

Section 6. Data Collection and Management

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6. Introduction

The purpose of this section is to provide site staff with information to complete and submit MTN-045 data.

The SDMC (Statistical and Data Management Center) for this study is RTI (Research Triangle Institute) International.

For questions about this section or about general data collection policies, procedures, or materials for MTN-045, please contact Ali Minnis (aminnis@rti.org) or Mary Kate Shapley-Quinn (mshapley@rti.org).

6.1 Case Report Forms (CRFs)

Table 6-01 lists the CRFs that are to be completed for MTN-045. Electronic CRFs (eCRFs) will be pre-loaded onto tablet computers and completed electronically, whereas paper-based CRFs will be filled out by hand.

Table 6-01: MTN-045 Case Report Form Completion Schedule

Form Acronym	Form Name	Completion Schedule	Population	Mode
DCE	Discrete Choice Experiment	During study visit	All enrolled	Electronic (tablet)
BDQ	Behavioral and Demographic Questionnaire	During study visit	All enrolled	Electronic (tablet)
PSF	Participant Status Form	During study visit	All enrolled	Paper
CO	MTN-045 Couples Observation Form	During study visit	All enrolled	Paper
IPA	Ideal Product Activity	During study visit	All enrolled	Paper
SH	Social Harms Report	If a social harm is reported	As needed	Paper
PD	Protocol Deviations Report	If a protocol deviation is identified	As needed	Paper

6.1.1 Electronic Case Report Forms (eCRFs)

Table 6-01 lists the eCRFs that are to be completed for MTN-045.

Detailed guidelines on eCRF completion are addressed in Appendix 6-1. There is a brief overview here.




1. Each site will have tablet computers that are pre-loaded with the data collection materials. The DCE and BDQ will be administered in private rooms where the participant and interviewer will not be interrupted or overheard.
2. Once the participant is situated in the room, staff should introduce themselves (if not done already), and complete the following:
 - a. Explain the upcoming procedures (watch the study video, complete the Individual DCE and BDQ, then rejoin their partner and complete the Couple's DCE)
 - b. Watch video, allow opportunity for questions or re-watch any portion of the video
 - c. Show placebo product forms
 - d. Open Qualtrics, select the "Individual" survey option, and enter information on the Home Screens
 - e. Lead participant through introductory information and questions before the DCE
 - f. Use practice questions throughout the introductory section to verify the participant's comfort and understanding of using touch screens as well as understanding of the product characteristics that will be used to compose the products participants will be asked to compare and choose between
 - g. Review any terms, definitions, or explanations that may be unknown or misunderstood by the participant
 - h. Go through the introduction to the DCE questions with the participant and ensure that they understand the upcoming activity

- i. Go through DCE choices with the participant, ensuring that the participant comprehends the choice sets, reviews all product characteristics, and how to indicate which they would prefer

The Individual DCE and BDQ will be continuous: once the interviewer launches the Individual DCE and it is completed, it will automatically launch the BDQ. Once the Individual DCE and BDQ have been completed and the End Survey screen thanking the participant has been reached, the data will be transmitted automatically to the Qualtrics server. At this point, the Individual DCE and BDQ data will not be accessible for editing at the site.

Once each member of the couple has completed their BDQ, the couple will come back together. The interviewer will relaunch the Qualtrics shortcut and select the “Couple” option to begin the Couple’s DCE. Again, once the Couple’s DCE is complete and the End Survey-Thank you screen has been reached, the data will be transmitted automatically to the Qualtrics server. At this point, the Couple’s DCE data will not be accessible for editing at the site.

Using the tablets:

1. **Orientation:** The entire DCE survey is designed to be administered with the tablet computer held in portrait mode (short edge on top/bottom, long edge on sides) to minimize the need to scroll-down. This is particularly critical in the choice set portion of the interview where the participant must be able to see all of the attributes to inform his or her preference for option A or B. Scrolling could bias the participant’s responses and impact data quality. Interviewers should ensure the tablet is positioned with this orientation throughout, even when using the tablet cases.
2. **Switching between interviewer and participant:** Red stop sign screens are placed at two points in the DCE to indicate that the tablet should be passed from the interviewer to the participant, or vice versa. If the participant is holding the tablet, the interviewer should be able to see the tablet screen so that they know when the screen is reached that indicates the tablet should be handed back to the interviewer
3. **Back buttons:** Only use the red forward and back buttons at the bottom of the screen  that are built into the Qualtrics survey. Do not use the back button on the browser , or the back button built into the tablet. 

Each site’s study coordinator or designee will log eCRFs (by PTID) that are completed on tablet computers each day. This will be logged in an Excel document (“Enrolled” tab of the Screening and Enrollment Tracker), saved with the current date in the filename each time it is updated, and sent weekly on a Friday (or other date as specified in the SOP) to the RTI data management team (MTN045datamgmt@mtnstopshiv.org). Study staff at each site will also have access to a Qualtrics dashboard that lists all eCRFs completed along with the associated PTID and completion date. This dashboard can be used to check that all eCRFs completed on tablets are logged as complete in Qualtrics, and to provide back-up documentation of dates of completion. The RTI Study Coordinator or Data Manager will review the log against the Qualtrics database on the day of receipt.

6.1.2 Paper-based Case Report Forms

Table 6-01 lists the paper-based case report forms that are to be completed for MTN-045. Please note that a Social Harms (SH) or protocol deviation (PD) form must be completed when an MTN-045 study-related SH or PD is identified.

Please refer to Appendix 6-5 for general guidelines on completing paper-based CRFs. Detailed form completion instructions are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, instructions for all form items are not listed on the back of each form; rather, instructions are provided only for those items needing a detailed explanation.

Most forms include a line in the lower-right corner for a staff member’s initials and the date on which the form was completed. When more than one staff member records data on a paper CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible. A similar process should be followed when a new data element is added to a CRF, whether by the original designated staff member or a new staff.

6.2 In-depth Interviews

Table 6-02 lists the interview guides that are to be used for MTN-045.

Table 6-02: MTN-045 Interview Guides

Guide Shorthand	Guide Name
Couples IDI Guide	MTN-045 Couples In-depth Interview Guide

The IDIs for this study will be conducted in a semi-structured format that follows a discussion guide, allowing for iteration, probing, and digression on relevant themes. IDIs will be audio-recorded, transcribed, and translated into English. Written notes will be taken during the interview. Notes may be recorded directly on the discussion guide, or on separate sheets of paper. Staff may record notes in other languages and extrapolate and translate responses immediately following the interview for later use in completing debrief reports (described in the Data Management SOP).

6.3 Form and Guide Supply

All master Case Report Forms and guides needed for MTN-045 will be supplied by RTI and should be printed locally. The current version of all forms (English and local language) will be posted on the MTN-045 website. The site is responsible for maintaining an adequate supply of the current version of blank CRFs and guides in all languages. One copy of previous versions of CRFs and guides should be maintained in an archive, and all other copies destroyed.

Should there be any updates to the eCRFs, a Data Communique will be sent out via email indicating the updates that were made and any needed action by site teams.

6.4 Tablet Security and Storage

All tablet computers should be stored in locked locations with limited access when not in use. All tablets will be password protected.

6.5 Form Security and Storage

Form storage will be detailed in the Data Management SOP for each site. It is recommended that study forms be stored in a flat file with either secure closures or a hard-cover binder for each participating couple/individual. To maximize confidentiality, all storage locations should be locked and have limited access.

- Hardcopies of all notes, guides, and checklists are stored in MTN-045 files.

- Paper CRFs are stored in MTN-045 couple data files.
- Participant consent forms are stored in a separate secure location.

6.6 How to Complete Interviewer-Administered Forms

The DCE and accompanying BDQ, as well as the IDI guide are interviewer-administered.

Note: Questions on the Couples Observation Form should not be read verbatim or asked directly of participants; rather, the form should be used by staff as a guide to document the necessary information from participant observations.

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that interviewers take a non-biased, non-judgmental approach to participant interviews. Study staff should ensure participants feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

6.7 Interrupted, Paused or Incomplete eCRFs

As each question of the eCRF is completed, responses are automatically saved; there is no “Save” button, as saving happens automatically once navigating to the next page. Responses are stored as ‘Responses in Progress’ until the End Survey-Thank you screen is reached whereby the responses move from ‘Responses in Progress’ to ‘Recorded Responses.’

If the eCRF is mistakenly closed, relaunch the eCRF and it will open to the last completed response. Closing the eCRF will pause the session, and the eCRF will continue to open to the last participant’s completed response for up to 7 days. If a participant decides he or she does not wish to continue the eCRF and stops before reaching the end of the survey, the interviewer must submit blank responses for the rest of the questions and advance to the End Survey-Thank you screen in order to record partial data as completed to the server. Note, the DCE questions cannot be skipped. If the participant decides not to continue before completing the DCE portion of the eCRFs, contact the study data management team (MTN045datamgmt@mtnstopshiv.org) to close out the survey.

If a participant decides to stop and continue the eCRF on another day, staff will need to contact the data management team to close the session and allow for the tablet to be used to start a new eCRF session. Until the session is closed by RTI, the tablet will not be able to be used for other participants. The RTI data management team can provide a hyperlink to return to the participant’s paused eCRF session at a later date.

6.8 Data Management Flow

MTN-045 data will be captured from electronic and paper-based CRFs and the IDIs administered at the site. All IDIs will be audio-recorded and note-taking is required during each session to supplement the audio recording.

As described in the site’s Data Management SOP, each site must perform two Quality Control (QC) review steps prior to data entry of paper-based CRFs and uploading IDI data to RTI. While paper-based CRFs, debrief reports, and transcripts are being reviewed, it is important that they be stored and tracked systematically.

- QC Review Step # 1 (same day as visit):
 - After the full IDI visit or IDI visit but before the participant has left the clinic, the interviewer should conduct an initial quality control (QC) check of the following:
 - Review visit checklists to ensure all required procedures were completed
 - Review paper-based CRFs to ensure completion

- CO
- IPA
- PSF
- SH (if needed)
- PD (if needed)
- Review all interview notes for clarity
- Same day as IDI, as soon as possible following the IDI:
 - The Interviewer (or note taker, if applicable) should verify that the audio recorder properly recorded the session. The audio file should be copied onto the password-protected hard drive of a computer at the site.
 - If the audio recording did not work, the interviewer will review the IDI guide and expand the notes they have taken during the discussion to serve as an alternate transcript and a protocol deviation should be reported via a PD CRF for missing source documentation.
 - As detailed in the Visit Checklists (available on the MTN-045 website), notes from the interview should be entered electronically into the Debrief Report (DR) form (using the DR Template, available on the MTN website) on the same day as the IDI session and should undergo a site-level QC review.
 - The audio file should be saved onto a secure, limited-access server (as back-up) as source documentation of the interview. The file will be labeled with the ID number of the participant.

NOTE on Audio File Destruction: As mentioned in SSP Manual Section 2 (Documentation Requirements), audio files of IDIs are considered source documentation and will NOT be destroyed until directed by DAIDS following study completion. Audio files will be retained for at least three years following study completion, or an alternate timeframe as directed by site IRBs/ECs. The destruction process will be the responsibility of the site Investigator or his/her designee and should be specified in the site Data Management SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files and confirmed via email with the data center (RTI).

- MTN-045 QC Review Step #2 (1 week – 1 month after visit)
 - Within one week of the visit: Before paper CRFs are entered into REDCap and before debrief reports are uploaded to the SFTP site, a second QC review should occur. The goal of this second QC review (as outlined in the site's Data Management SOP) is to correct data inconsistencies/errors and to ensure accuracy and completion, so that QC notes are prevented or minimized. This review should be done by someone other than the staff member who originally filled out the forms or wrote the report. Prior to entering CRFs into REDCap or uploading DRs to the SFTP:
 - All forms and reports:
 - Review visit checklists to ensure all required procedures were completed
 - Ensure no participant identifiers other than the PTID are present on the forms
 - Ensure the PTID is correct, and is the same on all forms/documents

- Ensure the Visit Date is correct, and is the same on all documents (unless in the case of split visit, in which case this should be marked in the comments on the visit checklist)
- Filename matches appropriate file naming convention (outlined in section 6.13)
- Paper CRFs:
 - Make sure a response has been recorded for each item, as required
Make sure skip patterns have been followed correctly
 - If a response box with “other”, “specify”, or “describe” line is selected, ensure text is present on this line
 - Make sure text responses are legible
- DRs:
 - All information in heading of DR is filled in and accurate
 - All sections of the DR template are filled in, listening to audio file sections as needed for accuracy and clarification
 - Double check PTID and visit date are accurate
 - After internal QC of the DR, sites should remove all comments and tracked changes so the document is clean when sending to RTI.
 - Sites will document which staff member reviewed each debrief report on the debrief report heading.
 - Once DR review is complete, sites should transmit the DR to RTI via SFTP (see process outlined in Appendix 6-2).
- Paper CRF Data Entry (1 week – 1 month after visit)
 - Each CRF will be entered into a REDCap database developed by RTI by two members of the site’s data team. A third member of the site’s data team will compare the two entered versions of each CRF.
 - Data entry practices:
 - Enter multiple response question data as completed on the paper CRF, even if a skip pattern was not followed correctly. If two responses were selected for a question requiring a single response, do not mark a response in the REDCap database.
 - All open-ended text response data (e.g. other specifies and comment fields) should be entered in all CAPS (uppercase). Do not correct spelling errors; enter text and all punctuation as it appears on the paper CRF.
 - Double data reconciliation
 - After all CRFs for a couple have been double entered, the “Data Comparison” tool in REDCap will be used to identify any discrepancies across the two entries.
 - All discrepancies are to be reconciled by reviewing the original paper CRF and selecting which of the two entries was correct, or by entering a new response that correctly reflects the response on the paper CRF.
 - A final, merged version of the two entries is created after the comparison is completed.
 - The site-specific procedures for data double-entry and reconciliation will be outlined in each site’s Data Management SOP.

NOTE: Additional details on data management will be outlined in each site's Data Management SOP. Data for quantitative analysis will be collected electronically in Qualtrics for the DCE and manually on paper CRFs at the site. Data should be checked for accuracy, clarity and completeness at the site.

- IDI (Within one month following interview): The audio file should be used to transcribe and translate the discussion per the process described in the Data Management SOP (using the Transcript Template, available on the MTN website). All transcripts will be simultaneously translated (when conducted in a local language) and transcribed in English unless there are unique local language sayings that should be preserved. These sayings can be kept in the local language with explanatory notes provided in parentheses to explain their meanings. All expanded notes will be written in English. Formatting guidelines are provided in Appendix 6-3. More details on guidelines for proper transcript punctuation, formatting and common QC issues can be found in Appendix 6-4. The completed transcript should undergo the internal QC process outlined in section 6.9 and uploaded to the SFTP within one month following the IDI.

6.9 Site Transcript QC Process

Quality checks of the transcription/translation should be performed at the site as described in the Data Management SOP and outlined below. This will include the following:

- A second staff member (i.e. one who did not translate the interview) who is fluent in the local language should listen to the entire audio file while reading the English transcript. The quality of **the first three transcripts per transcriber/translator** will be checked in this manner to determine that the quality of translation is sufficient. If the quality is insufficient, the IOR or designee can do more thorough checking of the subsequent three transcripts and provide feedback to the translator. These reviews will be continued in batches of three until the quality is acceptable for each transcriber.
- Following this determination, systematic quality checks will include listening to **at least three, 5-minute spots** per interview of the audio file as compared to the transcript for 10% of transcripts.
- Sites will **log the QC process** (including which transcripts were reviewed in its entirety and which were spot checked and by whom). Prior to start of the study, sites should send the template of what their QC log will look like to RTI. During the study, sites will send this QC log sheet to RTI **monthly**.
- If at any time the site coordinator decides that the direct transcription from audio to English transcript is not consistently of high quality, he/she will consult the MTN-045 Management Team to determine the corrective action, which may involve a temporary or permanent switch from a 1-step to a 2-step transcription/translation process for that translator.
- The text of each transcript should still be reviewed by a second staff member (who did not translate the interview) in its entirety even if the entire audio file is not reviewed for completion, content clarity and typos. **Sites will document which staff member reviewed each transcript on the transcript heading.**
- Once a transcript is deemed ready for RTI review, the transcriber should certify that the transcript is an authentic representation of the audio recording by adding his/her name and date to the top portion of the transcript.
- In addition to quality checks of the transcription, **a different staff member than the interviewer should also review the audio file of the first 2 IDIs for each interviewer** to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.) The feedback will serve to provide additional training to the interviewers and also to improve on the quality of the

data collected. Note-takers may serve this role for interviewers. If a different staff member performs this function, participants must be asked if they are comfortable having additional staff present during an interview. **All staff who sit in or participate in interviews should be documented in the debrief report and transcript headings.**

6.10 RTI-Site CRF QC Process

Once all CRFs for a couple have been double data entered, compared, reconciled, and merged into a third, final record in REDCap at the site:

- Final merged records will be reviewed and missing or potentially incorrect data will be collated into a Quality Control (QC) report.
- The QC report will be sent via e-mail to the study site weekly. Sites are asked to correct or clarify any problems identified on the QC reports and rectify the query only in the final, merged RedCap entry **within one week**.
- When RTI receives the communication that RedCap entries have been updated, RTI staff will review the corrected entries and determine whether the QC can be resolved. If the QC is resolved, no further action from the site is necessary. If the QC was not resolved adequately, RTI will write a more detailed query, which will be communicated to the site in the next QC Report. If the site determines a query cannot be resolved, RTI will make note and remove it from any future QC reports.

6.11 RTI-Site Debrief Report QC Process

Once a DR is received by RTI, RTI will then conduct a QC review of the Debrief Reports (DR), which will include the following process:

- DR will be read and reviewed by RTI data team members and queries will be made on the report using MS Word's review features. The following are examples of queries:
 - Typos that lead to ambiguous meaning: e.g. "sore the medication" vs. "store the medication" (track changes may be used for straightforward typo corrections)
 - Sentences that don't make sense
 - Clarification of local terms used
- RTI will upload the QCed DR on the SFTP site **within one week** of receipt of the DR.
- **Within one week** of receiving the DR from RTI, the site is asked to correct or clarify any problems identified in the report directly in the report text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query. The corrected DR is then uploaded onto the SFTP site.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected issues and either deems the issue resolved or requires further follow-up. If further clarification is necessary, RTI will upload the DR onto the SFTP site again and email the site. This process continues with the site until all necessary changes are made on the DR.
- Once all queries have been resolved, RTI will remove all comment bubbles and accept all tracked changes to create a final and "clean" copy of the DR in Word.
- A final PDF version of the DR will also be created. Both versions will be saved to an encrypted drive. The final PDF will be password protected and emailed to the site team and MTN045qualitative@mtnstopshiv.org simultaneously.

6.12 RTI-Site Transcript QC Process

After the site-level QC process described above is completed, the English language transcript will be uploaded to SFTP for RTI to review. RTI should receive an English language transcript within **one month** (30 days) of the interview or discussion date. Transcripts will then undergo a QC process similar to that of the debrief reports:

- Each transcript will be reviewed by a member of RTI's data team and queries will be made on the transcript using Microsoft Word's review feature (comment bubbles will primarily be used; track changes may be used for minor or straightforward typos). The QC includes the identification of the following:
 - Problems such as typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data
 - Issues identified by the protocol team requiring follow up, additional probing, or discussion with the interviewers. This could include general findings related to discussion facilitation techniques or specific issues that should be teased apart further in future IDIs.
- RTI-reviewed transcripts will be uploaded to the SFTP for the site **within approximately two weeks** of transcript receipt.
- The site must then respond to all comments **within two weeks** of receipt of the reviewed transcript. Responses will be made by making changes directly to the transcript using track changes and confirming the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within the comment bubble. When in-text changes are unable to be made, the site reviewer should respond using the comment box in the reviewing mode of MS Word. The corrected transcript is then uploaded onto the SFTP site.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected issues and either deems the issue resolved or requires further follow-up. If further clarification is necessary, RTI will upload the transcript onto the FTP site again and email the site. This process continues with the site until all necessary changes are made on the DR.
- Once there are no additional issues, RTI will accept all changes, save a clean, final copy of the transcript on an encrypted drive, and will upload to the SFTP for the site's records.
- The participant's final English transcript, and the final local language transcript (if applicable) must all be stored in the participant's file, or per site Data Management SOP.

Refer to Appendix 6-4 for more details on quality control general conventions.

An MTN-045 Qualitative Data Tracking Log (or equivalent) will be completed by RTI to maintain record of each debrief report and interview that is received along with details regarding the date of receipt, query status, and finalization date.

6.13 Interview Modes and File Naming Conventions

Interview Mode is the term used to describe the kind of interview that is being conducted in MTN-045. The abbreviations and definitions are as follows:

- C-IDI: Couples In-depth Interviews (i.e. jointly administered)
- M-IDI: Male partner In-depth Interviews
- F-IDI: Female partner In-depth Interviews

All data files should be named according to a standard naming format. The name should include the Study Name (MTN-045), interview mode, followed by the couples' ID, data type abbreviation (debrief report (DR), transcript (TS)), and the date the interview was conducted, in *ddMMMyy* format. There should be an underscore with no spaces between each part of the name, for example **"MTN-045_C-IDI_11111_DR_15OCT19"**.

Each time a document is edited, the editor should add his or her initials to the file name without changing any other part of the file name. There is no need to include the editor’s initials in the first iteration of the file that is sent to RTI for review. It is only upon subsequent review (during the QC process with RTI) that it becomes necessary to include the editor’s initials.

For example, the file sent to RTI would be labeled, “*MTN-045_C-IDI_11111_DR_15OCT19*” and after initial review from RTI it would become “*MTN-045_C-IDI_11111_DR_15OCT19_JR*”. After the site reviews it would become “*MTN-045_C-IDI_11111_DR_15OCT19_JR_NM*”, etc. Once the document is finalized, RTI will remove all initials and replace with “v1.0” so it becomes, “*MTN-045_C-IDI_11111_DR_15OCT19_v1.0*”.

The Debrief Report and Transcript Templates provided on the MTN website have a field in the header that is built to match the file name. After the file is renamed, staff will go to the header, right-click on the file name field, and select “update field” before saving.

Table 6-03: Example of File Naming Convention throughout the RTI-Site QC process:

Original File Name	File Name after First Review (By JR)	File Name after Second Review (by NM)	File Name once Finalized
MTN-045_C-IDI_11111_DR_15OCT19	MTN-045_C-IDI_11111_DR_15OCT19_JR	MTN-045_C-IDI_11111_DR_15OCT19_JR_NM	MTN-045_C-IDI_11111_DR_15OCT19_v1.0

6.14 Data Management SOP

As a condition for study activation, each study site must have an SOP for Data Management. This SOP should be reviewed and followed in combination with the information contained in the study protocol and this SSP Manual.

The Data Management SOP contains information on and outlines site staff responsibilities for several data topics, including but not limited to:

- Staff responsibilities
- Couples’ ID and Participant ID (PTID) assignment (see SSP Manual Section 3)
- Couples’ study file organization
- Source Data and Source Documentation
- Data storage
- Record retention
- Data collection procedures (DCE, CRF and IDI)
- Participant confidentiality
- Site data quality control (QC) processes
- Timing of form data transmission to SFTP
- RTI data QC processes
- Timing of qualitative data transmission

6.15 Staff Training

Site staff who collect data, enter data on debrief reports, or who manage and transfer participant data will receive protocol and SSP Manual training. The site IoR or designee is also responsible for notifying RTI and FHI 360 of any new staff and of the site's plans for training any new staff on study procedures. When new staff members join a site team, or when existing staff members assume new study responsibilities, this must be documented on the site delegation of duties (DoD) Log and the updated log must be sent to FHI 360. Additional training will be made available as needed by RTI staff to train and monitor quality of site data management or to provide training on new study procedures.

6.16 Study Monitoring

In addition to data quality monitoring and checks described above, FHI 360 and/or RTI may review study records during the course of the study through onsite or remote review of select couples' files. Sites will be asked to provide copies of couples' files for review. FHI 360 and/or RTI will review these documents and provide feedback to sites either by e-mail or conference call.

Appendix 6-1: Tablet Use and eCRF Completion

The DCE questionnaire will be completed using an electronic instrument administered on an Android operating system, loaded onto a Lenovo Tab 4, 10.1” tablet computer. RTI will provide 05 of these tablet computers to each site. The tablets should be stored in a secure, locked location, plugged in when not in use, and the batteries should be fully charged at the start of every workday. The complete user manual can be found here: [Lenovo TAB4 User Manual](#).

a. Turning on, unlocking, and locking the tablet computer

1. If turning on from sleep mode, press the Power button, smaller button on the top corner of the tablet.
2. If turning on from fully powered-off mode, press and hold the Power button.
3. Next, to unlock the tablet, swipe up from the bottom of the tablet screen, and enter the password when prompted by pressing the password line. Type the password and select the “Enter” or check mark on the right side of the keyboard.
4. The tablet can be locked by pressing the Power button on the top of the tablet. The tablet will automatically lock after 2 minutes of inactivity.


b. Navigating the tablet screens

1. To return to the home screen, press the white outlined “O” button at the bottom of the screen.
2. To display and manage all open apps and pages, press the “□” button at the bottom of the screen.
3. To close an application, press the “□” button at the bottom of the screen and swipe the app window right or left.
4. To launch the eCRF survey through Qualtrics, select the Qualtrics bookmark saved to the Home screen of the tablet.
5. Links to start the video are saved to the Home screen of the tablet. There are two icons saved on the home screen, one for the English version of the survey and one for the Shona/Luganda version. The icon is a white square with a red film reel labeled “CUPID Video”.
6. The tablet can be used in portrait or landscape mode, and the screen will automatically adjust depending on how the tablet is physically oriented. Note that the interview is designed to be administered with the tablet in portrait mode, with the edge buttons (power and volume) oriented on top.

c. Connecting to the wireless network

It is necessary to connect the tablet to WiFi internet in order to administer the eCRFs (DCE and BDQ).

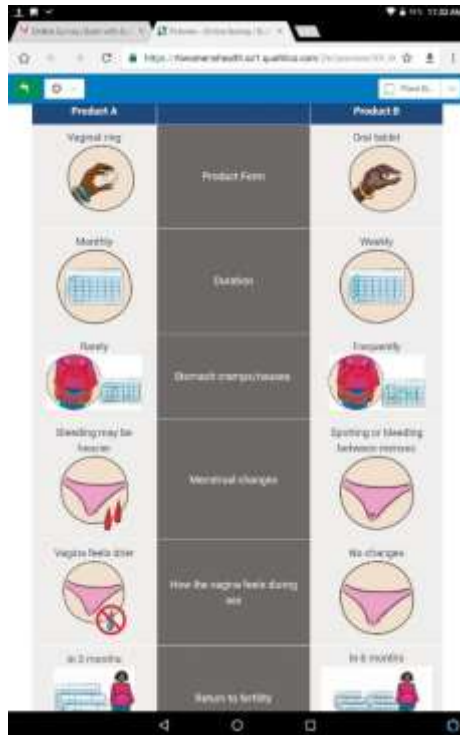
To connect the tablet computer to a wireless internet connection, complete the following steps:

1. Tap the  icon at the bottom of the screen
2. Select the “Settings” icon and then under “Wireless & networks” press “WLAN”
3. Make sure the WLAN switch is in the On position, and tap the WLAN Wifi network to connect to the internet.

Steps for administering the Individual DCE portion of the visit

1. At the start of the visit:
 - a. Ensure the battery is fully charged and the tablet computer is available for the visit.
 - b. Ensure the tablet has a functioning internet connection.
 - c. Begin the visit procedures, starting with the CUPID video.
2. Showing the video

- a. To show the CUPID video, select the language version required from the Home screen.
 - b. The volume on the tablet may be adjusted by pressing the Volume buttons on the top of the tablet.
 - c. Note that an internet connection is not required in order to show the video.
3. Administering the survey with the participant: Select the Qualtrics icon on Homescreen
 The survey consists of three sections that are each administered in slightly a different way: an introductory section, the choice sets, and a set of follow-up questions that cover topics including preferences, demographics, and sexual behavior.
- The purpose of the first section is to introduce the attributes of the hypothetical products in the DCE. The structure consists of text that is read aloud by the interviewer accompanied by images that the interviewer shows to the participant.
 - The second section consists of the choice sets. During this section, the participant is handed the tablet so that they can select answers themselves and will make choices between **9** pairs of hypothetical products. The interviewer should guide the participant through at least the first two choice sets, plus additional sets if needed for comprehension, by describing the choice activity, introducing the concept of two hypothetical products depicted as columns of attributes, or characteristics, and reading the attributes aloud. The attributes corresponding to each hypothetical product are displayed vertically in a column labeled as “Product A” or “Product B.” Once the participant has demonstrated understanding and ability to make choices on their own, the interviewer can hand the tablet to the participant for them to continue making choices on their own, while the interviewer observes and assists as needed.
 - In situations where this is not possible, be sure the participant has the tablet placed in front of them (in portrait mode) for easy viewing and decision-making in selecting their preferred products.
 - The tablet screen should always resemble the following during the choice sets:



NOTE: the blue bar across the top of the choice set only appears in the training version and will not appear during the survey.

- The third section consists of follow-up questions regarding product preferences. This section includes photos that the interviewer will show to the participant
- The last portion is a demographic questionnaire (BDQ) administered by the interviewer. After the participant has completed the choice set activity, the interviewer should pick up and hold the tablet, and administer the questions in a similar way to administering questions on a paper-based questionnaire.

Step-by-step instructions on how to administer the survey are as follows:

- a. Select the survey for the individual
- b. Complete the first screens, which are electronic cover sheets that are not read aloud to participants, by entering the Site ID, Couple ID, the Couple ID again, Sex ID, indicating the date of the interview, entering the interviewer initials, and interview location.
- c. To move to the next screen, tap the red forward arrow button at the bottom right of the screen.
- d. The first portion of the survey is interviewer-administered with visual aids. The interviewer should sit next to the participant, hold the tablet between herself and the participant, and read the questions aloud to him/her. The interviewer or participant can go back to a previous screen by tapping the red back arrow button at the bottom left, if necessary.
- e. The default language is English. The language of the form may be changed at any point during the interview. To change the questionnaire to another language version, tap the box indicating the interview language at the top of the screen. Note that the intro screens that are not read aloud to the participant will remain in English.
- f. The choice set portion of the survey is participant-administered in portrait mode with the interviewer assisting, after reading through the first two choices aloud to the participant. When the survey prompts the participant to select their preferred product, the interviewer should allow them to tap the response corresponding to their selection. Note that participants are not able to skip out of these choice-set questions, so if a participant refuses to answer a question in this section, they will not be able to proceed through the remaining questions.
 - a. For the first two choice sets, the interviewer should read the introductory statement aloud, and describe each product by going down the column and reading each attribute and level, starting with product A and then moving on to product B.
 - b. Next, allow the participant to choose their preferred product by tapping the appropriate area of the screen.
 - c. After the first two choice sets, the participants may proceed through and make choices by themselves, if they seem comfortable. The interviewer should stand by to observe and answer any questions or explain anything that is unclear. If needed, the interviewer can read any question or portion of text aloud during this section, but the participant should have the tablet visible in front of them (in portrait mode) and should tap their preferred product to select it.
 - d. Note that responses to these questions are required, and the program will not allow the participant to advance to the next screen until a preferred product has been selected.
- g. After all 9 choice sets have been completed, a final set of questions will appear. This section is interviewer-administered.
 - a. Note that participants may refuse to answer questions in this section. To indicate a participant has refused to answer, leave the question blank and continue to the next screen. The interviewer will be prompted to either go back and answer the question or confirm that the participant refused to answer. The appearance of this prompt is an indication that a question on the screen has been left blank.

- h. At the end of the questionnaire, when the interview is complete, an exit screen thanking the participant will appear. Enter any comments or notes about the interview and select the languages used for the survey. You must then hit the red forward arrow to transmit the final completed survey to the Qualtrics server. When you see the screen that says “We thank you for your time spent taking this survey. Your response has been recorded” the survey is complete, and the data has been transmitted to the Qualtrics server.
 - a. The comments field should be used to document any problems, abnormalities or insights at the end of the interview.
 - i. Examples of issues that should be documented in this comments field by the interviewer include: the participant had a two-year old child with her, so she was tired and distracted; the WiFi got disconnected after Question 7; the tablet had a problem resetting during the consent process; etc.

Steps for administering the Couple DCE portion of the visit

1. Select the Qualtrics icon on the Home screen.
2. Select that the survey is for the Couple.
3. Complete the first screens, which are electronic cover sheets that are not read aloud to participants, by entering the Site ID, Couple ID, the Couple ID again, the PTIDs for each member, date of the interview, interviewer initials, and interview location.
4. The couple will complete 9 choice set questions (just like in the Individual portion) but there is no introduction section and there are no follow-up questions.
5. At the end of the 9 choice sets, an exit screen thanking the participant will appear. Enter any comments or notes and select the languages used for the DCE choice sets. You must then hit the red forward arrow to transmit the final completed survey to the Qualtrics server. When you see the screen that says “We thank you for your time spent taking this survey. Your response has been recorded” the survey is complete, and the data has been transmitted to the Qualtrics server.

Interview Completion and Participant Reimbursement

Once responses are complete, the interviewer should ensure the questionnaire is saved by advancing all the way to the “thank you” screen and close out of the program. Note that if a participant decides he or she does not wish to complete the interview, and stops halfway through, the interviewer must submit blank responses for the rest of the questions and advance to the end of the survey in order to record and send the partial data to the server.

Appendix 6-2: Secure File Transfer Protocol (SFTP)

Overview

Secure File Transfer Protocol (SFTP) is a highly secure file directory used to transfer manually files from one computer to another computer. MTN-045 will use SFTP to transfer **large files** (unable to attach to an email) and/or **files with personally identifiable information**. Files with personally identified information **MUST** always be transferred in a secured way and should never be sent via email. Data needs may change throughout the study timeline and, as such, use-cases for SFTP and this SOP will evolve over time. Current (as of 31OCT2019) use-cases for SFTP include:

1. CRFs (CO, SH, PD) – *only if requested*
2. Debrief Reports
3. Transcripts

The goal of SFTP is *only* for file **transfer**; files will not be stored for an indeterminate amount of time on SFTP and should be deleted typically after 24 hours.

Access to SFTP is based on folders, not individuals—a username and corresponding password will provide a connection to that folder, regardless of who is logging in. Because of this, username and password will be provided by the SFTP administrator to a specific individual and that individual shall not distribute that username and password to anyone beyond themselves. An individual wishing to receive access to a folder needs to send a request to RTI and may be granted access by the SFTP administrator through an email communication. **Any violation of this could be considered an ethics violation and a breach in study confidentiality.**

Download FileZilla

FileZilla is a free, third-party program that allows access to an SFTP site. You must have this or a similar program to access SFTP.

Download FileZilla here (<https://filezilla-project.org/download.php>) and ensure in your download process that you are not downloading additional programs, bloatware, or viruses.

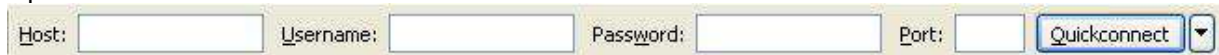
Connect to SFTP with FileZilla

Only connect to SFTP directories with the username and password provided to you by the SFTP administrator. Do not share your username or password information with **anyone**.

Quick Connect

To connect, you will need a **Host** (*sftp://ftp.rti.org*), **Username** and **Password** (provided via email from RTI staff), and **Port number** (22). Follow these instructions:

1. Open **FileZilla**



The image shows the FileZilla Quickconnect bar with the following fields: Host: [], Username: [], Password: [], Port: [], and a Quickconnect button with a dropdown arrow.

2. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar
3. Enter your username, password, and port number
4. Click on **Quickconnect** or press **Enter** to connect to the server.
5. Click **OK** when you get a warning about an unknown host key. (The first time you connect to the FTP server you may be asked to verify that it is a trusted site. Check the “Always trust certificate in future sessions” box. Then click “OK” to continue)

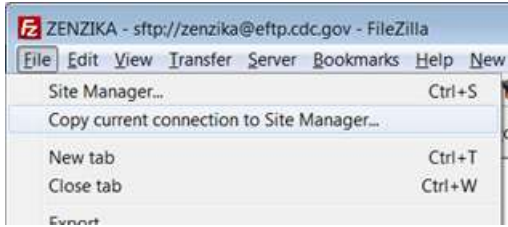
Each site will have a Username as follows:

- **Uganda:** MTN045-MU-JHU
- **Zimbabwe:** MTN045-UZCHS-CTRC

Passwords will be provided separately to the individual(s) at each site who are responsible for file transfer using SFTP.

Save a Connection with Site Manager

1. Perform Quick Connect
2. Click **File** and **Copy current connection to Site Manager...**



Now you are ready for file transfer!

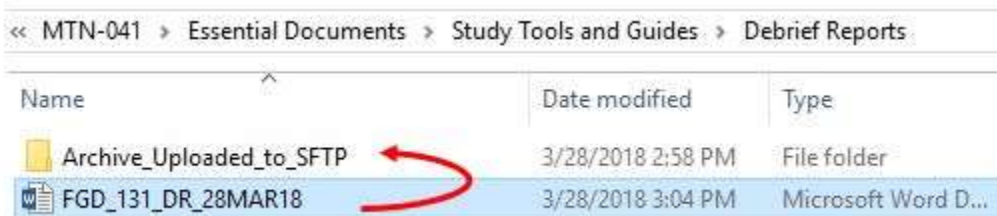
Transfer Files

Transferring files via SFTP requires administrative and technical actions. The process includes:

1. Appropriately name and save the file using the naming convention below to be copied to SFTP for transfer; please save all of the files uploaded to SFTP on the original computer
2. Upload the file via FileZilla (or other third-party program) to SFTP
3. Inform a specific group of people that it has been uploaded by email
4. Download the file via FileZilla (or other third-party program) to a secure location on another computer
5. Delete the file on SFTP after a specific time frame

Name and Save the Files to be Transferred

Please keep a folder on your computer of all files uploaded to SFTP. This is very important. It provides a chronological history of your hard work, can be referenced by date, and these files can serve as backups, if needed.



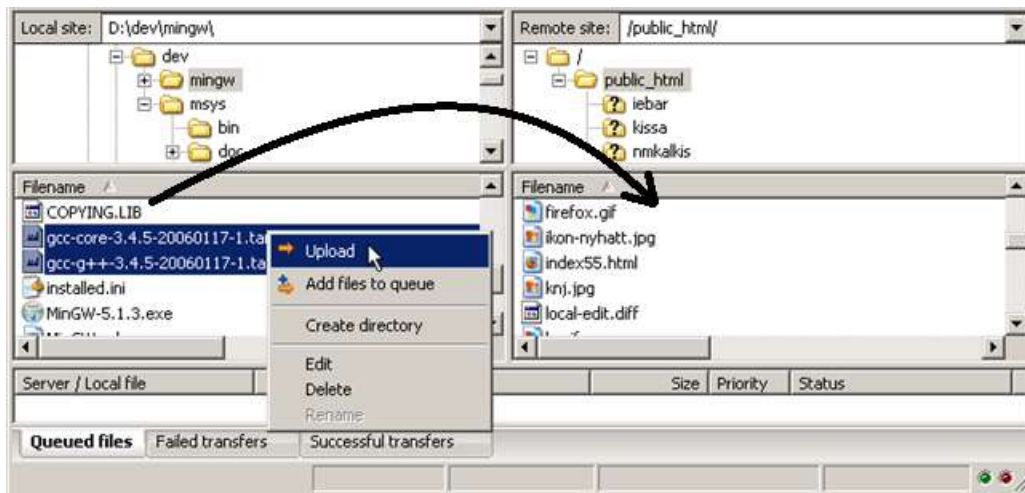
In the above photo, you can see that the upload is called FGD_131_DR_28MAR18.docx, which adopts the standard naming scheme for MTN-045. The name of the file tells us the file contains a *debrief report* from FGD number 131 conducted on March 28, 2018. Please adopt the naming scheme for files uploaded to SFTP:

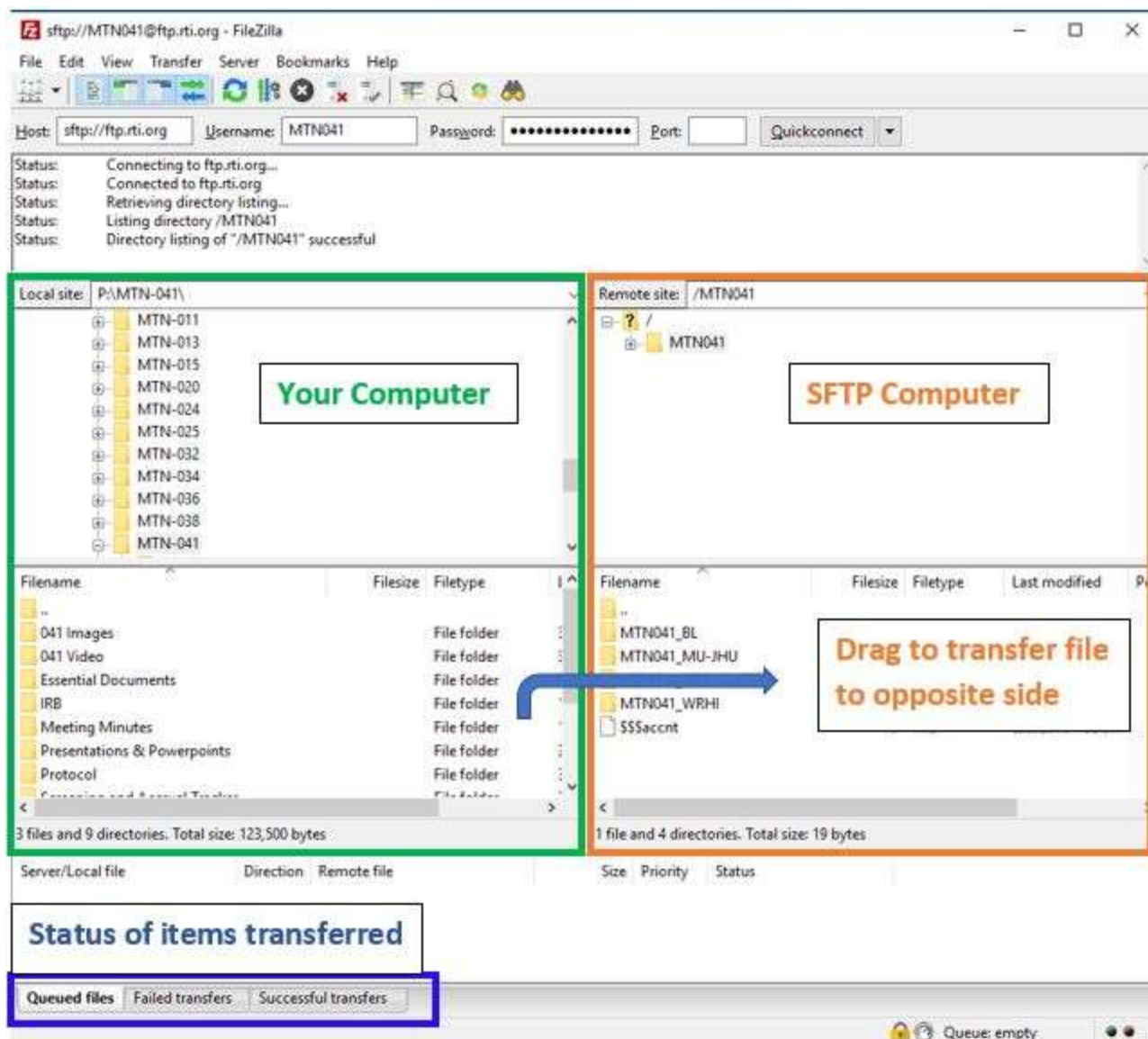
File	File Type	Name
------	-----------	------

CRF, Debrief Report, or Transcript	MS Word Doc	IDI_2001_DR_28MAR18.docx IDI_2001_TR_28MAR18.docx
------------------------------------	-------------	--

Upload the File

You can upload a file by double-clicking on it, by right-clicking one or more file and selecting Upload, or by dragging one or more files from one side and dropping them on the other side. Whichever method, the files will be added to the transfer queue and the transfer starts automatically.





Inform Recipient(s)

STFP is a manual process. There are no automatic alerts when a file is added to a folder. Because of this, the person uploading a file must alert the recipients that a file has been uploaded.

Example Email

“Hello [names of recipients],
 I’ve just uploaded <name of file> to the <name of folder> on STFP. Please download the file within the next <time frame, ~24 hours> before <name of designated deleter> removes the file. Please let me know if you have any questions.

Thank you,
 <name of sender>
 <sender affiliation>”

Download the File

Downloading a file is similar to uploading a file, only that the file is double-clicked, dragged, or right-clicked on the SFTP side of the navigation pane (i.e. the file directory on the right) and moved to your computer's side. Ensure you know where you are saving a file when moving it to your computer; double-clicking will pick an automatic folder whereas dragging allows you to choose a folder with your mouse.

Delete the File

SFTP is designed for file transfer, *not* for file storage. It is important that files uploaded be deleted (do **not** delete the original file from your computer, instead leave this in the Uploads folder you created above) after an adequate amount of time (typically, 24 hours). Because of this, RTI and each site will have one person who is the designated "deleter". It is the responsibility of the deleter to ensure that the people who most need the file have received and downloaded the file before they delete it.

REMINDER: Once you receive files from RTI, **please delete those files from the SFTP folder.** Only documents that are newly uploaded and waiting for RTI should be in the appropriate folders at any given time.

Please contact RTI (mshapley@rti.org) with any questions about this process.

Appendix 6-3: Transcript Formatting Expectations

Formatting Expectations:

- Heading should include filename of transcript.
- Use consistent Times New Roman or similar, 11 or 12-point font and 1.15 spacing.
- Header within document includes: Interview Type, Participant(s) ID, Interview Date, Audio Recording Length, Transcriber Name, Translator Name
- Certification of transcript
- After header, label next section “**Interview Text**,” insert a hard return and begin transcribing the content of the audio file verbatim.
- Use “I:” before Interviewer remarks and “R:” before respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms noted by [brackets]
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Explanation of unclear meanings, cultural terms, etc. can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis “...”
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described above in section 6.13

Appendix 6-4: Quality Control (QC) General Conventions for Transcripts and Debrief Reports

This general convention guidance is designed to help ensure qualitative data documents are clean, accurate and easily understandable. The goal is to create a transcript or debrief report that is clear enough so someone who is not familiar with the study could step in, pick up the document, and understand what is happening with minimal need for interpretation.

In order to make sure that across sites and studies there are consistent standards for how documents are created, the following guidelines have been created. The QC guidelines should help the QC process be smooth and efficient and eliminate confusion as much as possible.

The following are the three most common query types identified by the RTI data center in the QC process:

- A. **Punctuation:** correct punctuation is critical for making sure that the reader can read the document easily and understand the flow of the conversation (in the case of transcripts). Additionally, some punctuation can actually change the meaning of a sentence.
 - i. There are some punctuation issues that differ slightly between American and British English, *please inform RTI reviewers if there is something that comes up in the QC process that is just due to differences in grammar systems.*
 - ii. This document offers some general points on punctuation. However, it does not contain comprehensive information on the use of commas, periods, ellipses, colons, semicolons, quotation marks, etc. If there is doubt about general punctuation “rules,” please consult one of the many online guides to [punctuation](#). The review process is not aiming for *perfect* punctuation, just consistent punctuation that will allow the reader to easily understand the document they are reading.
- B. **Formatting:** Following the formatting guidelines for transcripts, summary reports, and debriefing reports, as outlined below, is important for making sure that they can be read and organized efficiently. It also allows analysts to easily understand the narrative and other pertinent information about what occurred during the interview or focus group.
- C. **Content:** Due to the nature of our research, there are often times when the content of documents is hard to understand – this can be due to language differences, cultural context, local jargon, or non-verbal cues. The reviewer will try to identify places where the meaning of something may be unclear, with the hope that the reviewers at a study site can provide clarifying information if possible.

Common issues in debriefing reports, and transcripts

- A. **Punctuation**
 - i. **Long responses:** Although some respondents – for many different reasons – give very short and cursory responses during interviews, oftentimes the best information comes out when respondents open up. This results in longer and more complicated responses. In order for them to be read and understood correctly, appropriate punctuation must be used. This includes periods at the end of each sentence, commas where natural breaks between phrases occur, quotation marks when the participant is quoting someone’s thoughts or words, ellipses when there is a long pause between thoughts, etc.
 - ii. **Punctuating the ends of lines:** There must be *some* kind of punctuation at the end of every line in a transcript (period, dash, question mark, exclamation point, ellipsis). Quotation marks, parentheses, commas, and brackets do not, in and of themselves, show the end of a line.

- a) **Speaker trails off:** If a speaker trails off while talking during an interview, use ellipses to show that pause.
 - b) **Speaker changes tracks (mid-sentence or mid-word):** When a speaker is in the middle of saying something, then stops, punctuation is used to show the reader that there was an abrupt change. This is indicated with a dash.
 - c) **Speaker is interrupted:** Sometimes the interviewer cuts off the respondent or vice versa. In that case, there should be a dash at the end of the line to show that the speaker didn't finish what they were saying because someone else cut them off. If this is not apparent in the transcript, adding an explanation that the speaker was interrupted can be done in brackets.
 - d) **Quotes, brackets and parentheses:** these types of punctuation marks separate out a section of text, but need a period, dash, question mark, exclamation point or ellipsis in addition to the quotation mark, bracket, or parentheses to show the end of a sentence.
- iii. **Audible noises:** Audible noises such as coughs, doors opening, cars honking, phones ringing or vibrating, and papers shuffling should be indicated by describing the sound inside of brackets.
 - iv. **Information added to transcript:** It is common that the reader needs more information to understand what the interviewer and/or participant is talking about. In those cases, if the interviewer or someone else at the site can provide information to help the reader understand, information should be added in brackets, within the same sentence that it is clarifying. Below in section C is more information about unclear responses.
 - v. **Punctuation quick reference:**

Name of punctuation	Symbol	When to use
Period	.	At the end of a sentence that is not an exclamation or question
Comma	,	To show pauses and natural breaks within sentences
Quotation marks	“ ”	To show where the speaker is repeating someone's words or thoughts
Dash	-	To show where someone abruptly changes tracks in a sentence or when someone is interrupted.
Question mark	?	At the end of each sentence that is a question
Exclamation point	!	At the end of each sentence that is an exclamation
Ellipsis	...	To show a pause where someone trails off
Brackets	[]	To show additional information added to the transcript to help understand it better, and to denote sounds that occurred during the interview, including where audio was paused and restarted
Parentheses	()	Recommend not to use

B. Formatting

- i. **Line numbers:** Use the line numbering function in Word to auto-number each line of text.
- ii. **Capitalization**

a) **Lines:** The beginning of each new line must be capitalized, as it is considered a new sentence.

b) Sentences: The beginning of each new sentence must be capitalized. That means that after each period, question mark, exclamation point, and ellipses or dash if they marked the end of a sentence, the next letter (after the appropriate space) must be capitalized.

c) Quotes, brackets, and parentheses: These can often be part of another sentence or standing alone. If they are at the beginning of a sentence or standing alone, the first letter must be capitalized. If they are within another sentence but not at the beginning, they do not need the first letter to be capitalized.

d) Proper nouns: All proper nouns (people, official names of places, official/brand names of things) should be capitalized. In these kinds of documents, most often the proper nouns used are people's names, the names of cities or towns, names of hospitals or organizations, and brand names of pharmaceutical products.

iii. **Speaker indication:** Each time the speaker changes, there should be an indication of the speaker

Example for speaker indication to show: ("I:" for the interviewer, "R:" for the respondent, or "Pseudonym:" in the case of focus group discussions) then a space, then the transcribed text of what that person said, starting with a capital letter. The quotation marks used in this parenthesis are ONLY to show that it is something that would be written like that in a transcript – in an actual transcript, quotation marks would not be used around the indication of who the speaker is.

iv. **Spacing:** In general, there should be only *one* space in between every word, and one space after punctuation before the next word.

v. **Text size, margins, font and line spacing:** These should be kept consistent across all transcripts and may be specified in your site SOP. Either 11 or 12-point font, standard margins, Calibri or Times New Roman and 1.15 spacing are recommended.

vi. **Footers:** Insert a footer with Page X of X on the right-hand side so the length of the transcript can be easily tracked.

vii. **Spellcheck:** Spellcheck should be used to check for any errors of spelling or grammar.

C. Content

i. **Unclear response:** RTI reviewers will query documents for sections that are unclear and where they would like the interviewer to fill in if there is any missing information due to language differences, local jargon, or cultural context that the reviewers may not have information about. These clarifications should be added into the text of the transcript, in brackets.

a) If the lack of clarity is due to transcription errors, typos, or missing punctuation, the correction should be made to the existing text of the transcript, not added in brackets.

b) The use of "may" and "can" can be confusing. I.e., "I may use the ring in the future" could mean that the respondent would be permitted to use the ring, that she would possibly use the ring, or that she would use the ring. "I cannot tell my partner about the ring" could mean that the respondent is incapable of telling her partner, or that she does not want to tell her partner. Please clarify, if possible, in

the transcript when text like this is ambiguous, and RTI reviewers will also query if it seems unclear.

c) If interviewer is not able to clarify where queried, it is completely acceptable to reply to the comment that, “there is no further information available.”

ii. **Use of local language:** In the information at the beginning of each report that includes the place of the interview, date, name of interviewer and note-taker, etc., there should also be a place to indicate the language(s) in which the interview was conducted. Depending on how the local language is used, the convention will be slightly different. There will also be some variation depending on the SOP. In the absence of specific guidance from the SSP, these are the default guidelines:

a) If the entire interview is in a local language, the transcriber will listen to the audio, and do a direct “one-step” translation to English so the original transcript will thus be in English.

1. If the participant uses a phrase or term in the local language that does not translate into English, that term should be left in the local language, in italics, and an explanation given in brackets.

b) Important phrases or idioms spoken in the local language should be retained in *italics*, and a direct translation will be placed in brackets – like a text clarification – along with any needed description of what the phrase means.

c) If a portion of the interview transitions into local language from English, the transcriber should place an explanation of that transition in brackets where the transcript changes to a language other than English, then do a direct translation for the portion conducted in a local language, and then indicate in brackets where the interview transitions back into English.

iii. **Pseudonyms:** Replace all references to individual names or other identifying data with pseudonyms. If the name of a location such as a town or city is mentioned it is fine to keep that name as-is, as long as it is not so specific it would easily identify the participant.

Appendix 6-5: CRF Form Completion

1. General Guidelines

Based on Good Clinical Practices (GCPs), the following guidelines should be used for completing CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before uploading CRFs.
- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.

2. How to Mark Response Boxes

Many items on CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.



Mark only one response box for each item unless the “Mark all that apply” instruction is present.

3. How to Record Numbers

Some questions on CRFs include boxes for recording a numeric response. The numbers in these boxes need to be recorded clearly. The following instructions should be followed when recording numeric responses:

- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

The following example shows how a value of 7 is recorded when three response boxes are provided:

Correct:

0 0 7

Incorrect:

□ □ 7

→ This example would result in a QC note.

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

In the following example, the 4 could be misinterpreted as a 7 or a 1:

Correct:

4

Incorrect:

4

- Write the number(s) simply, with few loops.

The following example shows the format in which numbers will be most easily read. Also included are some commonly used formats that may be difficult to identify.

Easily Identified:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

ø 1 2 3 4 7

4. How to Record Dates

Dates are recorded using the “dd MMM yy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yy” represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English*. Abbreviations are shown in the table below.

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, June 6, 2015 is recorded as:

0	6	J	U	N	1	5
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

Sometimes, only a month and a year are required (e.g., diagnosis date for a pre-existing condition), in which case the response boxes will look like this:

<i>MMM</i>			<i>yy</i>		

A diagnosis date of October 2015 would be recorded as follows:

<i>MMM</i>			<i>yy</i>		
O	C	T	1	5	

5. Data Corrections and Additions

Sometimes, data on a CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before uploading.

It is important to make these changes to the original CRF—*never* copy data onto a new form. After making the change, the CRF *must* be re-sent to RTI.

Note: If a correction or addition is made to one page of a multiple-page CRF, only re-upload the page that was changed. Initial and date all changes or additions.

Note: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

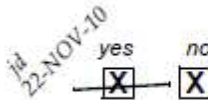
Whenever an entry on a CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



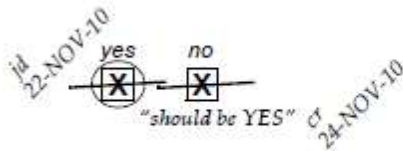
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and
- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item,
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:

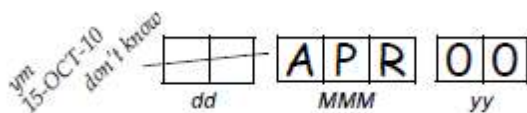


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is uploaded for the first time.

6. How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the “dd” boxes and write “don’t know” next to the response boxes, as shown below:



A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.