Section 11. Behavioral Measures

11.   Introduction

The behavioral assessments of the MTN-033 protocol will be collected via web-based Computer Assisted Self-Interviews (CASI) and In-Depth Interviews (IDI). This section contains information about the necessary preparation, equipment and process for participant completion of such assessments.

11.1   Overview

CASIs 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' motivations to join the trial, their rectal practices, sexual behaviors, Pre-Exposure Prophylaxis (PrEP) use, substance use, opinions surrounding product acceptability, and concerns about the dapivirine gel and applicator, and coital simulation device.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Visit
Baseline	CASI	Enrollment (Visit 2)
Visit 3 Follow-up	CASI	Visit 3
Visit 5 Follow-up	CASI	Visit 5
In-Depth Interview (IDI)	Web Video interview	Visit 3, Visit 5

11.2   Troubleshooting

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 mtn033casi@mtnstopshiv.org. Staff will be available to assist and troubleshoot any problems with the online questionnaires.

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 mtn033IDI@mtnstopshiv.org. Staff will be available to assist with 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 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 (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-033CASI Troubleshooting email alias (mtn033casi@mtnstopshiv.org).

The study site must have a desktop or laptop computer connected to the Internet that is for use by the MTN-033 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. The 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.

IDI
For the IDI, the study site must have a computer connected to the Internet with a video camera and access to a telephone. 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 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 before the ID commences.

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.

The staff member should provide instructions to participants for using both the keyboard and mouse, as well as moving from page to page to answer questions using the "next" 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.

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, sexual behavior, substance use, opinions surrounding product acceptability, concerns about the dapivirine gel and applicator, and coital simulation device. Additionally, participant data will be de-identified because the study site will only provide a number for each participant to the behavioral team conducting CASIs and IDIs. The behavioral team will only have access to this number, not any identifying information such as the name of the participant.

A staff member from the behavioral team will access the following web page for the CASI Baseline Questionnaire: www.scharp.org/MTN033/baseline. The staff member will enter the CASI ID admin information to log in.

Initially, the participants will be presented with simple practice questions (e.g., "choose all that apply," "select one response"). 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 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 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.

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 sites www.scharp.org/MTN033/baseline_redo.

11.4.1.2 Visit 3 Follow-up Survey

At Visit 3, each participant will complete a Visit 3 Follow-Up Questionnaire by CASI, which will cover a subset of the behaviors assessed at baseline. The Visit 3 Follow-Up Questionnaire should be completed before the participant receives any counseling. This questionnaire includes structured questions about recent sexual behavior, rectal practices, Pre-Exposure Prophylaxis (PrEP) use, and substance use. The assessment includes additional questions about participants' attitudes related to the rectal gel, applicator/coital simulation device and use experience since the previous CASI questionnaire.

At the appropriate time, a staff member will access the web page for the Visit 3 Follow-up Sequence A: www.scharp.org/MTN033/followupv3a and Visit 3 Follow-up Sequence B: www.scharp.org/MTN033/followupv3b. The staff member will then double enter the CASI ID. 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 "Next" button 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 Visit 5 Follow-Up Questionnaire

At Visit 5, each participant will complete a Visit 5 Follow-Up Questionnaire by CASI following procedures similar to those utilized for the Baseline and Visit 3 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 it in the future, attitudes towards the rectal gel, experiences using the gel (e.g., rectal discomfort, ease of use), and partners' reactions. Participants will answer questions about applying the rectal gel, as well as the use and acceptability of the applicator or coital simulation device.

At the appropriate time, a staff member will access the web page for the Visit 5 Sequence A: www.scharp.org/MTN033/followupv5a and Visit 5 Follow-up Sequence B: www.scharp.org/MTN033/followupv5b. 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 questionnaire (penultimate screen), a message will appear instructing participants to click the arrow facing to the left if they want 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.

11.4.2   In-Depth Interview (IDI)

At Visit 3 and Visit 5, all participants (expected 16 total) will complete an IDI. The interview will address study dapivirine gel and applicator/coital simulation device 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; they are anticipated to last approximately 45-60 minutes. These interviews will be conducted over the computer by a non-recorded, muted video and a 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). The audio from the interview will be recorded and transcribed for analysis. The interview notes, recording and transcript from the in-depth interview will be considered as source documentation.

Through open-ended questions, the interview will explore the participant's overall experiences and feelings about using the dapivirine gel and applicator/coital simulation device during the trial, including any physical, mental or emotional concerns or experiences encountered; experiences using the gel; partner attitudes towards the gel and applicator/coital simulation device, and preferences for HIV prevention.

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

11.4.2.1 Scheduling the Interview

When a participant attends their 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. 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.

The IDI is expected to happen at Visit 3 and Visit 5 and will last approximately 45 minutes to 1 hour. If the qualitative interviewer is not available during Visit 3 or Visit 5, or if the participant is too tired or unable to continue, the IDI may be rescheduled at Visit 4 or Visit 6, 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 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**, 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.

Site Login

Account email login: pittsburghmtn033@gmail.com
Password (case sensitive): microbicides033

11.4.2.2 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 on 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 UPenn 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 (UPenn Project Manager) 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, as necessary, to the position of the webcam) 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

11.4.2.3 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 and send an email invitation to the appointed site staff.

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. 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. 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 in chart notes or other site-specific documents. 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 (UPenn). The audio recording will be completely separate from the computer videoconference (that is not recorded).

Following the interview or discussion, the audio file should be uploaded onto a password protected hard drive. Audio files of IDIs will be destroyed following finalization of transcripts (transcript finalization process described below). 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.

The audio recording, notes, transcripts and analyses 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.

11.5.2 Transcription

Transcriptions of interviews will be generated using the audio files recorded at University of Pennsylvania. Both the audio files and the transcripts will be uploaded and managed using a qualitative software package. Interview notes will be kept at UPenn in the participant files.

Members of the behavioral data team will review each transcript for transcription errors. A designated staff member (UPenn Project Manager) 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 (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 <u>not</u> be available.

These unique circumstances should be documented in the chart notes and a brief description recorded on the applicable CRF (i.e., Enrollment, Follow-up 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 the participant 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 (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.

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 mtn033casi@mtnstopshiv.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 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 two practice sessions for each instrument.

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

Test CASI IDs
702056
702057
702058
702059
702060

Upon completion of testing at the site, an email should be sent to the MTN-033CASI alias mtn033casi@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.

IDI

Site staff assisting participants with the IDIs will be instructed in the use of the 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 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 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
<u>QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS</u>

- Prior to starting a questionnaire, make sure that the computer; Internet connection, 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.scharp.org/MTN033/baseline

  Baseline Questionnaire (Redo)
  - www.scharp.org/MTN033/baseline_redo

  Visit 3 Follow-up Questionnaires .
  - Sequence A (http://www.scharp.org/MTN033/followupv3a/)
  - Sequence B (http://www.scharp.org/MTN033/followupv3b/)

  Visit 5 Follow-up Questionnaires
  - Sequence A (www.scharp.org/MTN033/followupv5a/)
  - Sequence B (http://www.scharp.org/MTN033/followupv5b/)

- 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.
- 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, 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 11-2
QUICK TIPS FOR IN-DEPTH INTERVIEW

Scheduling

- Schedule IDI in Google calendar:
  - **Google calendar site**: google.com/calendar
  - **Login email**:
    For Pittsburgh: pittsburghmtn033@gmail.com
    Password for all sites (case sensitive): microbicides033
    Interviewer will indicate available hours in calendar and 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 <u>as soon as possible, by phone or text message.</u>

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 site, participant 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 UPenn 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 11-3
CONTACT INFORMATION FOR IN-DEPTH INTERVIEW SCHEDULING
AND ADVERSE EVENT/SOCIAL HARMS REPORTING TO CLINICAL SITES

<u>In-Depth Interview (UPenn)</u>
Primary Contact: Ryan Tingler Phone: 215-898-5519 Email: rtingler@upenn.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:

<u>Pittsburgh</u>
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