

Section 11. Behavioral Measures

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The behavioral assessments of the MTN-026 protocol will be collected via web-based Computer Assisted Self-Interviews (CASI) and an In-Depth Interview (IDI). This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of such assessments.

11.1 Overview

CASI computer interviews are source documentation and must be maintained in accordance with the guidelines for other study documentation. Table 1 outlines the timing (by study visit) and mode (by instrument) each behavioral assessment should be completed. The purpose of these assessments is to understand participant’s motivation to join the trial, their rectal practices, menstrual practices, pregnancy history, contraception use, sexual behavior, substance use, product acceptability, and concerns about the Dapivirine gel.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Visit
Baseline	CASI	Enrollment (Visit 2)
Follow-up	CASI	Visit 3
Exit	CASI	Visit 14
In-Depth Interview (IDI)	Web Video interview	Visit 3, Visit 14

11.2 Troubleshooting

CASI

For any problems with the computerized CASI questionnaires, either accessing them or completing them, please notify the team immediately by sending an email to the CASI Troubleshooting alias list mtn026casi@mtnstopshiv.org. A group of staff members will be available to assist and troubleshoot any problems with the online questionnaires.

IDI

For any problems with the IDI, either accessing the online video or audio please notify the team immediately by sending an email to the alias list mtn026IDI@mtnstopshiv.org. Staff members will be available to assist and troubleshoot any problems with the online video system for the interview.

11.3 Equipment Requirements and Set-up

CASI

The operations manual of the PC or laptop used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off, etc.). Other questions should be directed to mtn026casi@mtnstopshiv.org.

Each study site must have a desktop or laptop computer connected to the Internet that is for use by the MTN-026 study participants. Select a location for the CASI study computer that is private (i.e. the screen should be out of sight of staff members, but its location should allow study staff to be nearby to answer questions or assess whether the participant is having technical problems). Also, the location should be out of sight of other participants. The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The CASI study computer should be plugged into an AC power source. An external mouse should be connected to the computer unless a reliable wireless connection is used. 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.

Each study site will assign a CASI ID to the participant prior to beginning the CASI. Each site will be provided with a list of available CASI ID's and will be responsible for assigning a CASI ID to a participant. These ID's will follow the participant for each CASI throughout the study. If a participant is unable to complete the survey, email the MTN-026 CASI alias (mtn026casi@mtnstopshiv.org) to determine whether a new CASI ID should be assigned.

IDI

For the IDI, study sites must have a computer connected to the Internet with a video camera and speakers with microphone or headset. 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. The participant should be able to sit comfortably and be seen on the video camera by the interviewer, and be able to see the interviewer on the screen. A neutral background behind the interviewer and the participant is preferable. To allow better viewing of the participant and interviewer, they should not be sitting in front of a bright window or other light that would disrupt the camera.

11.3.1 Keyboard and Mouse Use

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

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

11.4 Data Collection Instruments

11.4.1 Computer Assisted Self-Interview (CASI) questionnaires

11.4.1.1 Baseline Questionnaire

Each participant will complete a Baseline Questionnaire by CASI at the Enrollment Visit prior to randomization. In addition to collecting demographic information, this baseline questionnaire assesses the participant’s motivation to join the trial, their rectal practices, menstrual practices, pregnancy history, contraception use, sexual behavior, substance use, product acceptability, and concerns about the Dapivirine gel. Additionally, participant data will be de-identified because each study site will only provide a number for each participant to the behavioral team conducting CASI and IDI. The behavioral team will only have access to this number, not any identifying information such as the name of the participant.

A staff member will access the following web page for the CASI Baseline Questionnaire: www.ssharp.org/MTN026/baseline and for the Silom site: www.ssharp.org/MTN026/baseline_thai. The staff member will enter the participant’s CASI ID to log in. On the next screen, the staff member will re-enter the CASI ID.

The staff member should provide instructions to participants for using both the keyboard and mouse, as well as moving from page to page to answer questions using the gray arrow buttons at the bottom of the page (not the browser arrows). Initially, the participants will be presented with simple practice questions (e.g., “choose all that apply,” “select one response”). The staff member should verify that participants are comfortable with using the mouse and keyboard, and navigating through the questionnaire. The participants should be given time to complete the practice questions, with assistance as needed. Staff should ensure that the participants understand how to answer questions by ticking boxes or entering numbers, and how to change invalid entries. Invalid entries are those that are not accepted by the program, either because they contradict information that a participant previously entered or because they are not permitted (e.g., numbers that are out of the possible range). Staff should inform the participants

that they can choose to skip a question that they do not want to answer. If participants are unsure of an answer, they should be encouraged to make their best guess rather than to skip. Participants should be informed that they may go back and change answers at any time, using the back arrow. Staff should then remind participants that the staff is available to answer any questions or assist with administration of the computer.

Following the practice questions, participants should be left alone to complete the Baseline Questionnaire. 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 member.

In the rare event the Baseline CASI questionnaire needs to be repeated (i.e. if the participant does not complete all enrollment visit procedures on the same day and needs to be rescheduled), the following link to a repeat questionnaire should be used: for the UAB or Pitt sites www.ssharp.org/MTN026/baseline_redo. For the Silom site, please use the following link: www.ssharp.org/MTN026/baseline_redo_thai

11.4.1.2 Follow-up Survey

At Visit 3, each participant will complete a Follow-Up Questionnaire by CASI, which will cover a subset of the behaviors assessed at baseline. The Follow-Up Questionnaire should be completed before the participant receives any counseling. This questionnaire includes structured questions about recent sexual behavior, rectal practices, menstrual experiences, substance use, and contraception use. The assessment includes additional questions about the participant's attitude related to the rectal gel and use experience since the previous CASI questionnaire.

At the appropriate time, a staff member will access the web page for the Follow-up Questionnaire for the UAB and Pitt sites: www.ssharp.org/MTN026/followup03. For the Silom site, use the following link: www.ssharp.org/MTN026/followup03_thai. The staff member will then double enter the CASI ID, followed by visit code and date. Additionally, the date of the last computer interview will be double entered. Next, participants should be left alone to complete the questionnaire.

At the end of the questionnaire (penultimate screen), a message will appear instructing participants to click the gray arrow pointing to the right to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

11.4.1.3 Exit Questionnaire

At Visit 14, each participant will complete an Exit Questionnaire by CASI following procedures similar to those utilized for the Baseline and Follow-up Questionnaire. The questionnaire will investigate the participant's overall experiences with the study products during the trial, and acceptability, including likes and dislikes, willingness to use in the future, attitudes towards the rectal gel, experiences using the gel (e.g., rectal discomfort, ease of use), and partners' reactions. The participant will answer questions about applying the rectal gel.

At the appropriate time, a staff member will access the Web page for the Exit Questionnaire for UAB or Pitt sites: www.ssharp.org/MTN026/exit. For the Silom site, use the following link

www.scharp.org/MTN026/exit_thai. The staff member will double enter the CASI ID. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

At the end of the questionnaire (penultimate screen), a message will appear instructing the participants to click 'NEXT' if they want to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

11.4.2 In-Depth Interview (IDI)

At Visit 3 and Visit 14, all participants (expected 27 total) across all sites will complete an IDI. The interview will address study Dapivirine gel use and acceptability during the trial. The purpose of this IDI is to ask participants about experiences with product use and participant concerns. It is also used to reflect on the whole experience of study participation and ways in which future trials could be improved. These interviews will be conducted by a trained qualitative interviewer and will follow a semi-structured questionnaire guide and are anticipated to last approximately 45-60 minutes. These interviews will be conducted over the computer by a non-recorded video with the Pittsburgh and Alabama sites. Due to the time difference, participants from the Silom site will only be conducting an IDI via telephone. An audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer (off-site at the University of Pennsylvania) with all sites. The audio from the interview will be recorded and transcribed for analysis.

Through open-ended questions, this interview will explore the participant's overall experiences and feelings using the Dapivirine gel during the trial, including any physical, mental or emotional concerns or experiences he/she/they encountered; his/her/their experiences using the gel; his/her/their and his/her/their partner's attitudes towards the gel, and preferences for HIV prevention.

The staff member should explain that these questions are being asked in person to more thoroughly explore the participant's feelings, and that his/her/their responses will be audio recorded but not video recorded.

11.4.2.1 Scheduling the Interview

When a participant attends his/her/their Visit 2 study coordinators will email the off-site qualitative interviewer to inform her and schedule the video calls. The qualitative interviewer will confirm the appointment via email. 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 interviewer as soon as possible, by phone or email message. Any scheduling changes will be confirmed by email.

The IDI is expected to happen at Visit 3 and Visit 14 and will last approximately 45 minutes to 1 hour. If the qualitative interviewer is not available during the Visit 3 or Visit 14, or if the participant is too tired or unable to continue, the IDI may be rescheduled to Visit 4 or Visit 15, respectively.

To minimize scheduling conflicts between sites, the qualitative interviewer will enter available hours and confirmed appointments in an online calendar (Google calendar) for each site. Study coordinators can view their 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**, go to <https://www.google.com/calendar> and sign in with the account login below, and click on the “Calendar” tab at the top left.

Pittsburgh Site Login

Account email login: pittsburghmtn026@gmail.com

Password (case sensitive): microbicides026

Alabama Site Login

Account email login: alabamamtn026@gmail.com

Password (case sensitive): microbicides026

Silom Community Clinic Site Login

Account email login: silomcommunitymtn026@gmail.com

Password (case sensitive): microbices026

11.4.2.2 Preparing for the IDI

Prior to the IDI, the study coordinators of Pitt or UAB 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 will need to ensure that no information either about the study or the research clinic is in the 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 on study records.

IDI procedures for UAB and Pittsburgh Sites:

- 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
- Go to the downloaded Skype or BlueJeans application and log in
- Make sure that no information either about the study or the research clinic is in the view of the camera
- Make sure that the microphone is disabled
- Call interviewer to inform them that a participant is ready for the IDI
- Check that the video properties are working properly (make adjustments as necessary to the position of the webcam) and that the participant and interviewer can see each other clearly.
- Dial (215)-573-9935 for interviewer
- 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

IDI procedures for Silom Site:

- Make sure that the office where the IDI will be held affords privacy
- Call interviewer (Titcha Ho) to inform them that a participant is ready for the IDI
- Dial +011(347) 280-6405 for Titcha
- 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.

11.4.2.3 Initiating and Conducting the Video Interview

Prior to conducting any video interviews, the interviewer will verify that each 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 Silom site will be connected via a telephone, not a video conferencing system.

The site staff will contact the interviewer to let her know that the participant is ready. The interviewer will initiate a videoconference meeting and send an email invitation to the appointed site staff.

For BlueJeans, click on link in meeting invitation and start video conference.

To sign into Skype for the video interview:

- Go to Skype in Applications
- Enter login information
 - Pittsburgh: pittsburghmtn026@gmail.com: Password: microbicides026
 - Alabama: alabamamtn026@gmail.com; Password: microbicides026

To set up Skype video:

- Run the program
- Verify your settings for the camera and microphone, make sure the video is working and click "Save Changes." The microphone should be disabled for the video teleconferences.
- If it does not work, click on "Troubleshoot your settings."

To initiate a teleconference:

- Double click on UPennMTN or to establish the teleconference
- A screen will pop-up
- Click on the webcam icon that is visible in the bottom of the screen (under the image)
- Once the other person accepts the request, the teleconference is ready to start
- To make the video image larger, place the mouse on the image, and a symbol will appear:  Click on the symbol, and the screen with the video will enlarge.
- Dial (215)-898-5519 for interviewer. Once interviewer answers, hand the phone to the participant.

To exit Skype:

- Click on Sign out
- Quit the Program

11.4.2.4 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. We expect the occurrence of AE or SH reporting during the IDI to be highly unlikely. However, in the rare event a suspected AE or SH is reported during the IDI, the qualitative interviewer will make note of the participants' comment(s) in the interview notes that will be maintained in the participant files at the University of Pennsylvania. The qualitative interviewer will alert the participant that she 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. 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.

11.5 Qualitative Data Management

11.5.1 Audio Files

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

Following the interview or discussion, the audio file should be uploaded onto a password-protected hard drive. The interview recording, along with transcripts, notes and analyses from the in-depth interview will be considered as source documentation. They will be kept securely stored by the University of Pennsylvania for the entire period of study implementation. The audio recordings, notes, and transcripts from these materials will be kept for at least two years after the gel is approved for marketing or two years after all developmental research on the gel is stopped. When destruction of files is permitted, the destruction process will be the responsibility of the University of Pennsylvania study team. The audio recordings will be deleted from the server and a log will be kept noting the file, the date deleted, the signature of the staff responsible for the deletion, and a signature of another team member who witnesses the deletion.

11.5.2 Transcription

The audio recordings will be transcribed at the University of Pennsylvania. 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 (Ryan Tingler and research assistants) 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.

11.5.3 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.

11.5.4 Special Cases and Technical Issues

11.5.4.1 Technical Problems Preventing CASI Completion

In the event of technical problems (i.e. 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 chart notes and a brief description recorded on the applicable CRF (i.e. CASI Tracking Summary and/or CASI Tracking).

11.5.4.2 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, she can 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 (i.e. attend to a call, go to the bathroom), at the discretion of the site staff, they can do so, and resume the CASI where they left it, as long as the survey window remains open.

11.5.4.3 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 for the administrative section (or by participants to the site staff on the questionnaire section), notify the CASI troubleshooting team via email at mtn026casi@mtnstopshiv.org. Please include the following information in the message text: PTID, CASI ID, date, visit code, the name of the CASI questionnaire, and a description of the error. Also, to facilitate the troubleshooting process, please indicate in your email a description of the problem, including a copy of the error message(s), if any, and date and time of when the problem occurred. The CASI troubleshooting team will assess the problem and communicate with site staff about resolutions. If this occurs, it should be documented in the participant's chart.

11.6 Staff Training

CASI

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

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

Silom Test IDs	Pittsburgh Test IDs	UAB Test IDs
813014	702014	821014
813015	702015	821015
813016	702016	821016
813017	702017	821017

Upon completion of testing at each given site, an email should be sent to the MTN-026 CASI alias mtn026casi@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

IDI

Site staff that will be assisting participants with the IDIs will be instructed in the use of the Skype or BlueJeans videoconference system. Prior to conducting any IDI at a site, the qualitative interviewer will assist site staff in setting up any software required to use Skype or 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 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 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 11-1
QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS

- Prior to starting a questionnaire, make sure that the computer; Internet connection, keyboard and mouse are connected and working properly.
- Make sure that the participant is comfortable and has privacy to ensure the confidentiality of responses.
- Start the questionnaire by typing the web address to the corresponding Questionnaire:
Baseline Questionnaire (Enrollment Visit)
 - UAB or Pitt: www.ssharp.org/MTN026/baseline.
 - Silom site : www.ssharp.org/MTN026/baseline_thai

- Follow-up Questionnaire (Visit 3)
 - UAB or Pitt: www.ssharp.org/MTN026/followup03
 - Silom site: www.ssharp.org/MTN026/followup03_thai

- Exit Questionnaire (Visit 14/Early Termination Visit)
 - UAB or Pitt: www.ssharp.org/MTN026/exit
 - Silom site: www.ssharp.org/MTN026/exit_thai

- Make sure 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.
- Enter or select: 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, she can complete the CASI questionnaire later as long as it is **during the same visit**. However if the computer window is closed before the CASI is completed, she will need to start a **new** CASI survey from the beginning.

Section Appendix 11-2
QUICK TIPS FOR IN-DEPTH INTERVIEW

Scheduling

- Schedule IDI in Google calendar:
 - **Google calendar site:** google.com/calendar
 - **Login email:**
For Pittsburgh: pittsburghmtn026@gmail.com
For UAB: alabamamtn026@gmail.com
For Silom: silomcommunitymtn026@gmail.com
 - **Password for all sites (case sensitive):** microbicides026
- Interviewer will indicate available hours in calendar and site staff will be able to see conflicts in scheduling between each site.
- Each site should add their appointment with their assigned colors as follows:
 - University of Alabama: Blue
 - Pittsburgh: Red
 - Silom: Green
- 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 the computer with a webcam is available in a private space, and has a phone that is operational. If privacy is guaranteed at site, participant may use the speakerphone function.
- Ensure the video system is ready and connected.
- Once participant is ready, notify interviewer by phone.

Initiating the Video Interview

- Interviewer will initiate a meeting by sending an email to the designated site staff.
- Click on the link in the email to join the meeting, log into the meeting, click join via computer, and turn on the video feed.
- 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 11-3
CONTACT INFORMATION FOR IN-DEPTH INTERVIEW SCHEDULING
AND ADVERSE EVENT/SOCIAL HARMS REPORTING TO CLINICAL SITES

In-Depth Interview (University of Pennsylvania)

Primary Contact: Ryan Tingler, Phone: 215-898-5519 Email: rtingler@upenn.edu

Thai Interview Contact: Titcha Ho, Phone:734-764-4647 Email: kedsri@gmail.com

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:

University of Alabama

Primary contact: Shay Warren, phone: (205) 975-8657, email: swarren@uabmc.edu

Back up contact: Megan Tilley, phone: (205) 975-8586, email: mlansdon@uabmc.edu

Pittsburgh

Primary contact: Stacey Edick, phone: 412-383-1482, email: edicksm2@upmc.edu

Back up contact: Danielle Camp, phone: 412-624-5734, email: campdm@upmc.edu

Silom Community Clinic

Primary contact: Dr. Chaiwat Ungsedhapand (Chaiwat), phone:+66 81 850 4343, email: vis1@cdc.gov

Back up contact: Pikunchai Luechai (O) phone: +66 85 123 8730, email: hqc6@cdc.gov