

Section 6. Behavioral Measures

6.	Introduction.....	6-1
6.1	Overview.....	6-1
6.2	Trouble Shooting.....	6-2
6.3	Equipment Requirements and Set-up.....	6-2
6.4	Data Collection Instruments.....	6-3
6.4.1	Computer Assisted Self-Interview (CASI) questionnaires.....	6-3
6.4.2	Guidance on Completing CRFs with Behavioral Content.....	6-4
6.4.3	In Depth Interview (IDI).....	6-4
6.5	Qualitative Data Management.....	6-8
6.5.1	Audio Files.....	6-8
6.5.2	Interview Notes.....	6-9
6.5.3	Debriefing Reports.....	6-9
6.5.4	Transcription.....	6-9
6.5.5	File Naming Conventions.....	6-10
6.5.6	Data Tracking.....	6-10
6.6	Special Cases and Technical Issues.....	6-10
6.6.1	Technical Problems Preventing CASI Completion.....	6-10
6.6.2	Interrupted Visits.....	6-10
6.6.3	Management of Errors on CASI.....	6-11
6.7	Staff Training.....	6-11
6.7.1	CASI.....	6-11
6.7.2	IDI.....	6-11

6. Introduction

This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the MTN 038 behavioral assessments, which include Computer Assisted Self-Interview (CASI) questionnaires, a qualitative In-Depth Interview (IDI), and the behavioral CRF questions (see SSP Section 12 Data Collection).

6.1 Overview

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

Table 6-1: Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Participant	Visit
Ring Insertion/Removal	CRF	All	Visit 3 (Enrollment), Visit 6 (Day 28), Visit 8 (Day 56), Visit 9 (Day 91)
Ring Adherence	CRF	All	Visit 6 (Day 28), Visit 8 (Day 56), Visit 9 (Day 91)
Baseline	CASI	All	Visit 2 (Enrollment)
Visit 6 Follow-Up	CASI	All	Visit 6 (Day 28)
Visit 8 Follow-Up	CASI	All	Visit 8 (Day 56)
Exit	CASI	All	Visit 9 (Day 91) PUEV Visit or Early Termination Visit

In Depth Interview (IDI)	Web Video interview	~8 per site	Visit 9 (Day 91) PUEV Visit or Early Termination Visit or Final Contact Visit or a separately-scheduled time between PUEV and Final Contact Visits if window allows
--------------------------	---------------------	-------------	---

6.2 Trouble Shooting

CASI

For any problems accessing or completing CASI questionnaires or problems with the CASI study computer, please notify the team immediately by sending an email to the CASI Troubleshooting alias list mtn038casi@mtnstopshiv.org. The alias list includes the following protocol team members:

- RTI International: Imogen Hawley and Sarah Roberts
- SCHARP: Amanda Brown and Jen Berthiaume
- 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 mtn038idi@mtnstopshiv.org. The alias list includes the following protocol team members:

- RTI International: Imogen Hawley and Mary Kate Shapley-Quinn

6.3 Equipment Requirements and Set-up

CASI

The CASI program is managed by Illume, an online data collection platform that requires a stable Internet connection hosted by the following web browsers: Internet Explorer 7.0 or higher, Firefox 2.0 or higher, Safari 2.0 or higher, Opera 8.0 or higher, Netscape 4.0 or higher, or Google Chrome. The URL link to the survey will be sent to each site and may be bookmarked on a web browser so it is easily accessible. A webinar training on CASI access and administration will be conducted by SCHARP prior to study initiation. Questions should be directed to the MTN-038 CASI Troubleshooting email alias (mtn038casi@mtnstopshiv.org).

Once a participant has signed the consent form, the site needs to email SCHARP (abrown@scharp.org) and specify for each participant which CASI ID has been associated with which PTID. SCHARP will associate the two IDs in Illume prior to the Enrollment visit, so the participant can successfully complete surveys throughout the study.

Study staff must 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 of other participants while answers are being entered. The computer should have a stable internet connection at all times, supported by an Ethernet cable if necessary. 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 may 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.

If a participant is unable to complete her survey at any given visit, once logged back in to that survey, she will start the survey over.

IDI

The in-depth interviews will be conducted over encrypted (AES-128) video calls using BlueJeans online video conference platform. Each study site must have a computer (either desktop or laptop) connected to the internet via Ethernet cable with a video camera and either speakers and a microphone or a 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 6/Day 28 and Visit 8/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 6/Day 28.

6.4.1.3 Exit Questionnaire

At the Visit 9/Day 91 PUEV Visit or Early Termination Visit (if applicable), 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 Visit 9/Day 91/PUEV 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.

6.4.2 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 after verifying the insertion process, whether 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 6/Day 28, Visit 8/Day 56 and Visit 9/Day 91/PUEV/Early Termination. This CRF contains questions about timing and duration of, and reasons for, ring removals and expulsions.

6.4.2.3 CASI Tracking and Behavioral Summary CRFs

The Behavioral Assessment Summary CRF documents whether participants complete a CASI questionnaire at each visit, providing an explanation for any visit without a questionnaire completed. The CASI Tracking CRF documents the date, time, survey title and any problems or issues related to the administration or completion of the questionnaire.

6.4.3 In Depth Interview (IDI)

A subset of approximately 24 randomly selected participants across the sites, (approximately 8 per site) will complete an IDI. See SSP section 12.2.2 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 CRF Completion Guidelines (CCGs).

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 IDI will ideally be conducted at the Visit 9/Day 91/ PUEV Visit or Early Termination Visit, but may also take place at Visit 10/Final Contact Visit or a separately-scheduled time between PUEV and Final Contact Visits to accommodate participants' schedules. If any participant randomized to the IDI discontinues study

participation early, or has a modified Visit 9/Day 91/PUEV Visit, but has completed at least 1 month of the study, s/he may complete the IDI at study exit.

The interview will address study VR use and acceptability during the study. These interviews will be conducted by a trained qualitative interviewer (off-site at RTI) and will follow a semi-structured questionnaire guide and are anticipated to last approximately 60 minutes. These interviews will be conducted over the computer by a non-recorded video. An audio recording and backup recording will be made with handheld digital audio recording devices that are operated by the qualitative 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 with the line on speaker.

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 by site staff in the Behavioral Assessment Summary CRF.

6.4.3.1 Scheduling the Interview

Study coordinators will notify the off-site qualitative interviewer of a scheduled IDI by updating a shared Google calendar as appointments are scheduled at the Enrollment Visit, and inviting mtn038IDI@mtnstopshiv.org to inform them of all scheduled interviews. Each site will schedule events in their own time zone because the Google calendar will adjust event times by users' locations. The qualitative interviewer will confirm the appointment by updating the event with the BlueJeans video call information 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, interviewers should be notified as soon as possible by phone or text message. Contact information for the qualitative interviewers is listed below..

To minimize scheduling conflicts between sites, the qualitative interviewer will enter unavailable hours and confirmed appointments in the online calendar. Study coordinators can view the calendar prior to scheduling appointments to make sure the interviewer will be available to do the interview, and that it will not overlap with interviews at the other sites. Please note that there will be two interviewers available (unless indicated otherwise on the calendar), so two sites may have IDIs at the same time but not all three sites. In the unlikely event that all three sites have a participant scheduled for PUEV on the same day, the last site to update the calendar to try to reschedule the IDI for the participant's last visit. Study coordinators can email mtn038IDI@mtnstopshiv.org if any issues arise, copying the other site coordinators.

To access the calendar, go to <https://www.google.com/calendar> and sign in with the account login below (Fig. 1), and click on the "Calendar" tab at the top left.

Account email login: mtn038IDIscheduling@gmail.com

Password (case sensitive): 038IDIconnect

Figure 1: Email login information

When updating the calendar with a scheduled IDI, each site should add their expected IDI time (approx. 1 hour) with their assigned colors (see Fig. 2 below):

- San Francisco: blue
- Birmingham: red
- Pittsburgh: purple

Site coordinators should remember to invite mtn038IDI@mtnstopshiv.org to each scheduled appointment on the calendar. Calendar IDI events should be titled with the PTID followed by IDI: e.g. 999-12345-9 IDI.

When already creating internal events in an Outlook account, site coordinators may invite mtn038IDIscheduling@gmail.com to that event and it will appear on the shared calendar at the same time.

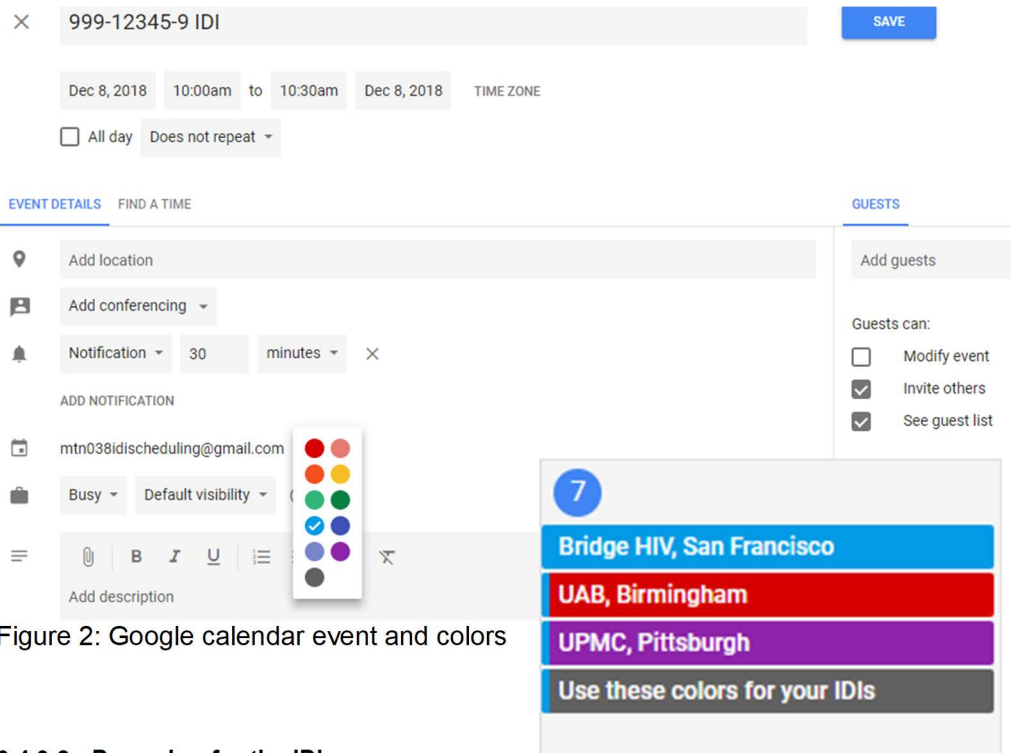


Figure 2: Google calendar event and colors

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 handheld audio recording device is turned on and functioning.
- Ensure backup handheld audio recording device is turned on and functioning.
- Begin the video call.

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.
- Join the video call.

6.4.3.3 Initiating and Conducting the Video Interview

Prior to conducting the first video interview at each site, the interviewer will verify that the 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 interviewer will initiate the scheduled meeting in BlueJeans using the meeting ID provided in the interview date email confirmation. If there are any delays to the scheduled IDI time, the site staff will contact the interviewer by call or text to let him/her know when the participant is ready. The site staff will click on the link in the email to join the meeting, log into the meeting, use the landline option to call in to 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 speakers and microphone, or 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 explain that these questions are being asked to more thoroughly explore the participant's feelings. The interviewer will also 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, but not video recorded.

If s/he does not agree to audio recording, s/he will not be able to participate in the IDI. 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 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 complete, the recording will be stopped and the interviewer will ask the participant to bring the site staff back into the room to close out of BlueJeans. The site staff will later document that an IDI was completed in the participant's Behavioral Assessment Summary CRF.

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 management team.

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. In the 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. 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 send an email. 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. The interviewer will also document the potential AE, SH, or PD on the Debriefing Report, along with the actions taken to report it to the clinic staff.

6.5 Qualitative Data Management

6.5.1 Audio Files

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

Following the interview or discussion, the audio files from the handheld devices will be uploaded onto a secure HIPAA drive at RTI. After confirming the files have been uploaded successfully, the files will be deleted from the handheld devices. 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 from the HIPAA drive 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, including any reference to potential AE, SH, and/or PD. Interview notes will be maintained in participant files in the RTI offices, stored in a locked file cabinet accessible only by study staff at RTI.

6.5.3 Debriefing Reports

On the same day as the IDI, the Interviewer will 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 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 a designated RTI qualitative research analyst 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 the qualitative research analyst 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, 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 the reviewer finds no additional issues and all queries are resolved, the Interviewer will accept all changes, remove all comment bubbles, PDF, and circulate the final clean DR to the MTN-038 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 a secure RTI HIPAA folder 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 RTI. 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 first by the interviewer, and then by another member of RTI's data team, who will add queries to the transcript using comment bubbles within two weeks of the IDI date. 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 within six weeks of the IDI date. The final version of the transcript will be saved in a secure RTI HIPAA folder and old versions will be archived.

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 “V1.”

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 Behavioral Assessment Summary CRF. The mtn038CASI@mtncstopshiv.org team should be notified as soon as possible to determine whether the participant will complete the CASI at a later date.

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 mtn038casi@mtntopshiv.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

6.7.1.1 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.

Prior the enrollment of the first participant, RTI and SCHARP will conduct a CASI-specific training will with each site to review the CASI system 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 survey, using the practice log-in CASI ID and practice PTIDs provided over email.

Upon completion of testing at each given site, an email should be sent to the MTN-038 CASI alias mtn038casi@mtntopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered. RTI and SCHARP will determine whether the site staff can then administer the CASI to participants, or if significant problems were encountered, whether further troubleshooting and testing is required.

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.

Following the mock interview, clinic staff and the qualitative interviewer(s) will review the procedures for documenting and following up on reports of potential AEs, PDs, or SHs that participants may report during the IDI based 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 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 computer.
- Confirm that it is the correct questionnaire.
- Enter CASI ID, PTID, and survey visit code.
- Confirm that all values entered by staff are correct.
- Allow participant to complete the practice questions.
- Assist the participant as needed with the practice questions.
 - If necessary, explain to the participant that “heterosexual” means being attracted to people of the opposite gender and is the same as “straight”.
 - Questions that require a number of times, days, etc. may be answered with zero (0) when not applicable.
- Instruct the participants that when they reach the end of the survey, they will receive a confirmation notice on the screen. 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, who will exit the browser.
- 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**. If the program is terminated or the survey is exited before the CASI is completed, the site or participant may choose to continue the survey from the previous section or start a new CASI survey from the beginning.

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

Scheduling

- Schedule IDI with participant during Enrolment Visit. Email interviewers and mtn038idi@mtnstopshiv.org with date and time of scheduled IDI (approx. 3 months in advance).
- Interviewer will confirm the appointment via email with BlueJeans call information for the time it is scheduled.
- Notify interviewer of all changes or cancellations at least 24 hours before 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/PROTOCOL DEVIATION NOTIFICATION TO
CLINICAL SITES

In-Depth Interviewers

Primary Interviewer:

Imogen Hawley

Phone: 415-848-1339

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

Email: ihawley@rti.org

Secondary Interviewer:

Ariana Katz

Phone: 415-848-1385

Mobile phone (for text messages): 415-793-6944

Email: awkatz@rti.org

Back-up Interviewer:

Mary Kate Shapley-Quinn

Phone: 415 848-1316

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

Email: mshapley@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), Social Harms (SH), or protocol deviations (PD) reported during the IDI:

University of Alabama

Primary contact: Shay Warren (205) 975-8657

Backup contact: Faye Heard (205) 996-8657

San Francisco

Primary contact: Megan Henry (415) 437-7448

Backup contact: Allison Phillips (415) 437-7447

University of Pittsburgh

Primary contact: Carol Sprinkle (412) 641-5091

Backup contact: Melissa Byrne (412) 641-4791