6. Please indicate the reason why you used less than the specified amount of gel?

7. During the trial, did you use any other product on your penis besides the gel the staff gave you or hygiene products?
 1. No
 2. Yes. Please indicate what you used _____
 3. Refuse to answer
8. During the trial, how many times did you masturbate? _____
Refuse to answer
[IF RESPONSE IS 0 SKIP TO QUESTION 11]
9. During the trial, when was the last time that you masturbated?
 1. Today
 2. Yesterday
 3. Before yesterday
 4. Refuse to answer
10. The last time you masturbated, did you have the study gel on your penis?
 1. No
 2. Yes
 3. Refuse to answer

11. During the trial, how many times did you have any kind of sex with a partner in which your penis was touched? _____
Refuse to answer
[IF RESPONSE IS 0 SKIP TO NEXT SECTION]
12. During the trial, when was the last time that you had sex with a partner in which your penis was touched?
1. Today
 2. Yesterday
 3. Before yesterday
 4. Refuse to answer
13. The last time when you had sex with a partner in which your penis was touched, did you use a condom?
1. Yes
 2. No
 3. Refuse to answer
14. The last time when you had sex with a partner in which your penis was touched, did you have the study gel on your penis?
1. Yes
 2. No
 3. Refuse to answer

SECTION K. EXPERIENCES USING THE GEL

Now you will be asked some questions about problems you may have experienced when using the gel.

1. Thinking about your experiences using the gel, did you experience any stickiness?

1. None [SKIP TO Q 3]
2. Some
3. A lot
4. Refuse to answer

2. How much were you bothered by stickiness?

1—2—3—4—5—6—7—8—9—10
Not at all Very much

Refuse to answer

3. Did you experience any soiling or uncomfortable wetness of your underwear or bed sheets?

1. None [SKIP TO Q 5]
2. Some
3. A lot
4. Refuse to answer

4. How much were you bothered by soiling of underwear or bed sheets?

1—2—3—4—5—6—7—8—9—10
Not at all Very much

Refuse to answer

5. Did you experience any burning or irritation as a result of using the gel?

1. None [SKIP TO Q 7]
2. Some
3. A lot
4. Refuse to answer

6. How much were you bothered by the burning or irritation?

1—2—3—4—5—6—7—8—9—10
Not at all Very much

Refuse to answer

7. Did you experience any itching as a result of using the gel?

1. None [SKIP TO Q 9]
2. Some
3. A lot

4. Refuse to answer
8. How much were you bothered by the itching?

1—2—3—4—5—6—7—8—9—10
Not at all Very much

Refuse to answer

9. Did you experience any pain or trauma caused by applying this product?
1. None [SKIP TO Q 11]
 2. Some
 3. A lot
 4. Refuse to answer

10. How much were you bothered by the pain or trauma?

1—2—3—4—5—6—7—8—9—10
Not at all Very Much

Refuse to answer

11. Did the gel feel cold to you?
1. No [SKIP TO Q 13]
 2. Yes
 3. Refuse to answer

12. How would you describe the cold sensation?

1— 2— 3— 4—5—6—7—8—9—10
Very Unpleasant Very Pleasant

Refuse to answer

13. Did the gel feel warm to you?
1. No [SKIP TO NEXT SECTION]
 2. Yes
 3. Refuse to answer

14. How would you describe the warm sensation?

1— 2— 3— 4—5—6—7—8—9—10
Very Unpleasant Very Pleasant

Refuse to answer

SECTION L. LIKELIHOOD OF PRODUCT USE IN THE FUTURE

Now you will be asked about your likelihood of using the gel in the future.

Remember, if you are not sure what a word in bold means, use the mouse to place the arrow or cursor on the word to see its meaning.

1. If a microbicide were available that provided some protection against HIV, and it looked like the gel you have used in this study, how likely would you be to use it (a microbicide gel) every time you have **intercourse**?

1. Very unlikely
2. Unlikely
3. Likely
4. Very likely
5. Refuse to answer

2. If a microbicide were available that provided some protection against HIV, and it looked like the gel you have used in this study, how likely would you be to use it (a microbicide gel) every time you have **intercourse**, on a scale of 1 to 10?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

3. How likely would you be to use a microbicide gel every time you have **intercourse** with a **spouse or steady girlfriend/boyfriend**??

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

4. How likely would you be to use a microbicide gel every time you have **intercourse** with a **one-night stand**?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

5. How likely would you be to use a microbicide gel every time you have intercourse with **other sexual partners**, women or men who were neither **spouse or girlfriend/boyfriends** nor **one-night stands**?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

6. How likely would you be to use a microbicidal gel if you don't use condoms?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

7. How likely would you be to use a microbicidal gel every time you have intercourse if you were using drugs or alcohol?

1—2—3—4—5—6—7—8—9—10
Very Unlikely Very Likely

Refuse to answer

8. How would you feel if your **spouse or girlfriend/boyfriend** used a microbicidal gel?

1—2—3—4—5—6—7—8—9—10
Very against it Very in favor

Refuse to answer

9. How would you feel if a one-night stand used a microbicidal gel?

1—2—3—4—5—6—7—8—9—10
Very against it Very in favor

Refuse to answer

10. How would you feel if other sexual partners used a microbicidal gel?

1—2—3—4—5—6—7—8—9—10
Very against it Very in favor

Refuse to answer

11. How much would you be willing to spend on a microbicidal gel?

1. About as much as one spends for condoms
2. Twice as much as one spends for condoms
3. Three times as much
4. Other (please specify): _____
5. Refuse to answer

SECTION M. RECOMMENDATIONS

Please help us understand how we could make the gel more attractive to people like you.

1. Would you change anything about the gel's appearance?
 1. No
 2. Yes (Please specify what you would change:)

 3. Refuse to answer

2. Would you change anything about the gel's scent?
 1. No
 2. Yes (Please specify what you would change:)

 3. Don't know, I did not smell the gel
 4. Refuse to answer

3. Would you change anything about the gel's taste?
 1. No
 2. Yes (Please specify what you would change:)

 3. Don't know, I did not taste the gel
 4. Refuse to answer

4. Would you change anything about the gel's color?
 1. No
 2. Yes (Please specify what you would change:)

 3. Refuse to answer

5. Would you change anything about the consistency of the gel (how thick or thin it is)?
 1. No
 2. Yes (Please specify what you would change:)

 3. Refuse to answer

6. If you have any other recommendations, please write your recommendations below.

That completes the questionnaire. Thank you for your participation.