

## Section 14. Behavioral Measures

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This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the web-based behavioral assessments and the qualitative In-Depth Interview. The behavioral assessments of the MTN-024/IPM 031 protocol will be collected via Computer Assisted Self-Interview (CASI) questionnaires, an In-Depth Interview (IDI) and CRFs (see SSP Section 11).

### 14.1 Overview

Behavioral assessments will be captured through web-based CASI. CASI computer interviews are source documentation and must be maintained in accordance with the guidelines for other study documentation. Table 1 outlines the timing (by study visit) and mode (by instrument) each behavioral assessment should be completed.

**Table 1 – Behavioral Assessments: Timing and Mode of Administration**

Questionnaire	Mode of Administration	Visit
Baseline	CASI	Enrollment
Follow-up	CASI	4-Week and 8-Week Study Visits
Exit	CASI	12-Week Final Clinic Visit or Early Termination Visit
In Depth Interview (IDI)	Web Video interview	12-Week Final Clinic Visit or Early Termination Visit

### 14.2 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 [mtn024casi@mtncstopshiv.org](mailto:mtn024casi@mtncstopshiv.org).

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

RTI International: Helen Cheng, Andrea Hanson, and Ariane van der Straten

SCHARP: Corey Miller

FHI 360: Sherri Johnson and Stephanie Horn

#### 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 [mtn024rti@mtncstopshiv.org](mailto:mtn024rti@mtncstopshiv.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 staff: Nicole Laborde, Andrea Hanson, and Ariane van der Straten.

## **14.3 Equipment Requirements and Set-up**

### **CASI**

The operations manual of the PC or laptop used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-024/IPM 031 CASI Troubleshooting email alias.

Each study site must have a desktop or laptop computer connected to the internet that is for use by the MTN-024/IPM 031 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 and of hearing of other participants while answers are being entered. The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The CASI study computer should be plugged into an AC power source. An external mouse should be connected to the computer. 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.

### **IDI**

For the IDI, each study site must have a computer connected to the internet with a video camera and speakers with microphone or headset. The computer must be in a private room where participants will not be overheard during the interview. Select a location in a room with a door that closes to allow privacy for the participant and to allow the participant and interviewer to hear each other without noise disturbance. The participant should be able to sit comfortably and be seen on the video camera by the interviewer, and be able to see the interviewer on the screen. A neutral background behind the interviewer and the participant is preferable. To allow better viewing of the participant and interviewer, they should not be sitting in front of a bright window or other light that would disrupt the camera.

#### **14.3.1 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.

## **14.4 Data Collection Instruments**

### **14.4.1 Computer Assisted Self-Interview (CASI) questionnaires**

#### **14.4.1.1 Baseline Questionnaire**

Each participant will complete a Baseline Questionnaire by CASI at the Enrollment Visit. 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

experiences around menopause. The assessment includes questions on history of use of vaginal products and behavioral practices.

A staff member will access the following web page for the CASI Baseline Questionnaire: [www.scharp.org/MTN024\\_Baseline](http://www.scharp.org/MTN024_Baseline). The staff member will select the participant's ID (PTID) to log in. On the next screen, the staff member will re-enter the PTID, select the visit code, and enter the date.

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' and '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 refuse to answer any question by ticking the **"refuse to answer"** button in the bottom corner of the screen. If participants are unsure of an answer, they should be encouraged to make their best guess rather than to refuse. 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 the participants to click 'NEXT' if they want to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

#### **14.4.1.2 Follow-up Questionnaire**

At the 4-Week and 8-Week study visits, each participant will complete a Web-based behavioral questionnaire, which will cover a subset of the behaviors assessed at baseline. At the appropriate time, a staff member will access the web page for the Follow-up Questionnaire: [www.scharp.org/MTN024\\_Followup](http://www.scharp.org/MTN024_Followup). The staff member will then double enter the PTID, followed by visit code and date. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

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). At the end of the questionnaire (penultimate screen), a message will appear instructing the participant to click 'NEXT' if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

#### **14.4.1.3 Exit Questionnaire**

At the 12-Week Final Clinic Visit/Early Termination Visit, each participant will complete a Web-based Exit Questionnaire following procedures similar to those utilized for the Baseline and Follow-up

Questionnaire. At the appropriate time, a staff member will access the Web page for the Exit Questionnaire: [www.scharp.org/MTN024\\_Exit](http://www.scharp.org/MTN024_Exit). The staff member will double enter the PTID, select the visit code, and enter the date. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

The Exit Questionnaire will investigate the participant's overall experiences with the study products during the trial, and acceptability, including likes and dislikes, willingness to use in the future, attitudes towards the ring, experiences using the ring (e.g., genitourinary discomfort, ease of use/removal, displacement), effect on sex, and partners' reactions. Condom acceptability experience with menopause and HIV prevention product preference will also be assessed at that visit. At the end of the questionnaire (penultimate screen), a message will appear instructing the participants to click 'NEXT' if they want to save their answers. The final screen will indicate to the participants that they have completed the questionnaire and that they should communicate this to the staff member.

#### **14.4.1.4 CASI Question-by-Question Instructions**

A question-by-question guide that explains the purpose and intention of each question has been developed as reference for the CASI questionnaires. These guides are available on the MTN-024 Study Implementation Materials webpage: <http://www.mtnstopshiv.org/node/4924>. Staff should become familiar with the question-by-question guides and ensure that they are reviewed prior to the enrollment of the first participant. The guides should be consulted if participants request assistance in the interpretation of a CASI question, or if staff members are unclear with the meaning of a CASI question.

#### **14.4.2 In Depth Interview (IDI)**

At the 12-Week Final Clinic Visit/Early Termination Visit, a subset of approximately 24 randomly selected participants across all sites, (approximately 8 per site) will complete an IDI. The interview will address study VR use and acceptability during the trial. 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. If the participant consents, an audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer (off-site at RTI). The audio from the interview will be recorded and transcribed for analysis.

Through open-ended questions, this interview will explore the participant's overall experiences and feelings using the ring during the trial, including any physical, mental or emotional concerns or experiences she encountered; her experiences using the ring; her and her partner's attitudes towards the ring, including during sexual intercourse, 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 her responses will be audio recorded but not video recorded.

##### **14.4.2.1 Scheduling the Interview**

Study coordinators will email the off-site qualitative interviewer to inform her of all scheduled appointments, so that they can prepare for video calls. The qualitative interviewer will confirm the appointment via email. The qualitative interviewer should be notified of all changes or cancellations within 24 hours of the scheduled appointment, if possible. If last minute changes do occur, please notify

interviewer as soon as possible, by phone or text message. Any scheduling changes will be confirmed by email.

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 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>

### **Cleveland Site Login**

Account email login: MTN024IDICW

Password (case sensitive): 024IDIconnect

### **Pittsburgh Site Login**

Account email login: MTN024IDIPITT

Password (case sensitive): 024IDIconnect

### **UAB Site Login**

Account email login: MTN024IDIUAB

Password (case sensitive): 024IDIconnect

## **14.4.2.2 Preparing for the IDI**

Before each IDI the following should occur:

### **Off-site Qualitative Interviewer:**

- Ensure the correct version of the guide and other supplemental tools (e.g. ring model or picture to use as a reference for describing issues related to ring or ring use) are ready for use.
- Ensure the video system is ready and connected and the interviewing space is ready.
- Contact the site to confirm the visit and time of the IDI.

### **Site:**

- 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 the video system is ready and connected.

### **14.4.2.3 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.

The site staff will contact the interviewer to let her know that the participant is ready. The interviewer will initiate a meeting in WebEx and send an email invitation to the appointed site staff. 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. The site staff will then leave the room and close the door.

The interviewer will welcome the participant to the IDI and review the IDI introductory checklist which reviews the content, length and confidentiality of the interview and ensures that participant agrees to audio recording the session. If she agrees, the interviewer will start the recording. Following the last question on the IDI, the recording will be stopped. If she does not agree to audio recording, the interviewer will take long hand notes.

At the end of the interview, the interviewer should quickly review the guide and 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 they bring the site staff back into the room. The interviewer will confirm with the site staff that the in-depth interview has been completed and the interviewer will then end the video meeting.

Then the interviewer can further expand 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 12-Week Final Clinic Visit, but has completed at least 1 month of study, she may complete the IDI at study exit.

### **14.4.2.4 Safety Reporting**

As required by DAIDS safety reporting policies, any potential reportable Adverse Event (AE) or Social Harm (SH) reported by a study participant during the IDI will be brought to the attention of the clinical staff. We expect the occurrence of AE reporting during the IDI to be highly unlikely. However, in the rare event a suspected AE or SH is reported during the IDI, the qualitative interviewer and site staff should do the following:

- The interviewer will make note of the participants' comment(s) in the interview notes that will be maintained in the participant files at RTI.
- The interviewer will alert clinic staff (by phone) that the participant reported an AE or SH.
- The interviewer and clinic staff will document in chart notes the notification made to clinic staff (by the interviewer) and the receipt of the notice (by clinic staff).
- Clinic staff will follow up with the participant to assess the AE or SH as needed and report/document the AE on the AE Log CRF or the SH per SSP section 8.7..

- After following up with the participant to assess the reported or potential AE or SH, clinic staff will alert the interviewer (by email) with the outcome of the AE (i.e., whether it was a pre-existing condition, an existing AE, a new AE or if it was determined not to be an AE).

The qualitative interviewer will not be involved in the assessment or reporting beyond notifying the clinical site of the participant’s report. The qualitative interviewer will not disclose to clinic staff the details of what was discussed during the interview beyond the brief mention of the suspected AE or SH reported.

## 14.5 Qualitative Data Management

### 14.5.1 Audio Files

The audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer off site (RTI). The audio recording will be completely separate from the computer video conference (that is not recorded).

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

### 14.5.2 Interview Notes

When an IDI is conducted, notes will be taken during each session to supplement the audio recording (or replace, if recording doesn’t work or is refused). 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 stored in a locked cabinet.

### 14.5.3 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 in “real time.” A DR template will be developed by RTI. Debriefing reports may be maintained electronically until final versions are provided by RTI as described below.

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 comment bubble.

- When the revised information is received, the reviewer, the Qualitative Data Manager or a designated qualitative data team member reviews the corrected areas and deems the issue resolved or further follows up with the Interviewer until all necessary changes are made on the DR.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles and email the final clean DR to the Behavioral Qualitative Team. This final version of the DR should be printed and filed in the participant chart at RTI.
- After the DR is finalized, it will be circulated to the appropriate members of the Protocol and Management Teams.

#### 14.5.4 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. 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 another member of the RTI data team by listening to audio recordings if necessary, Responses will be recorded either through changes directly in the transcript using track changes or through using the comment bubble in the reviewing mode of MS Word, when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].
- A designated RTI staff member reviews the corrected areas and deems the issue resolved or further follows up as needed until all necessary changes are made.

Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript.

#### 14.5.5 File Naming Conventions

All data files should be named according to a standard naming format. 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 “*IDI\_1001\_Transcript\_18NOV12*” would become “*IDI\_1001\_Transcript\_18NOV12\_CM*” and “*IDI\_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.”

##### **File Naming Conventions:**

Initial format: [Interview Mode]\_[PTID]\_[Data Type]\_[Date of IDI]

Query format: [Interview Mode]\_[PTID]\_[Data Type]\_[Date of IDI]\_[Initials]

Final format: [Interview Mode]\_[PTID]\_[Data Type]\_[Date of IDI]\_FINAL

#### 14.5.6 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.

## 14.5.7 Special Cases and Technical Issues

### 14.5.7.1 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).

### 14.5.7.2 Interrupted Visits

Site staff should ensure that CASI questionnaires are always completed at the appropriate scheduled visit, and that all CASI data from a given questionnaire is collected during the visit. If a participant is interrupted and does not complete a CASI questionnaire in one sitting, based on site staff judgment and length of interruption, she can complete the CASI questionnaire later as long as it is **during the same visit**. 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.

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 computer window is closed 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 close the interview window 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 applicable CRF (i.e. Enrollment, Follow-up CASI Tracking).

### 14.5.7.3 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), notify the CASI troubleshooting team via email at [mtn024casi@mtnstopshiv.org](mailto:mtn024casi@mtnstopshiv.org). Please include the following information 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, 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 by keeping a record in the participant's file.

## 14.6 Staff Training

## CASI

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

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

Case Western Test PTIDs	Pittsburgh Test PTIDs	UAB Test PTIDs
999-00001-8	999-00011-2	999-00021-4
999-00002-9	999-00012-3	999-00022-0
999-00003-3	999-00013-9	999-00023-7
999-00004-1	999-00014-7	999-00024-5
999-00005-7	999-00015-1	999-00025-3
999-00006-5	999-00016-4	999-00026-1
999-00007-6	999-00017-0	999-00027-2
999-00008-2	999-00018-8	999-00028-6
999-00009-0	999-00019-6	999-00029-9
999-00010-5	999-00020-8	999-00030-0

Upon completion of testing at each given site, an email should be sent to the MTN-024 CASI alias [mtn024casi@mtnstopshiv.org](mailto:mtn024casi@mtnstopshiv.org) indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

## IDI

Site staff that will be assisting participants with the IDI will be instructed in the use of the WebEx 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 WebEx 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.

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 IDI. The qualitative interviewer will be trained on the appropriate DAIDS procedures for safety reporting and file maintenance.

**Section Appendix 14-1**  
**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 her responses.
- Start the questionnaire by typing the Web address to the corresponding Questionnaire:
  - Baseline Questionnaire (Enrollment Visit): [www.ssharp.org/MTN024\\_Baseline](http://www.ssharp.org/MTN024_Baseline)
  - Follow-up Questionnaire (4-Week and 8-Week Study Visits):  
[www.ssharp.org/MTN024\\_Followup](http://www.ssharp.org/MTN024_Followup)
  - Exit Questionnaire (12-Week Final Clinic Visit/Early Termination Visit):  
[www.ssharp.org/MTN024\\_Exit](http://www.ssharp.org/MTN024_Exit)
- Make sure that the participant is comfortable with using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's ID to enter the questionnaire.
- Enter or select: participant's ID, visit code, and double enter the 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 that says "Thank you for completing this questionnaire!" The participants are not finished until they reach this end screen and click on the NEXT button. At that point the participants should leave the computer as it is and notify a staff member.
- If a participant is interrupted and does not complete a CASI questionnaire in one sitting, based on site staff judgment and length of interruption, she can complete the CASI questionnaire later as long as it is **during the same visit**. However if the computer window is closed before the CASI is completed, she will need to start a **new** CASI survey from the beginning.

**Section Appendix 14-2**  
**QUICK TIPS FOR IN-DEPTH INTERVIEW**

**Scheduling**

- Schedule IDI in Google calendar:
  - **Google calendar site:** <https://www.google.com/calendar>
  - **Login email:**  
For UAB [MTN024IDIUAB@gmail.com](mailto:MTN024IDIUAB@gmail.com)  
For Cleveland [MTN024IDICW@gmail.com](mailto:MTN024IDICW@gmail.com)  
For Pittsburg [MTN024IDIPitt@gmail.com](mailto:MTN024IDIPitt@gmail.com)
  - **Password for all sites (case sensitive):** 024IDIconnect
- 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: Green
  - Cleveland: Yellow
  - Pittsburg: Pink
- 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 headset with microphone plugged into the computer that is operational.
- Ensure the video system is ready and connected.
- Once participant is ready, notify interviewer by phone.

**Initiating the Video Interview**

- Interviewer will initiate a meeting by sending an email to the designated site staff.
- Click on the link in the email to join the meeting, log into the meeting, click join via computer, and turn on the video feed.
- Once the connection is established and the video feed is running, click to enlarge the video window.
- Help the participant get set up at the computer with the headset.
- Leave the room and close the door.

**Ending the Video Interview**

- Participant will notify you when the interview is done.
- Disconnect from the meeting.

**Section Appendix 14-3**  
**CONTACT INFORMATION FOR IN-DEPTH INTERVIEW SCHEDULING**  
**AND ADVERSE EVENT/SOCIAL HARMS REPORTING TO CLINICAL SITES**

In-Depth Interview

Contact: Nicole Laborde      Phone: 415 225-9773  
Email: [nlaborde/contractor@rti.org](mailto:nlaborde/contractor@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: Shay Warren, phone: (205) 975-8657, email: [sjwarren@uab.edu](mailto:sjwarren@uab.edu)  
Back up contact: Megan Lansdon, phone: (205) 975-8586, email: [megan85@uab.edu](mailto:megan85@uab.edu)

Cleveland

Primary contact: Trisha Walton, Research nurse, phone: (216) 844-3259, email:  
[walton.trisha@clevelandactu.org](mailto:walton.trisha@clevelandactu.org)

Back up contact: Kristen Allen, Research nurse, phone: (216) 844-8136, email:  
[allen.kristen@clevelandactu.org](mailto:allen.kristen@clevelandactu.org)

Pittsburgh

Primary contact: Carol Sprinkle, Study Coordinator, phone: 412-641-5091, email:  
[sprinklecl@mail.magee.edu](mailto:sprinklecl@mail.magee.edu)  
Back up contact: Shenay Jeffrey, primary research assistant, phone: 412-641-5496