

Section 7. Behavioral Measures

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7. Introduction

The behavioral assessments of the MTN-037 protocol will be collected via web-based self-interviews (WSI) using 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.

7.1 Overview

CASI computer interviews are source documentation and must be maintained in accordance with the guidelines for other study source 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, sexual behavior, Pre-Exposure Prophylaxis (PrEP) use, substance use, product acceptability, and concerns about the PC-1005 gel and applicator.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Visit
Baseline	CASI	Enrollment (Visit 2)
Follow-Up 1	CASI	Visit 3
Follow-Up 2	CASI	Visit 5
Follow-Up/Exit	CASI	Visit 7
In-Depth Interview (IDI)	Web Video interview	Visit 8

7.2 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 mtn037wsi@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 mtn037IDI@mtnstopshiv.org. Staff members will be available to assist and troubleshoot any problems with the online video system for the interview.

7.3 Equipment Requirements and Set-up

CASI

The operations manual of the PC/laptop/tablet used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the device (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-037 Troubleshooting email alias (mtn037wsi@mtnstopshiv.org).

Each study site must have a PC/laptop/tablet connected to the Internet for use by the MTN-037 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 device should be plugged into an AC power source. An external mouse should be connected to the computer unless a reliable wireless mouse 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 device 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-037 CASI alias (mtn037casi@mtnstopshiv.org) to determine whether a new CASI ID should be assigned.

IDI

For the IDI, study sites must have a PC/laptop/tablet connected to the Internet with a video camera and speakers or telephone 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.

7.3.1 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.

7.4 Data Collection Instruments

7.4.1 Computer Assisted Self-Interview (CASI) questionnaires

7.4.1.1 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 PC-1005 and applicator. 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.scharp.org/MTN037/baseline. The staff member will enter the 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 "next" or "previous" buttons (not the browser arrows). Initially, the participants will be presented with simple practice questions (e.g., "choose all that apply," "select one response"). The staff member should verify that participants are comfortable with using the mouse and keyboard, and navigating through the questionnaire. The participants should be given time to complete the practice questions, with assistance as needed. Staff should ensure that the participants understand how to answer questions by ticking boxes or entering numbers, and how to change invalid entries. Invalid entries are those that are not accepted by the program, either because they contradict information that a participant previously entered or because they are not permitted (e.g., numbers that are out of the possible range). Staff should inform the participants that they can skip questions they do not want to answer. 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 www.scharp.org/MTN037/baseline_redo.

Prior to study start, staff who will be present during the CASI administration should review the content of the CASI questionnaires to ensure they understand the meaning, purpose, and intent of each question and its responses. Staff should become familiar with the questions to ensure that they feel confident explaining questions to participants who request assistance in the interpretation of a CASI question.

7.4.1.2 Follow-up Survey

At Visits 3, 5, and 7, 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 anytime after gel administration during the follow-up visit. 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 the participant's attitude related to the rectal gel and applicator and use experience since the previous CASI questionnaire.

At the appropriate time, a staff member will access the web page for the Follow-up at the following links:

- Follow-up Questionnaire (Visit 3)
 - <http://www.scharp.org/MTN037/visit3/>
- Follow-up Questionnaire (Visit 5)
 - <http://www.scharp.org/MTN037/visit5/>
- Follow-up/Exit Questionnaire (Visit 7)
 - <http://www.scharp.org/MTN037/visit7/>

The staff member will then double enter the CASI ID. 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 "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.

7.4.2 In-Depth Interview (IDI)

At Visit 8, all participants (expected 12 total) will complete an IDI. The interview will address PC-1005 and applicator 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. Participants provide consent to be audio recorded as part of the main study consent, however, they may change their mind and decline to be recorded. Participants who do not agree to be audio recorded will not be able to participate in the IDI, and this should be documented in the chart notes

Through open-ended questions, this interview will explore the participant's overall experiences and feelings using the PC-1005 and applicator during the trial, including any physical, mental or emotional concerns or experiences he or she encountered; his or her experiences using the gel; his/her/their and his/her/their partner's attitudes towards the gel and applicator, 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.

7.4.2.1 Scheduling the Interview

When a participant attends his/her/their Visit 2, study coordinators will email the off-site qualitative interviewer to inform them 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 8 and will last approximately 45 minutes to 1 hour. If the qualitative interviewer is not available during the Visit 8, or if the participant is too tired or unable to continue, the IDI may be scheduled at an interim visit any time prior to study exit.

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.

Site Login

Account email login:

Pittsburgh:

pittsburghmtn037@gmail.com

Alabama:

alabamamtn037@gmail.com

Password (case sensitive): microbicides037

7.4.2.2 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 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:

- 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 University of Pennsylvania (UPENN) project manager.
- 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 him that a participant is ready for the IDI at the number provided in confirmation email.
- 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 number provided in confirmation email 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

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

7.4.2.4 Safety Reporting

As required by DAIDS safety reporting policies, any potential reportable Adverse Event (AE), Social Harm (SH), or protocol deviation (PD) described by a study participant during the IDI will be brought to the attention of the clinical staff. We expect the occurrence of potential AE, SH, or PD notification during the IDI to be highly unlikely. However, in the rare event a suspected AE, SH, or PD is described 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 UPenn. The qualitative interviewer will then alert the clinic staff immediately after the IDI (by phone) that the participant described an AE, SH or PD. If the appropriate clinic staff are not available, the interviewer will contact them the next business day. The clinic staff will document the notification in chart notes. Clinic staff will follow up with the participant to assess the AE, SH, or PD as needed and report/document the AE or SH on the AE Log CRF or the PD on the Protocol Deviation CRF. The qualitative interviewer will not be involved in the assessment or reporting beyond notifying the clinical site of the participant's account.

7.5 Qualitative Data Management

7.5.1 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. The IDI source recordings, along with transcripts, notes, and analyses will be kept securely stored by UPenn for entire period of study implementation. Thereafter, instructions for record storage will be provided by DAIDS. The destruction process will be the responsibility of the UPenn 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.

7.5.2 Transcription

The audio recordings will be transcribed at the University of Pennsylvania.

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.

When an IDI is conducted, notes will be taken during each session to supplement the audio recording (or replace, if the recording doesn't work). Immediately following the IDI, the interviewer reviews the guide, and adds or expands on notes and comments as needed. Interview notes will be filed in participant files in the UPenn offices that will be stored in a locked cabinet.

Once the team finds no additional issues, changes will be accepted and finalized in the transcript.

7.5.4 Data Tracking

A Qualitative Data Tracking Log housed at UPenn 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.

7.5.4 Special Cases and Technical Issues

7.5.4.1 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. Enrollment, Follow-up CASI Tracking).

7.5.4.2 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, he/she/they 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.

7.5.4.3 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 mtn037wsi@mtntstopshiv.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. 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.

7.6 Staff Training

CASI

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

For testing, please access questionnaires through the websites indicated above in section 7.4.1. The following test CASI IDs should be used:

Test CASI IDs PITT	Test CASI IDs UAB
702025	821025
702026	821026
702027	821027
702028	821028
702029	821029
702030	821030

Upon completion of testing at each given site, an email should be sent to the MTN-037 CASI alias mtn037wsi@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, unless determined otherwise.

IDI

Site staff that will be 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 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.

Appendix 7-1

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)
www.scharp.org/MTN037/baseline
 - Follow-up Questionnaire (Visit 3)
<http://www.scharp.org/MTN037/visit3/>
 - Follow-up Questionnaire (Visit 5)
<http://www.scharp.org/MTN037/visit5/>
 - Follow-up/Exit Questionnaire (Visit 7)
<http://www.scharp.org/MTN037/visit7/>
- 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.

Appendix 7-2

QUICK TIPS FOR IN-DEPTH INTERVIEW

Scheduling

- Schedule IDI in Google calendar:
 - **Google calendar site:** google.com/calendar
 - Login email:

For Pittsburgh: pittsburghmtn037@gmail.com

For Alabama: alabamamtn037@gmail.com

Password for all sites (case sensitive): microbicides037

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 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

- 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.

Appendix 7-3

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.edu

Secondary Contact: Omar Bruce, Phone: 215-646-8218 Email: obruce@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:

Pittsburgh

Primary contact: Carol Mitchell, phone: 412-383-1292, email: mitchellcl@upmc.edu

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

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