

Section 10. Behavioral Measures

10.	Introduction	10-1
10.1	Overview.....	10-1
10.2	Troubleshooting for behavioral assessments	10-2
10.3	Equipment Requirements and Set-up.....	10-2
10.3.1	Keyboard and Mouse Use	10-3
10.4	Data Collection Instruments	10-3
10.4.1	Computer Assisted Self-Interview (CASI) questionnaires	10-3
10.4.1.1	Baseline Questionnaire	10-3
10.4.1.2	Product Use End Visits Follow-up Survey (Visits 3, 5 and 7) & Conjoint Analysis (Visit 8)	10-4
10.4.2	In-Depth Interview (IDI).....	10-4
10.4.2.1	Brief In-Depth Interview (IDI).....	10-5
10.4.2.3	Scheduling the Interview	10-5
10.4.2.4	Preparing for the IDI.....	10-6
10.4.2.5	Initiating and Conducting the Video Interview	10-6
10.4.2.6	Safety Reporting	10-6
10.5	Qualitative Data Management	10-7
10.5.1	Audio Files	10-7
10.5.2	Transcription	10-7
10.5.3	Data Tracking.....	10-7
10.5.4	Special Cases and Technical Issues	10-7
10.5.4.1	Technical Problems Preventing CASI Completion	10-7
10.5.4.2	Interrupted Visits	10-7
10.5.4.3	Management of Errors on CASI	10-8
10.6	Staff Training	10-8
Section Appendix 10-1.1	10-10
Section Appendix 10-2	10-15
Section Appendix 10-3	10-16

10. Introduction

The behavioral assessments of the MTN-035 protocol will be collected via web-based Computer Assisted Self-Interviews (CASI), Short Message Service (SMS), and In-Depth Interviews (IDI). This section contains information about the necessary preparation, equipment, and process for participant completion of such assessments.

10.1 Overview

CASI questionnaires, SMS messages/responses, and IDI recordings, transcripts and interview notes 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. The purpose of these assessments is to understand participants' rectal product use, lubricant use, substance use, discriminatory experiences, experiences of transactional sex,

sexual behavior and practices, HIV knowledge, concerns with product and acceptability, technology use, motivations to participate in the trial, PrEP use, product adherence, and mental health.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Visit
Baseline	CASI	Enrollment (Visit 2)
Product End Use	CASI	Visits 3,5,7
Conjoint Analysis	CASI	Visit 8
SMS Messages	SMS	In between visits 2 & 3, 4 & 5, 6 & 7
Product End Use (15 mins)	In-Depth Interview	Visits 3, 5, 7
Final/Early Term (1 hour, subset)	In-Depth Interview	Visit 8

10.2 Troubleshooting for behavioral assessments

CASI

For any problems with the CASI questionnaires, including accessing or completing them, please notify the behavioral team immediately by emailing the CASI troubleshooting alias list at mtn035casi@mtntopshiv.org. Staff will be available to assist and troubleshoot any problems with the online questionnaires.

SMS

For any problems with the SMS questionnaires, including accessing or completing them, please notify the behavioral team immediately by emailing the SMS troubleshooting alias list at mtn035sms@mtntopshiv.org. Staff will be available to assist and troubleshoot any problems with the short message services.

IDI

For any problems with the IDI, including accessing the online video or audio, please notify the behavioral team immediately by emailing the IDI troubleshooting alias list at mtn035IDI@mtntopshiv.org. Staff will be available to assist with and troubleshoot any problems with the online video system for the interview.

10.3 Equipment Requirements and Set-up

CASI

The operations manual of the desktop or laptop used for the CASI study computer should be consulted for both hardware and software specifications and instructions on how to use the computer (e.g., turning a computer on and off, etc.). Other questions should be directed to the MTN-035 CASI Troubleshooting email alias (mtn035casi@mtntopshiv.org).

The study site must have a desktop or laptop computer connected to the Internet that is for use by the MTN-035 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 and other study participants, but its location should allow study staff to be nearby to answer questions or assess whether the participant is having technical problems). The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. If internet connection is unavailable at the site, study staff should notify the behavioral team and CASI surveys should be completed when connection is restored. The CASI study computer should be plugged into an AC power source. An external mouse should also 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.

SMS

At Enrollment (Visit 2), study staff will provide the participant with general use instructions and training on using Short Message Service (SMS) to report on study product (insert, suppository, or douche) use during the 4 weeks he/she is using the product. The training should be done using the cell phone that the participant will use during the study. When scheduling the participants' Screening visit, remind participants who will be using their own cell phones to bring them to their Screening visit (Visit 1). Site staff should follow the general use instructions, as well as the training script available on the MTN-035 webpage under Study Implementation Materials.

IDI

For the IDIs (conducted at Visits 3, 5, 7, and 8), the study site must have a computer connected to the Internet with a video camera and access to a telephone. If internet connection is unavailable at the site, study staff should notify the behavioral team and the IDI should be completed when connection is restored. The computer must be in a private room where participants will not be overheard during the interview. Select a location in a room with a door that closes to allow privacy for the participant and to allow the participant and interviewer to hear each other without noise disturbance. A sign reading "Interview in progress, do not interrupt" should be available to post on the door when the room is in use. The participant should be able to sit comfortably and be seen on the video camera by the interviewer and should be able to see the interviewer on the screen. A neutral background behind the interviewer and the participant is preferable. To allow for better viewing of one another, the participant and interviewer should not sit in front of a bright window or other light that could disrupt the camera. Site staff should verify IDI setting and connection with the interviewer before the IDI commences.

10.3.1 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:

- To 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 on the mouse.

The staff member should assess participant's experience using a keyboard and mouse, if necessary, 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" or "previous" buttons (not the browser arrows). The staff member should verify that participants are comfortable with using the mouse and keyboard and navigating through the questionnaire.

10.4 Data Collection Instruments

10.4.1 Computer Assisted Self-Interview (CASI) questionnaires

10.4.1.1 Baseline Questionnaire

Each participant will complete a Baseline Questionnaire by CASI at Enrollment (Visit 2) prior to randomization. In addition to collecting demographic information, this baseline questionnaire assesses the participant's motivation to join the trial, rectal product use, lubricant use, substance use, discriminatory experiences, experiences of transactional sex, sexual behavior and practices, HIV knowledge, concerns with products and acceptability, technology use, PrEP use, and mental health. Additionally, participant data will be de-identified because the study site will only provide a CASI ID for

each participant to the behavioral team conducting CASIs and IDIs. The behavioral team will only have access to this number and not any identifying information such as the name of the participant.

A site staff member will access the associated web page for the CASI Baseline Questionnaire (Appendices 10-1). The staff member will enter the CASI ID information provided to them during training using the CASI ID log. Each participant should be assigned a CASI ID during enrollment and the number will follow the participant throughout the study.

Initially, the participants will be presented with simple practice questions (e.g., “choose all that apply,” “select one response”). Participants should be given time to complete the practice questions with assistance as needed. Staff should ensure that 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 skip questions they do not want to answer. Participants should be informed that they may go back and change answers at any time before completing the survey using the back arrow. Staff should then remind participants that they are available to answer any questions or assist with administration of the CASI.

Following the practice questions, participants should be left alone to complete the Baseline Questionnaire. At the end of the questionnaire, a message will appear instructing participants to click ‘NEXT’ 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.

In the rare event the Baseline CASI questionnaire needs to be repeated (e.g. if the participant does not complete all enrollment visit procedures on the same day and needs to be rescheduled), the links in Appendix 10-1 should be used for repeat questionnaires.

10.4.1.2 Product Use End Visits Follow-up Survey (Visits 3, 5 and 7) & Conjoint Analysis (Visit 8)

At each Product Use End Visit (PUEV, Visits 3, 5, 7), each participant will complete a PUEV Follow-Up Questionnaire by CASI, which will cover a subset of the behaviors assessed at baseline. The PUEV Follow-Up Questionnaire should be completed before the participant receives any counseling. This questionnaire includes structured questions about recent sexual behavior, rectal practices, social influence, and substance use. The assessment includes additional questions about participants’ attitudes related to the study product used during the prior four weeks. At the appropriate time, a staff member will access the web page for the PUEV Follow-up. The staff member will then double enter the CASI ID. Next, participants should be left alone to complete the questionnaire.

At Visit 8, each participant will complete a Conjoint Analysis by CASI following procedures similar to those utilized for the previous questionnaires. The questionnaire will investigate preferred product characteristics, undesirable traits, and ideal products. At the appropriate time, a staff member will access the web page for the Conjoint Analysis (Appendix 10-1). The staff member will double enter the CASI ID. Next, the participant will be left to answer the questionnaire on their own.

At the end of the questionnaires (penultimate screen), a message will appear instructing participants to click the “Next” button to save their answers. The final screen will indicate to participants that they have completed the questionnaire and that they should communicate this to the staff member.

10.4.2 In-Depth Interview (IDI)

10.4.2.1 Brief In-Depth Interview (IDI)

At Visit 3, 5, and 7, all participants (expected 210 total) will complete a brief IDI. The interview will address study product use and acceptability during the trial. The purpose of this IDI is to ask participants about experiences with product use and participant concerns. These interviews will be conducted by a trained qualitative interviewer and will follow a semi-structured questionnaire guide; they are anticipated to last approximately 15 minutes. These interviews will be conducted via computer by a non-recorded muted video and a recorded phone line. The audio recording will be made through a telephone system with a digital audio recording device that is operated by the qualitative interviewer (off-site at UPenn and Columbia). The audio from the interview will be recorded and transcribed for analysis.

Through open-ended questions, the interview will explore the participant's overall experiences using the products during the trial, including any problems with using the products in the context of receptive anal sex, partners' reactions to product use, storage of the products and privacy of use, and other rectal practices. The interviewer will also review the participant's SMS data with him/her and to verify the accuracy of reports.

The staff member should explain that these interviews are being conducted using video to more thoroughly explore participant's feelings and that responses will be audio recorded but the video will not be recorded.

10.4.2.2 Subset In-Depth Interview (IDI)

At Visit 8, a subset of participants (expected 70 total) will complete a final IDI. The interview will address study product use and acceptability during the trial. The purpose of this IDI is to ask participants about experiences with product use and participant concerns. These interviews will be conducted by a trained qualitative interviewer and will follow a semi-structured questionnaire guide; it is anticipated to last approximately 45-60 minutes. These interviews will be conducted via computer by a non-recorded muted video and a recorded phone line. The audio recording will be made through a telephone system with a digital audio recording device that is operated by the qualitative interviewer (off-site at UPenn and Columbia). The audio from the interview will be recorded and transcribed for analysis.

Through open-ended questions, the interview will explore the participant's overall experiences in the study, prior experiences with anal sex and use of rectal products, general impressions of acceptability and adherence to each study product, overall product preferences, social influences on product use, and participants' perceptions of the video conferencing and SMS used in the study.

The staff member should explain that these interviews are being conducted using video to more thoroughly explore participant's feelings, and that responses will be audio recorded but the video will not be recorded.

10.4.2.3 Scheduling the Interview

Sites are asked to notify the qualitative interviewer of expected enrollment visits for the upcoming week. The qualitative interviewer should be notified of all changes or cancellations within 24 hours of the scheduled appointment, if possible. If last-minute changes do occur, please notify the interviewer as soon as possible, by phone or email message. Any scheduling changes will be confirmed by email. When a participant presents at Enrollment (Visit 2), study site coordinators will email the off-site qualitative interviewer to inform them of this and schedule the video calls. The qualitative interviewer will confirm the appointment via email.

If the qualitative interviewer is not available during Visit 3, Visit 5, or Visit 7 or if the participant is too tired or unable to continue, the IDI may be scheduled within the visit window at Visit 4, Visit 6, or Visit 8 respectively.

To minimize scheduling conflicts among sites, study coordinators can view the site's calendar prior to scheduling appointments to make sure the interviewer will be available to do the interview.

To access the **Google calendar site**, refer to Appendix 10-2 for log-in information.

10.4.2.4 Preparing for the IDI

Prior to the IDI, the study coordinators and interviewer will ensure that the microphone, either attached to the computer located at the research sites or built in to the webcam, is disabled. In addition, to make sure that no information is transmitted over the Internet that could potentially identify the nature of the conversation or the identity of the participant, research staff at each site must ensure that no information about either the study or the research clinic is in view of the camera. The interviews will be audio-recorded using a digital voice recorder. A video record of the interview will not be made. No identifying information about participants will be recorded on the audio files or appear in transcripts, or study records.

IDI procedures:

- ☐ Make sure that the office where the IDI will be held affords privacy
- ☐ Check the computer and Internet connection to make sure that the equipment and connection are working properly
- ☐ Click on the BlueJeans meeting link sent by the BRWG Project Manager.
- ☐ Make sure that no information about either the study or the research clinic is in view of the camera
- ☐ Make sure that the microphone is disabled
- ☐ Call interviewer at the number provided in the confirmation email to inform him/her that a participant is ready for the IDI
- ☐ Check that the video properties are working properly (make adjustments, to the position of the webcam, as necessary) and that the participant and interviewer can see each other clearly
- ☐ Once participants are connected with the interviewer, they should be informed where they may find study staff if assistance is needed or in case equipment fails. Study staff should leave the room to give participants privacy

10.4.2.5 Initiating and Conducting the Video Interview

Prior to conducting any video interviews, the interviewer will verify that the site has completed video interview set-up and ensure that all necessary add-on software is installed in the Internet browser of the site's interview computer. A computer equipped with a webcam and with broadband access to the Internet will be used to facilitate communication between the interviewer and participants; however, audio will not be transmitted over the computer and Web. To ensure confidentiality, the interviews will be conducted by telephone.

The site staff will contact the interviewer to let him/her know that the participant is ready. The interviewer will initiate a BlueJeans meeting using the link provided in the email invitation from the appointed site staff.

10.4.2.6 Safety Reporting

As required by DAIDS safety reporting policies, any potential reportable Adverse Event (AE) or Social Harm (SH) reported by a study participant during the IDI will be brought to the attention of the clinical staff. The occurrence of AE or SH reporting during the IDI is not expected. However, in the rare event a suspected AE or SH is reported during the IDI, the qualitative interviewer will make note of the participant's comment(s) in the interview notes that will be maintained in the participant files at the University of Pennsylvania or Columbia University. The qualitative interviewer will alert the participant that s/he will need to report the AE or SH to the clinic staff. The qualitative interviewer will then alert the clinic staff (by phone) that the participant reported an AE or SH. The qualitative interviewer and the clinic staff

will document in chart notes the notification made to clinic staff (by the qualitative interviewer) and the receipt of the notice (by clinic staff). Clinic staff will follow up with the participant to assess the AE or SH as needed and report/document the AE on the AE log CRF or SH on the Social Impact Log CRF, AE Log CRF or other applicable site-specific document. The qualitative interviewer will not be involved in the assessment or reporting beyond notifying the clinical site of the participant's report. The qualitative interviewer will not disclose to clinic staff the details of what was discussed during the interview beyond the brief mention of the suspected AE or SH reported.

10.5 Qualitative Data Management

10.5.1 Audio Files

The audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer off site (UPenn or Columbia). The audio recording will be completely separate from the computer videoconference (that is not recorded).

Audio files generated by the in-depth interviews will be transcribed and translated into English by the interviewers at Columbia University. Once the transcripts are cleaned and final, both the transcripts and the interview summary sheets will be electronically transferred to the central study team at the University of Pennsylvania using a secure File Transfer Protocol site, where they will be uploaded and managed using a qualitative software package. The qualitative data from MTN-035 will include the IDI transcripts and the summary sheets detailing major points of interest regarding acceptability and adherence from each interview. The research team at the University of Pennsylvania will manage all qualitative data for the study. A convention for file naming will be developed, and all data will be labeled according to this process. The research team will save all versions of the files on a secure, password-protected server.

10.5.2 Transcription

The audio recordings will be transcribed at the University of Pennsylvania and Columbia University. Transcripts will be transmitted over a secure FTP site provided by the transcription agency.

Members of the behavioral data team will review each transcript for transcription errors. A designated staff member (BRWG Project Managers) will review the corrected areas and deem the issue resolved or will follow up as needed until all necessary changes are made.

Once the team finds no additional issues, changes will be accepted and finalized in the transcript. Transcripts from non-English speaking participants will then be translated into English by the interviewers.

10.5.3 Data Tracking

A Qualitative Data Tracking Log will be completed to maintain record of each audio file and transcript that is submitted along with details regarding the submission date, query status, and finalization date.

10.5.4 Special Cases and Technical Issues

10.5.4.1 Technical Problems Preventing CASI Completion

In the event of technical problems (e.g., server or power outage) that would preclude a participant's ability to complete a CASI questionnaire online, hard copy versions of CASI questionnaires will not be available. These unique circumstances should be documented in the participant's chart notes and a brief description recorded on the applicable CRF (i.e., Enrollment, Follow-up CASI Tracking).

10.5.4.2 Interrupted Visits

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 during the visit. If a participant is

interrupted and does not complete a CASI questionnaire in one sitting, based on site staff judgment and length of interruption, the participant may complete the CASI questionnaire later as long as it is **during the same visit window**. In the case of a split visit, the CASI may be completed on any day a participant is at the clinic during the same visit from the beginning.

If participants need to interrupt their computer sessions (e.g., 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 off, as long as the survey window remains open.

10.5.4.3 Management of Errors on CASI

Once a CASI questionnaire is completed, no one can change the responses or administrative fields, including site staff. If site staff notes any errors on the administrative section (or by participants on the questionnaire section), notify the CASI troubleshooting team via email at mtn035casi@mtntestshiv.org. Please include the following information in the message text: CASI ID, date, visit code, the name of the CASI questionnaire, and a description of the error/screenshot. Also, to facilitate the troubleshooting process, please indicate in the email a description of the problem, including a copy of the error message(s), if any, and the date and time that 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 in the participant's chart. mtn035casi@mtntestshiv.org. Please include the following information in the message text: CASI ID, date, visit code, the name of the CASI questionnaire, and a description of the error/screenshot. Also, to facilitate the troubleshooting process, please indicate in the email a description of the problem, including a copy of the error message(s), if any, and the date and time that 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 in the participant's chart.

10.6 Staff Training

CASI

Site staff assisting participants with CASIs are required to complete at least two practice sessions for each instrument.

For testing, please access questionnaires through the websites indicated in Appendix 10-1. The following test CASI IDs should be used:

Pitt Test CASI IDs	UAB Test CASI IDs	San Fran Test CASI IDs	San Miguel Test CASI IDs	Blantyre Test CASI IDs	Chiang Mai Test CASI IDs	Wits Test CASI IDs

Upon completion of testing at the site, an email should be sent to the MTN-035 CASI alias mtn035casi@mtntestshiv.org indicating, the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered. In the event problems

are encountered during testing, the team will work to resolve any issues as soon as possible. After the change has been made and the issue is resolved, the site will be notified to test the CASI survey again to ensure the problem is resolved. This process will be repeated to full resolution of the problem and prior to approving site readiness for behavioral requirements. mtn035casi@mtnstopshiv.org indicating, the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered. In the event problems are encountered during testing, the team will work to resolve any issues as soon as possible. After the change has been made and the issue is resolved, the site will be notified to test the CASI survey again to ensure the problem is resolved. This process will be repeated to full resolution of the problem and prior to approving site readiness for behavioral requirements.

SMS

Site staff assisting participants with SMS are required to complete at least the initial setup and practice session to understand the process.

IDI

Site staff assisting participants with the IDIs will be instructed in the use of the BlueJeans video conference system. Prior to conducting any IDI at a site, the qualitative interviewer will assist site staff in setting up any software required to use BlueJeans on the interview computer and will instruct staff on how to connect participants to a video for the IDIs. Site staff will participate in a brief mock interview with the qualitative interviewer to ensure that the video system is operating correctly.

Prior to conducting any IDIs, clinic staff and the qualitative interviewer will be trained on the procedures for documenting and following up on reports of potential adverse events (AEs) or social harms that participants may report during the IDIs. The qualitative interviewer will be trained on the appropriate DAIDS procedures for safety reporting and file maintenance.

Section Appendix 10-1.1

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS (US Sites ONLY)

- Prior to starting a questionnaire, make sure that the computer, Internet, keyboard and mouse are connected and working properly.
- Ensure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding questionnaire:

Baseline Questionnaire (Enrollment Visit)

- www.ssharp.org/MTN035/baseline

Baseline Questionnaire (Redo)

- www.ssharp.org/MTN035/baseline_redo

PUEV Insert Follow-up Questionnaire

- www.ssharp.org/MTN035/PUEVinsert

PUEV Suppository Questionnaire

- www.ssharp.org/MTN035/PUEVsuppository

PUEV Douche Follow-up Questionnaire

- www.ssharp.org/MTN035/PUEVdouche

Visit 8 Conjoint Analysis Questionnaire

- www.ssharp.org/MTN035/conjointanalysis

- Ensure that the participant is comfortable with using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's CASI ID to enter the questionnaire.
- Re-Enter participant's CASI ID
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire).
- 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 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, s/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, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 10-1.2

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS (San Miguel Site ONLY)

- Prior to starting a questionnaire, make sure that the computer, Internet, keyboard and mouse are connected and working properly.
- Ensure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding questionnaire:

Baseline Questionnaire (Enrollment Visit)

- www.ssharp.org/MTN035/715/baseline

Baseline Questionnaire (Redo)

- www.ssharp.org/MTN035/715/baseline_redo

PUEV Insert Follow-up Questionnaire

- www.ssharp.org/MTN035/715/PUEVinsert

PUEV Suppository Questionnaire

- www.ssharp.org/MTN035/715/PUEVsuppository

PUEV Douche Follow-up Questionnaire

- www.ssharp.org/MTN035/715/PUEVdouche

Visit 8 Conjoint Analysis Questionnaire

- www.ssharp.org/MTN035/715/conjointanalysis

- Ensure that the participant is comfortable using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's CASI ID to enter the questionnaire.
- Re-enter participant's CASI ID
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire).
- 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, s/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, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 10-1.3

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS (Chiang Mai Site ONLY)

- Prior to starting a questionnaire, make sure that the computer, Internet, keyboard and mouse are connected and working properly.
- Ensure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding questionnaire:

Baseline Questionnaire (Enrollment Visit)

- www.ssharp.org/MTN035/791/baseline

Baseline Questionnaire (Redo)

- www.ssharp.org/MTN035/791/baseline_redo

PUEV Insert Follow-up Questionnaire

- www.ssharp.org/MTN035/791/PUEVinsert

PUEV Suppository Questionnaire

- www.ssharp.org/MTN035/791/PUEVsuppository

PUEV Douche Follow-up Questionnaire

- www.ssharp.org/MTN035/791/PUEVdouche

Visit 8 Conjoint Analysis Questionnaire

- www.ssharp.org/MTN035/791/conjointanalysis
- Ensure that the participant is comfortable using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's CASI ID to enter the questionnaire.
- Re-enter participant's CASI ID
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire).
- 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, s/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, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 10-1.4

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS (Blantyre Site ONLY)

- Prior to starting a questionnaire, make sure that the computer, Internet, keyboard and mouse are connected and working properly.
- Ensure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding questionnaire:

Baseline Questionnaire (Enrollment Visit)

- www.ssharp.org/MTN035/760/baseline

Baseline Questionnaire (Redo)

- www.ssharp.org/MTN035/760/baseline_redo

PUEV Insert Follow-up Questionnaire

- www.ssharp.org/MTN035/760/PUEVinsert

PUEV Suppository Questionnaire

- www.ssharp.org/MTN035/760/PUEVsuppository

PUEV Douche Follow-up Questionnaire

- www.ssharp.org/MTN035/760/PUEVdouche

Visit 8 Conjoint Analysis Questionnaire

- www.ssharp.org/MTN035/760/conjointanalysis

- Ensure that the participant is comfortable using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's CASI ID to enter the questionnaire.
- Re-enter participant's CASI ID
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire).
- 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, s/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, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 10-1.5

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS (Wits Site ONLY)

- Prior to starting a questionnaire, make sure that the computer, Internet, keyboard and mouse are connected and working properly.
- Ensure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding questionnaire:

Baseline Questionnaire (Enrollment Visit)

- www.ssharp.org/MTN035/805/baseline

Baseline Questionnaire (Redo)

- www.ssharp.org/MTN035/805/baseline_redo

PUEV Insert Follow-up Questionnaire

- www.ssharp.org/MTN035/805/PUEVinsert

PUEV Suppository Questionnaire

- www.ssharp.org/MTN035/805/PUEVsuppository

PUEV Douche Follow-up Questionnaire

www.ssharp.org/MTN035/805/PUEVdouce

Visit 8 Conjoint Analysis Questionnaire

- www.ssharp.org/MTN035/805/conjointanalysis
- Ensure that the participant is comfortable using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's CASI ID to enter the questionnaire.
- Re-enter participant's CASI ID
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions (Baseline Questionnaire).
- 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, s/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, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 10-2

QUICK TIPS FOR IN-DEPTH INTERVIEW

Scheduling

- Schedule IDI in Google calendar:
 - **Google calendar site:** google.com/calendar
 - **Site Login email:**
 - Pittsburgh: pittsburghmtn035@gmail.com
 - UAB: alabamamtn035@gmail.com
 - San Fransico:bridgemtn035@gmail.com
 - Lima: sanmiguelmtn035@gmail.com
 - Chiang Mai: cmumtn035@gmail.com
 - Blantyre: blantyretn035@gmail.com
 - Johannesburg: witsmtn035@gmail.com

Password for all sites (case sensitive): microbicides035

Site staff will be able to see conflicts in scheduling between each site.

- Interviewer will confirm the appointment via email.
- Notify interviewer of all changes or cancellations within 24 hours of the scheduled appointment, if possible.
- If last-minute changes do occur, please notify interviewer as soon as possible, by phone or text message.

Preparing for Interview

- Ensure that the computer with a webcam is available in a private space and has a phone that is operational. If privacy is guaranteed at the site, participants may use the speakerphone function.
- Ensure that the video system is ready and connected.
- Once the participant is ready to begin, notify the interviewer by phone.

Initiating the Video Interview

- Connect to BlueJeans and call BRWG interviewer.
- Once the connection is established and the video feed is running, click to enlarge the video window.
- Help the participant get set up and with phone/speakerphone.
- Leave the room and close the door.

Ending the Video Interview

- Participant will notify you when the interview is done.
- Disconnect from the meeting.

Section Appendix 10-3
CONTACT INFORMATION FOR IN-DEPTH INTERVIEW SCHEDULING
AND ADVERSE EVENT/SOCIAL HARMS REPORTING TO CLINICAL SITES

In-Depth Interview (UPenn)

Primary Contact: Ryan Tingler

Phone: 215-898-5519

Email: rtingler@upenn.eduIn-Depth Interview (Columbia)

Secondary Contact: Rebecca Giguere

Phone: 646-774-6943

Email: Rebecca.giguere@nyspi.columbia.edu

For last minute changes to scheduling or to notify interviewer that participant is ready, call listed phone number. For non-urgent matters and advanced scheduling, use email.

To Report Potential Adverse Events (AEs) or Social Harms (SH) reported during the IDI:

Site	Contact Name	Phone Number	Email