

Section 6. Behavioral Measures

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6. Introduction

This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the Computer Assisted Self-Interview (CASI) behavioral assessments, the qualitative In-Depth Interview (IDI), and the behavioral CRF questions. The behavioral assessments of the MTN-036/ IPM 047 protocol will be collected via CASI questionnaires, an IDI and CRFs (see SSP Section 12 Data Management).

6.1 Overview

Table 1 lists the behavioral assessments, mode of administration, and schedule. CASI assessments and IDI audio files and transcripts are source documentation and must be maintained in accordance with the guidelines for other study documentation.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

| Questionnaire | Mode of Administration | Participant | Visit |
|--------------------------|------------------------|--------------|---|
| Baseline | CASI | All | Visit 2 (Enrollment) |
| Visit 8 Follow-Up | CASI | All | Visit 8 (Day 28) |
| Visit 9 Follow-Up | CASI | All | Visit 9 (Day 56) |
| Exit | CASI | All | Visit 10 (Day 91) PUEV Visit or Early Termination Visit |
| In Depth Interview (IDI) | Web Video interview | ~12 per site | Visit 10 (Day 91) PUEV Visit or Early Termination Visit or Final Contact Visit or a separately-scheduled time between PUEV and Final Contact Visits |

6.2 Troubleshooting

CASI

For any problems with the computerized CASI questionnaires, either accessing them or completing them, or with the CASI study computer, please notify the team immediately by sending an email to the CASI Troubleshooting alias list mtn036casi@mtnstopshiv.org.

A group of staff members will be available to assist and troubleshoot any problems with the CASI questionnaires. They include the following:

- RTI International: Imogen Hawley and Ariane van der Straten
- SCHARP: Tanya Harrell
- FHI 360: Rachel Scheckter and Tara McClure

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 mtn036idi@mtnstopshiv.org.

Staff members will be available to assist and troubleshoot any problems with the online video system for the interview. They include the following:

- RTI International: Imogen Hawley, Mary Kate Shapley-Quinn, and Ariane van der Straten

6.3 Equipment Requirements and Set-up

CASI

The operations manual of the tablet computers 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, inserting memory cards, etc.). The CASI-specific manual should be consulted for instructions on administering the CASI to participants using the software configured by Population Council. Other questions should be directed to the MTN-036 CASI Troubleshooting email alias (mtn036casi@mtnstopshiv.org)

Population Council will ship three tablet computers and one data transfer laptop to each site for use in CASI data collection. Select a location for the CASI 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 and of hearing of other participants while answers are being entered. The CASI tablet computers should be fully charged at the start of each day and plugged in when not in use. 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. Staff members will assist the participant with practice questions at the start of the CASI questionnaire, and will then leave the room once the participant is comfortable with answering the questions using the touch screen.

IDI

For the IDI, each study site must have a computer (either desktop or laptop) connected to the internet via Ethernet cable with a video camera, speakers, microphone or headset. If the computer has Google Chrome software already, no additional plugins are required to use the video conferencing site, BlueJeans, on the browser. If the computer has Firefox, Internet Explorer, or Safari, an additional plugin should be downloaded from BlueJeans.com to support the video calls. 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 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.

6.4 Data Collection Instruments

6.4.1 Computer Assisted Self-Interview (CASI) questionnaires

6.4.1.1 Baseline Questionnaire

Each participant will complete a Baseline Questionnaire by CASI at the Enrollment Visit. This questionnaire may be conducted either before or after randomization, depending on the site-specific clinic flow, but should occur prior to provision of the VR. In addition to collecting demographic information, this baseline questionnaire assesses the participant's motivation to join the trial, recent sexual behavior, vaginal and sexual practices, partner types, condom use, and initial worries about the ring. The assessment includes questions on history of use of vaginal products and behavioral practices.

6.4.1.2 Follow-up Questionnaires

At Visit 8/Day 28 and Visit 9/Day 56 study visits, each participant will complete a CASI behavioral questionnaire, which will cover a subset of the behaviors assessed at baseline.

This questionnaire includes structured questions about recent sexual behavior, as well as the participant's attitude related to the vaginal ring and use experience since the previous CASI questionnaire. The participant will answer questions about inserting and removing the ring (including occurrences of removal voluntary and involuntary expulsion of the ring as well as circumstances surrounding these events). An expanded set of acceptability questions will be asked at Visit 8/Day 28.

6.4.1.3 Exit Questionnaire

At the Day 91 PUEV/Early Termination Visit, each participant will complete an Exit Questionnaire following procedures similar to those utilized for the Baseline and Follow-up Questionnaires. Participants who permanently discontinue study product use early are requested to complete all visit procedures scheduled to occur at the Day 91/PUEV/Early Termination Visit at the visit when study product use is permanently discontinued. Behavioral assessment procedures will be discontinued for the remaining study visits that occur after permanent study product discontinuation.

The Exit Questionnaire will investigate the participant's overall experiences with the study products during the study, and acceptability, including likes and dislikes, willingness to use in the future, attitudes towards the ring, experiences using the ring (e.g., ease of use/removal, displacement), effect on sex, and partners' reactions. Condom acceptability and HIV prevention product preference will also be assessed at that visit.

6.4.1.4 CASI Question Content Review and Staff Comprehension

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 that may be confusing if participants request assistance in the interpretation of a CASI question. During the CASI-specific training, the MTN behavioral team will walk through the questions to explain the content and intent, and will provide written guides posted on the MTN-036 website if staff members are unclear with the meaning of certain CASI questions.

6.4.2 Guidance on Completing CRFs with Behavioral Content

6.4.2.1 Ring Insertion and Removal CRF

The Ring Insertion and Removal CRF documents the insertion and/or removal (as applicable) of the ring at the clinic. The CRF asks whether the participant attempted to insert the ring him/herself or whether a study staff member inserted it. It also contains several questions related to the experience of inserting the ring, including a question on ease or difficulty of correctly placing the ring. The following definitions should be used to quantify the responses:

- Very difficult: 3+ attempts and/or caused pain, severe discomfort
- Difficult: Required 2 attempts and/or caused moderate discomfort
- Easy: Required 1 attempt with some ring repositioning and/or caused mild discomfort
- Very easy: Smooth insertion and positioning in one attempt with no discomfort

After the participant inserts or attempts to insert the ring him/herself, the clinician should ask him/her how their experience was and whether any difficulty or pain was experienced, in order to complete these questions on the CRF. The CRF also documents whether the participant needed help from the clinician to insert the ring, and whether, upon verifying following the insertion process, the ring was inserted correctly by the participant (see SSP section 8.2 for details on verification of correct ring placement). If a participant does not attempt to insert the ring herself, the clinician should insert the ring for the participant and indicate on the CRF that the participant did not attempt to insert the ring and document the reason in chart notes.

6.4.2.2 Ring Adherence CRF

The Ring Adherence Summary CRF and Ring Adherence CRF is completed at Visit 8 (Day 28), Visit 9 (Day 56) and Visit 10 (Day 91/PUEV/Early Termination). This CRF contains questions about reasons for ring removals and expulsions. Note the CASI questionnaires at these visits collect more detailed adherence information about the timing and duration of ring removals and expulsions.

6.4.3 In Depth Interview (IDI)

A subset of approximately 24 randomly selected participants across both sites, (approximately 12 per site) will complete an IDI. See SSP section 12.3.1 for instructions on randomly selecting participants for the IDI. Note that only participants who report having had male sexual partners in the past year will be included in the IDI. Sex with a male partner is defined as having penile-vaginal sex, including with a trans man with a reconstructed penis; this definition will appear on the Medidata site. Given an expectation that the SF Bridge HIV CRS site may enroll fewer women

who have had male partners in the past year than the Alabama CRS site, the IDI randomization will oversample from that site.

The IDI will ideally be conducted at the Visit 10 (Day 91/ PUEV Visit or Early Termination Visit), but may also take place at Visit 11/Final Contact Visit or a separately-scheduled time between PUEV and Final Contact Visits to accommodate participants' schedules. The interview will address study VR use and acceptability during the study. 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. An audio recording will be made with a handheld digital audio recording device that is operated by the qualitative interviewer (off-site at RTI), and a backup recording will be made with audio recording software also operated by the interviewer. In the event of a computer malfunction or lack of internet connectivity, landline telephones will be used for the interview and a recording will be made with the handheld digital audio recording device operated by the interviewer at RTI. The line will be put on speaker and, with the participant's consent, an additional RTI staff member will be present to act as notetaker in case the recording quality is poor.

The audio recording from each interview will be transcribed for analysis. 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. The interviewer will ask for the participant's verbal confirmation of consent prior to commencing the interview. Participants who do not agree to be audio recorded will not be able to participate in the IDI, which should be documented.

Through open-ended questions, this interview will explore the participant's overall experiences and feelings using the ring during the trial, including any physical, mental or emotional concerns or experiences s/he encountered; his/her experiences using the ring; his/her and his/her partner's attitudes towards the ring, including during sexual intercourse, experiences with disclosure of use of the study product, and preferences for HIV prevention.

The off-site interviewer should explain that these questions are being asked to more thoroughly explore the participant's feelings, and that his/her responses will be audio recorded but not video recorded.

6.4.3.1 Scheduling the Interview

Study coordinators will notify the off-site qualitative interviewer by updating a Google calendar as appointments are scheduled at the Enrollment Visit, and inviting mtn036IDI@mtnstopshiv.org to inform him/her of all scheduled interviews, so that he/she can prepare for video calls. The qualitative interviewer will confirm the appointment via email to the sites' study specific Google email addresses with an invitation to the BlueJeans video call for the scheduled date and time. 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 text message. Contact information for the qualitative interviewer is listed in Appendix 6-3. Any scheduling changes will be confirmed by email. RTI staff will ensure that all participants taking part in IDIs have been scheduled by reviewing a report of PTIDs indicating enrollment dates and whether they were randomized and accepted for IDI. This report will be generated by SCHARP on a biweekly basis and posted to the MTN-036 ATLAS website.

To minimize scheduling conflicts between sites, the qualitative interviewer will enter unavailable 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 calendar, 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.

Google calendar site: <https://www.google.com/calendar>

San Francisco Site Login

Account email login: MTN036IDISF@gmail.com

Password (case sensitive): 036IDconnect

UAB Site Login

Account email login: MTN036IDIUAB@gmail.com

Password (case sensitive): 036IDconnect

6.4.3.2 Preparing for the IDI

Before each IDI the following should occur:

Off-site Qualitative Interviewer:

- Ensure the correct version of the guide is ready for use.
- Contact the site to confirm the visit and time of the IDI.
- Ensure the video system is ready and connected and the interviewing space is ready.
- Ensure principal audio recording software is turned on and functioning.
- Ensure backup handheld audio recording device is turned on and functioning.

Site:

- Ensure there is signage on the door indicating an interview is in process and the occupant should not be disturbed.
- Ensure the computer with a webcam is available in a private space, and has a headset with microphone plugged into the computer that is operational. If using a laptop, ensure that the laptop is plugged in.
- Ensure the video system is ready and connected.
- Hand the IDI visual aid inside an envelope to the participant. The site staff should explain to the participant that s/he will be prompted to examine the visual aid at the appropriate time during the video interview.
- Begin the video call.

6.4.3.3 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 any necessary web browser plug-ins are installed on the site’s interview computer.

The site staff will contact the interviewer by call or text to let him/her know that the participant is ready. The interviewer will initiate the scheduled meeting in BlueJeans using the meeting ID provided in the interview date email confirmation. The site staff will click on the link in the email to join the meeting, log into the meeting and turn on the video feed. Once the connection is established and the video feed is running, the site staff will click to enlarge the video window. The site staff should help the participant get set up at the computer with the headset, and provide the IDI visual aid in an envelope. The site staff will then leave the room and close the door.

The interviewer will welcome the participant to the IDI and remind the participant that the session will be audio recorded to make sure his/her words are being recorded exactly as s/he says them. Then the interviewer will start the recording on two devices, and will ask the participant to confirm they agree to be recorded. Following the last question on the IDI, the recording will be stopped. If s/he does not agree to audio recording, s/he will not be able to participate in the IDI.

At the end of the interview, the interviewer should quickly review the guide and his/her notes for completeness and clarify with the participant any unclear parts or gaps in the notes.

Once the interview is done, the interviewer will thank the participant, and ask that s/he bring the site staff back into the room. The interviewer will confirm with the site staff that the IDI has been completed and the interviewer will then end the video meeting.

Then the interviewer will further expand his/her notes (on the same day) to ensure completeness of the information, and complete a Debriefing Report that will be circulated for review to the behavioral qualitative team.

If any participant randomized to the IDI discontinues study participation early, or has a modified Day 91/PUEV Visit, but has completed at least 1 month of the study, s/he may complete the IDI at study exit.

6.4.3.4 Safety and Protocol Deviation Reporting

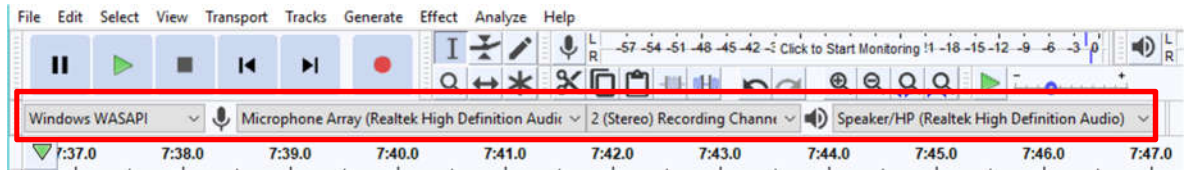
As required by DAIDS safety reporting policies, any potential reportable Adverse Event (AE), Social Harm (SH), or protocol deviation (PD) described by a study participant during the IDI will be brought to the attention of the clinical staff. We expect the occurrence of potential AE, SH, or PD notification 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 RTI. 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.

6.5 Qualitative Data Management

6.5.1 Audio Files

The audio recording will be made with handheld digital audio recording device, and a backup file will be made with a digital audio recording software, both operated by the qualitative interviewer off-site (RTI). The audio recordings will be completely separate from the computer video conference (which is not recorded).

Interviewers should ensure that both sides of the interview are being recorded by having the volume on speaker phone and setting the software audio host to Windows WASAPI; the recording device to microphone; the recording channels to 2 (Stereo); and the playback device to Speaker/HP. The participant should wear a headset to improve quality of the audio recording.



Following the interview or discussion, the audio files from the software and the handheld device will be uploaded onto a secure HIPAA drive at RTI. The source recordings, along with transcripts, notes, and analyses will be kept securely by RTI for at least two years after the vaginal ring is approved for marketing or two years after all developmental research on the vaginal ring is stopped, and then deleted. The destruction of files will be documented with a log maintained by RTI of the date of deletion, names of files, signature of staff responsible for the deletion, and a signature of another team member who witnesses the deletion.

6.5.2 Interview Notes

When an IDI is conducted, the interviewer will take notes 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 RTI offices that will be saved to the secure HIPAA drive accessible only by study staff at RTI.

6.5.3 Debriefing Reports

On the same day as the IDI, the Interviewer should complete a Debriefing Report (DR) which will list basic information about the session and provide a summary report of the interview that can be used within a week to provide feedback to the site and staff. A DR template will be developed by RTI. Debriefing reports must be maintained electronically until final versions are provided by the RTI data team as described below. Debriefing reports must be sent to the data team within 24 hours of the IDI. Refer to section 6.5.5 for qualitative data file naming conventions.

At RTI, the DR will be read and reviewed by data team members and queries will be made on the DR using MS Word's comment feature within **one week** of receipt of the file. The following are examples of queries:

- Problems such as typos that lead to ambiguous meaning (e.g. "sore the medication" vs. "store the medication"), confusing terms or missing /potentially incorrect data
 - Sentences that are unclear
 - Clarification of local terminology or context
- Within **one week**, the Interviewer is asked to correct or clarify any problems identified directly in the DR text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within a reply to the original comment bubble.
 - When the revised information is received, the reviewer, the Qualitative Data Manager or a designated qualitative data team member will review the corrected areas and deem the issue resolved or note that it require further follow up with the Interviewer. This process will continue until all necessary changes are made on the DR.
 - Once RTI finds no additional issues and all queries are resolved, RTI will accept all changes, remove all comment bubbles, PDF, and circulate the final clean DR to the MTN-036/ IPM 047 Management Team with the IoR and Study Coordinator of the site at which the interview took place cc'ed. Sites are to print and file the DR in the interviewee's PTID binder. This final version of the DR will be saved in secure RTI folders and older versions will be archived.

6.5.4 Transcription

The audio recordings will be sent to an external agency for transcription. Transcripts will be transmitted over a secure FTP site provided by the transcription agency. Transcriptionists will redact any proper nouns from the transcribed interviews, and any other content that was not spoken verbatim by the participant or interviewer will be inserted in [brackets]. When a transcript is received back from the transcribing agency, it will undergo the following QC process:

Each transcript will be reviewed by a member of RTI's data team, and queries will be made on the transcript using comment bubbles. The QC may include the identification of the following:

- Problems such as typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data
- Sentences that are unclear
- Clarification of local terminology or context
- Responses to queries will be made by the interviewer by listening to audio recordings if necessary.
- The designated RTI staff member will review the corrected areas and deem the issues resolved or follow up as needed until all necessary changes are made.

Final review of the transcript will happen by either the original reviewer or different data team member. Once the reviewer finds no additional issues they will accept all changes, remove all comment bubbles, and finalize the transcript

6.5.5 File Naming Conventions

All data files should be named according to a standard naming format:
PTID_DataType_DateofInterview.

- Data type: either debriefing report, indicated with "DR," transcript, indicated with "Transcript", or audio file, indicated with "Audio".
- Date of interview: ddMMMyy; i.e. 27OCT17

Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to RTI for review, there is no need to include the editor's initials. It is only upon subsequent review (QCing) that this occurs. For example, when reviewed for the first time, the IDI transcript "**1001_Transcript_18NOV12**" would become "**1001_Transcript_18NOV12_CM**" and "**1001_Transcript_18NOV12_CM_NM**" for the second revision. Once the document is finalized, all initials will be removed from the name and replaced with the word "FINAL."

6.5.6 Data Tracking

A Qualitative Data Tracking Log will be completed by RTI to maintain record of each audio file, DR, and transcript that is submitted along with details regarding the submission date, query status, and finalization date. All source documents will be kept securely on a HIPAA drive, and any hardcopy documents (i.e. interview notes) will be stored in a locked file cabinet accessible only by study staff at RTI.

6.6 Special Cases and Technical Issues

6.6.1 Technical Problems Preventing CASI Completion

In the event of technical problems that would preclude a participant's ability to complete a CASI questionnaire, 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 CASI Tracking CRF.

6.6.2 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, s/he can complete the CASI questionnaire later as long as it is **during the same visit**. In the case of a split visit, the CASI should be completed on any one day of a split visit that a participant is at the clinic.

If participants need to briefly 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. However, if the program is terminated or the survey is exited before the CASI is completed, participants will need to start a **new** CASI questionnaire from the beginning. If participants need to leave the clinic in the middle of the CASI, resulting in a split visit, they must exit the interview and begin a new CASI questionnaire when they resume the visit.

If duplicate CASI questionnaires are present for the same PTID and date, the fully-completed CASI questionnaire will be the one used in study analyses. These unique circumstances should be documented in the clinic chart notes and a brief description recorded on the CASI Tracking CRF.

6.6.3 Management of Errors on CASI

Once a CASI questionnaire is completed, no one can change the responses or administrative fields, including site staff. If errors are noted by site staff for the administrative section (or by participants to the site staff on the questionnaire section), the CASI troubleshooting team should be notified via email at mtn036casi@mtnstopshiv.org. The following information should be included in the message text: PTID, date, visit code, the name of the CASI questionnaire and a description of the error. Also, to facilitate the troubleshooting process, staff should 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 by keeping a record in the participant's file.

6.7 Staff Training

6.7.1 CASI

Prior the enrollment of the first participant, a CASI-specific training will be conducted at each site to review the CASI system, practice the data transfer process, and familiarize staff with question content, in particular any questions that site staff anticipate may be confusing to participants.

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

The following test PTIDs should be used:

| San Francisco Test PTIDs | UAB Test PTIDs |
|--------------------------|----------------|
| 999000018 | 999000112 |
| 999000029 | 999000123 |
| 999000033 | 999000139 |
| 999000041 | 999000147 |
| 999000057 | 999000151 |

| | |
|-----------|-----------|
| 999000065 | 999000164 |
| 999000076 | 999000170 |
| 999000082 | 999000188 |
| 999000090 | 999000196 |
| 999000105 | 999000208 |

Upon completion of testing at each given site, an email should be sent to the MTN-036 CASI alias mtn036casi@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

6.7.2 IDI

Site staff that will be assisting participants with the IDI 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 IDI. Site staff will participate in a mock interview with the qualitative interviewer to ensure the video system is operating correctly. This training may be completed by the qualitative interviewer remotely or in-person.

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 AEs or SHs that participants may report during the IDI. The qualitative interviewer will be trained on the appropriate DAIDS procedures for safety reporting and file maintenance.

Section Appendix 6-1

QUICK TIPS FOR CASI BEHAVIORAL ASSESSMENTS

- Prior to starting a questionnaire, make sure that the tablet computer is turned on and working properly.
- Make sure that the participant is comfortable and has privacy to ensure the confidentiality of his/her responses.
- Make sure that the participant is comfortable with using the tablet computer, including the touch screen.
- Confirm that it is the correct questionnaire.
- Enter participant's ID to enter the questionnaire.
- Enter or select: survey language, visit code, age of respondent, month of visit date, and exact visit date.
- 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 to log in to a new survey. The participants are not finished until they reach this end screen. 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 program is terminated or the survey is exited before the CASI is completed, s/he will need to start a **new** CASI survey from the beginning.

Section Appendix 6-2 QUICK TIPS FOR IN-DEPTH INTERVIEW

Scheduling

- Schedule IDI in Google calendar:
 - **Google calendar site:** <https://www.google.com/calendar>
 - **Login email:**
For UAB MTN036IDIUAB@gmail.com
For San Francisco MTN036IDISF@gmail.com
 - **Password for all sites (case sensitive):** 036IDIconnect

- 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: Red
 - San Francisco: Blue
- Site coordinators should invite mtn036IDI@mtnstopshiv.org to each scheduled appointment on the calendar, listing which arm the participant was randomized to (4/5-week use period or 13-week use period).
- Interviewer will confirm the appointment via email with BlueJeans call information for the time it is scheduled.
- 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 headset with microphone plugged into the computer that is operational.
- Ensure a sign reading “Interview in progress, do not interrupt” is available to post on the door when the room is in use.
- Ensure the video system and digital audio recording software are ready.
- 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 at the computer with the headset.
- Provide the visual aid in an envelope and explain to the participant that he/she will be prompted to open it by the interviewer at the appropriate time.
- Leave the room and close the door.

Ending the Video Interview

- Participant will notify site study staff member when the interview is done.

Interviewer will stop audio recording, disconnect from the meeting, and save audio file to secure HIPAA drive.

Section Appendix 6-3

**CONTACT INFORMATION FOR IN-DEPTH INTERVIEW SCHEDULING
AND ADVERSE EVENT/SOCIAL HARMS REPORTING TO CLINICAL SITES**

In-Depth Interview

Contact: Mary Kate Shapley-Quinn

Phone: 415 848-1316

Mobile phone (for text messages): 919 260-4144

Email: mshapley@rti.org

Back-up contact: Imogen Hawley

Phone: 415-848-1339

Mobile phone (for text messages): 206-455-1700

Email: ihawley@rti.org

For last minute changes to scheduling or to notify interviewer that participant is ready, call listed phone number or send text message. 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: Megan Tilley (205) 975-8586

Backup contact: Shay Warren (205) 975-8657

San Francisco

Primary contact: Megan Henry (415) 437-7448

Backup contact: Allison Phillips (415) 437-7447