Section 7. Data Management

7. Introduction

The purpose of this section is to provide site staff with the information they need to successfully complete and submit MTN-032 data, including debrief reports (DR), case report forms (CFR), and transcripts (TR).

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-032, please contact Liz Montgomery (emontgomery@rti.org) or Ariana Katz (awkatz@rti.org).

7.1 PTIDs

For all individuals on SCHARP Recruitment Lists, sites will assign a MTN-032 (AHA) PTID distinct from the ASPIRE or HOPE PTID of the individual or individual's partner, up to the point where the accrual target is met. . The AHA PTID will be recorded on the Screening and Enrollment Log and PSF..

For more information on assigning PTIDs for MTN-032, please refer to Section 3 of this manual.

7.2 Case Report Forms

Table 7-01 lists the case report forms that are to be completed for MTN-032. Additionally, a Social Harms (SH) or protocol deviation (PD) form must be completed when an SH or PD related to MTN-032 study participation is identified.

Table 7-01: MTN-032 Case Report Form Completion Schedule

Phase	Form Acronym	Form Name	Completion Schedule	Completion Population
Phase 1	PSF	MTN-032 Participant Status Form	Upon screening, enrollment, and/or study completion	All randomly selected and screened
Phase 1	DEM	MTN-032 Demographic Form	On date of qualitative discussion	All enrolled
Phase 1	BA	MTN-032 Behavioral Assessment Form	On date of qualitative discussion	All enrolled
Phase 1	SH	Social Harms Report	If a social harm is reported	As needed
Phase 1	PD	Protocol Deviations Report	If a protocol deviation is identified	As needed
Phase 2	PSF P2	MTN-032 Participant Status Form (PSF) Phase 2	Upon screening, enrollment, and/or study completion	All randomly selected and screened
Phase 2	DEM P2	MTN-032 Demographic Information Form (DEM) Phase 2	On date of qualitative discussion	All enrolled
Phase 2	BA P2	MTN-032 Behavior Assessment (BA) Phase 2	On date of qualitative discussion	All enrolled
Phase 2	SH	Social Harms Report	If a social harm is reported	As needed
Phase 2	PD	Protocol Deviations Report	If a protocol deviation is identified	As needed

7.3 Interview Guides

Table 7-02 lists the interview guides that are to be used for MTN-032.

Table 7-02: MTN-032 Interview Guides

Phase	Guide Shorthand	Guide Name
Phase 1	FGD	MTN-032 Phase 1 FGD Guide
Phase 1	IDI	MTN-032 Phase 1 IDI Guide

Phase	Guide Shorthand	Guide Name
Phase 2	Female IDI	MTN-032 Phase 2 Female IDI Guide
Phase 2	Male FGD	MTN-032 Phase 2 Male FGD Guide
Phase 2	Male IDI	MTN-032 Phase 2 Male IDI Guide

7.4 Form and Guide Supply

All master case report forms and guides needed for MTN-032 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-032 website. A version control log will also be posted on the MTN-032 website for reference (http://www.mtnstopshiv.org/node/7104). The site is responsible for maintaining an adequate supply of the current version of CRFs (blank) and guides in all languages. One blank copy of previous versions of CRFs and guides should be maintained in an archive, and all other copies destroyed.

7.5 Form Storage

Form storage will be detailed in each site's Data Management SOP. It is recommended that study forms be stored in a flat file with either secure closures or a hard-cover binder for each participant (see also Section 2). Hardcopies of all notes, guides, and checklists are stored in MTN-032 files. CRFs are stored in MTN-032 participant data files. Participant consent forms are stored in a separate secure location. To maximize confidentiality, all storage places are locked and have limited access.

7.6 How to Complete Interviewer-Administered Forms

For MTN-032, the Demographic Form, Behavioral Assessment Form, Phase 1 In-depth Interview (IDI) Guide, Phase 1 Focus Group Discussion (FGD) Guide, Phase 2 Female Participant IDI guide, and Phase 2 Male Partner FGD and IDI guides are interviewer-administered.

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant. When administering site-specific translated CRFs, provide participant responses in English only.

7.6.1 Case Report Forms (CRFs)

Please refer to Appendix 7-5 for general guidelines on completing 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 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 member.

7.6.2 In-depth Interviews/Focus Group Discussions

The IDIs/FGDs for this study will be conducted in a semi-structured format, audio-recorded, and written notes taken during the interview. Notes may be recorded directly on the discussion guide, on separate sheets of paper, and on tools used during the IDI/FGD, such as the Drug Level Results over-time tool, or opinion tool (i.e. to explain any markings made). 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 Section 5 and the Data Management SOP). For the MTN-032 discussion guides the following information is provided as general information about the collection of data.

7.7 Data Management Flow

MTN-032 data will be captured from CRFs and the IDI/FGD given at the site. All IDIs/FGDs 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 uploading data to RTI. While CRFs, debrief reports, and transcripts are being reviewed, it is important that they are stored and tracked systematically.

7.7.1 Prior to the participant leaving the clinic:

- QC Review Step # 1:
    - After the interview 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 CRFs based on participant responses to ensure completion
            - PSF
            - DEM
            - BA
            - SH (if needed)
            - PD (if needed)
        - Review all interview notes for clarity
        - Review all tools for completion and clarity

7.7.2 Same day as interview, as soon as possible following the IDI/FGD:

- The Interviewer (or Note-Taker, if involved) 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 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-032 website), the Interviewer's (or Note-taker if present) notes should be entered electronically into the Debrief Report (DR) form (created in Microsoft Word) on the same day as the IDI/FGD session and should undergo a site-level QC review.

7.7.3 Within one week following the interview:

- The audio file should be saved onto a CD as source documentation of the interview. The CD should be labeled with the PTID or the FGD ID number and filed in the participant's file (if an IDI) or in the FGD file (if an audio recording of the FGD).

NOTE on Audio File Destruction: As mentioned in Section 2, audio files of IDIs/FGDs are considered source documentation and thus the CDs will NOT be destroyed until directed by DAIDS following study completion. 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). After notification from RTI, audio files saved on the computer should be deleted and the deletion confirmed with RTI via email.

- MTN-032 QC Review Step #2
    - Before forms and debrief reports are uploaded to the SFTP site, a second QC review should occur. The goal, 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 a different staff member than who filled out the forms or wrote the report. Prior to uploading the CRFs or DRs to RTI.
        - All forms, reports and tools:
            - Review visit checklist 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 PSF form)
            - Filename matches appropriate file naming convention (outlined in section 7.6)
        - 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 present, ensure text is present on this line
            - Make sure text responses are legible
        - DRs:
            - Make sure all necessary tools are included and legible and clearly marked with PTID and visit date
            - 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 is accurate
            - All tools are correctly named
- After internal QC of the DR, sites should remove all comments and track 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 all documents are reviewed, sites should upload the following documents to RTI via a secure SFTP* server (see *MTN-032 SFTP Instruction Guide available on MTN-032 site:* http://www.mtnstopshiv.org/node/7104).
- SFTP:
    - Clean DR (Word) to the "Debrief report & Tools" folder,
    - Scanned (PDF) copies of all tools (i.e. opinion tool) that contain notes or comments to the "Debrief report & Tools" folder,
    - Scanned (PDF) copies of completed CRFs for all screened and enrolled participants to the "CRF" folder.

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

7.7.4 Within one month following interview:

- Following the IDI/FGD session, the audio-file should be used to transcribe and translate the discussion per the process described in the Data Management SOP. All transcripts will be simultaneously transcribed and translated (when conducted in a local language) and written up 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.
- Examples of formatted transcripts are available in Appendix 7-2 for IDIs and 7-3 for FGDs.
- More details on guidelines for proper transcript punctuation, formatting and common QC issues can be found in Appendix 7-4.

7.7.4.1 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**.

* *SFTP is set by RTI's IT department with encryption security settings dictated by MTN-032 compliance regulations. FTP use is account, username, and password protected with only designated team members from RTI and the site given access. See Appendix 7-2 for SFTP instructions.*

- 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-032 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 their 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 observe or sit-in on the first 2 IDI or first FGD 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 or facilitators. If a different staff member performs this function, participants must be asked if they are comfortable for additional staff to be present during an interview. **All staff who sit-in or participate in interviews should be documented in the debrief report and transcript headings.**

7.8 RTI-Site CRF QC Process:

Once a CRF is received at RTI:

- Each CRF will be entered into RTI's database by at least two members of RTI's data team.
- RTI's database will mark any missing or potentially incorrect data and collate 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 re-upload the corrected CRFs to the SFTP site **within one week**. Filenames of returned CRFs should follow the same convention as other documents, as outlined in Table 7-3.
- When RTI receives the updated CRFs, RTI staff will review the corrected pages and determine whether the QC can be resolved. If the QC is resolved, no further action from the site is necessary. It the QC cannot be resolved, RTI will write a more detailed query, which will be communicated to the site in the next QC Report.

PLEASE NOTE: If a change is made to a CRF but the updated page is not re-uploaded to the SFTP, the change will not be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC, the QC will continue to appear on subsequent QC reports until the modified CRF is received at RTI. Therefore, it is very important that the site re-upload updated CRF pages to the SFTP any time a change is made to a CRF

See Appendix 7-5 for more detailed instructions on correct CRF form completion practices.

7.9 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:

- At RTI, the DR will be read and reviewed by 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 within the comment bubble. 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 RTI finds no additional issues, 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 debrief report will also be created and both versions will be saved that to an encrypted drive. The final PDF version will be password protected and emailed to the Protocol Team and the site.

See Section Appendix 7-1 for flow chart of the MTN-032 quantitative data flow and Appendix 7-4 for more details on quality control general conventions.

7.10 RTI-Site Transcript QC Process

After the site level QC process as described above in 7.7.4.1, the English language transcript will be uploaded to the SFTP for RTI review to the "Transcript folder". RTI should receive an English language transcript within **one month** (30 days) of the interview or discussion date. Transcripts will then undergo a similar QC process 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 (comments will primarily be used though track changes may be used for smaller/straightforward typos). 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
    - 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/FGDs.
- 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 either through changes directly in the transcript using track changes and confirm 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 through 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 SFTP site again and email the site. This process continues with the site until all necessary changes are made on the DR.
- Once RTI finds 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 sites 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.

See Section Appendix 7-1 for flow chart of the MTN-032 quantitative data flow and Appendix 7-4 for more details on quality control general conventions.

A MTN-032 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.

7.11 Interview Modes and File Naming Conventions

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

- IDI: In-depth Interviews
- FGD: for focus group discussions

All data files should be named according to a standard naming format. The name should include the interview mode, followed by the PTID or FGD #, data type abbreviation (audio file (AF), debrief report (DR), transcript (TR)), and the date the interview was conducted. There should be an underscore with no spaces between each part of the name.

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 (during the QC process with RTI) that this occurs. For example, the file sent to RTI would be labeled, "***FGD_131_TR_18NOV17"*** and after initial review from RTI it would become *"**FGD_101_TR_18NOV17_AK**"* and after the site reviews it would become *"**FGD_101_TR_18NOV17_AK_NM"***, etc. Once the document is finalized, RTI will remove all initials and replace with the word "FINAL" so it becomes, "**FGD_101_TR_18NOV17_FINAL"**

Table 7-03: Example of File Naming Convention throughout the RTI-Site QC process:

File Name	File Name after First Review (By CM)	File Name after Second Review (by NM)	File Name after Finalized
FGD_131_ TR_18NOV17	FGD_101_TR_18NOV17_ AK	FGD_101_TR_18NOV1 7_AK_NM	FGD_101_TR_18NOV1 7_FINAL

See Section Appendix 7-1 for MTN-032 data flow.

7.12 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, 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
- Participant ID (PTID) assignment (see SSP Section 3)
- Participant study file organization
- Source Data and Source Documentation
- Data storage
- Record retention
- Data collection procedures (CRF and IDI/FGD)
- Participant confidentiality
- Site data quality control (QC) processes
- Timing of form data transmission to SFTP
- RTI data QC processes

- Timing of qualitative data transmission

7.13 Staff Training

Site staff who collect data, enter data on debrief reports, or who manages and transfers participant data will receive Protocol and SSP training. Site IoR or designee is also responsible for notifying RTI and FHI 360 of any new staff and of the sites plans for training the new staff on study procedures. 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 (e.g. Phase 2 activities).

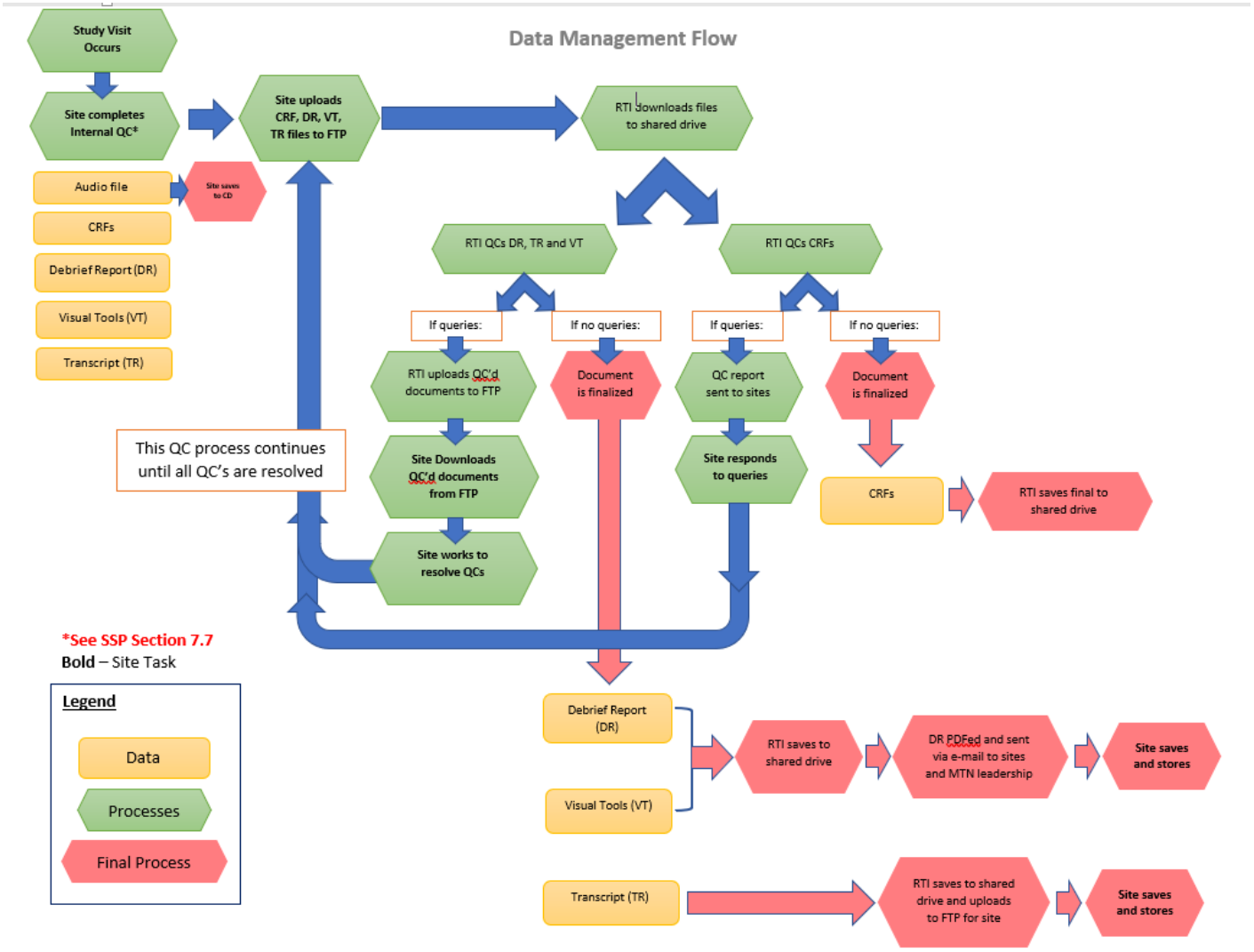
7.14 Study Monitoring

In addition to data quality monitoring and checks described above, FHI 360 will conduct monitoring of this study through remote review of select participant and/or FGD files. Sites will be asked to provide copies of participant files for review. FHI 360 and/or RTI will review these documents and provide feedback to sites either by e-mail or conference call.

7.15 Documentation of MTN-032 Management Team Correspondence

A record of all correspondence with decisions from the MTN-032 Management Team should be saved and stored in the sites Essential Documents file, as outlined in the Data Management SOP.

Appendix 7-1: Data Flow



Appendix 7-2: Example Formatted IDI Transcript

Filename example: IDI_1001_TR_28Nov17

Interview Type: IDI**/ Participant ID**: 1001/ **Interview Date**: 28 November 2017/ **Clinical Site**: MRC Botha's Hill/ **Audio File Name**: IDI_1001_Audio File_28NOV17.WMA/ **Audio Recording Length**: 45m:11s/ **Interviewer Name(s)**: Funeka Mthembu/ **Note-Taker Name(s):** Mercy Tembo/ **Transcriber/Translator**: Hlamalani Rikhotso/ **Interview Language**: IsiZulu & English

I, [*Transcriber/translator name***], certify on [***Date***], that this transcript is an accurate and complete representation of the original audio file.**

Interview Text:

1. I: How is living in the new house?
2. *R: It's alright, but it is boring.*
3. I: Why?
4. *R: Everything is far away.*
5. I: Like?
6. *R: The shops, and the ATM [automatic teller machine] and most of the things are far away. If you do not have money you suffer [Laughing].*
7. I: Do you take taxis when you go to withdraw?
8. *R: I do not have money for the taxi. If I have money I can buy bread because there is a spaza shop [an informal shop operating from home]. A car is a necessity and we need to have it. It is alright at least I have my own space and privacy [*Laughing*].*
9. I: It is better. I was thinking about you and how the situation is in your new home? Are the children still there?

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 ID, Interview Date, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Note-Taker Name, Transcriber Name, Translator Name, Interview Language
- 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 is this
- Replace all references to individual names or other identifying data with pseudonyms
- 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 "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described above in section 7-7

Appendix 7-3 Example Formatted FGD Transcript

Filename example: FGD_131_TR_28Nov17

FGD Type: FGD**/ FGD No**.: 131/ **Participant IDs**: 1301, 1324, 1328, 1329, 1331 / **FGD Date**: 28 November 2017/ **Clinical Site**: MRC Botha's Hill/ **Audio File Name**: FGD_131_Audio File_28NOV17.WMA/ Audio Recording Length: 45m:11s/ **Interviewer Name(s):** Funeka Mthembu / **Note Taker Name(s)**: Hlengiwe Mkwanyana/ **Transcriber/Translator Name**: Hlamalani Rikhotso / **Interview Language**: IsiZulu & English

I, [*Transcriber/translator name***], certify on [***Date***], that this transcript is an accurate and complete representation of the original audio file.**

Interview Text:

1. I: [Laughs]. Thanks for coming, we really appreciate this and we hope that we are going to use this hour fruitfully and to learn from you as we said before. All right, what can you tell us about the tablets? Anywhere you can start…
2. *Candy: Okay my name is Candy. I have been taking tablets but I had complications in the beginning. I used to feel dizzy, vomit, maybe my body was not used to them, but I came to the clinic and they told me that is the process I have to go through and it will eventually stop. I think I am now used to taking the tablets. I just want to ask that I am taking the tablets is there something happening in my bodies?*
3. I: Okay. Since you know; I'm not sure if some of you have similar concerns; as to what will happen to your bodies since you are no longer taking the tablet? But those are the questions that can be answered by the nurses and doctors because we [are] not nurses, so we don't want to give misinformation; information that is not appropriate. So, we will jot [write] that down and later on, we will call a nurse to explain. Okay
4. *Pinky: I want to know that if the programme stops, I mean the ASPIRE, the MTN programmes, is there another programme or will it continue to maybe next year?*
5. I: If the MTN study stops?
6. *Pinky: Yes… because they say my last day is the 28th.*

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: FGD No., Participant IDs, Study Group, FGD Date, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Note-Taker Name, Transcriber Name, Translator Name, Interview Language
- 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 insert the participant's pseudonym before respondent remarks. Italicize all 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
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described above in section 7-7

Appendix 7-4 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, all the information on how to use commas, periods, ellipses, colons, semicolons, quotation marks, etc. correctly is not here. 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, often times 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 during 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 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 site can provide information to help 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 all be kept consistent across all transcripts, and may be specified in your SSP. 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 local language is used, the convention will be slightly different. There will also be some variation depending on the SSP. 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. Indicate the name is a pseudonym by putting it in brackets, for example [Sugarplum]. 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.

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.
- 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.

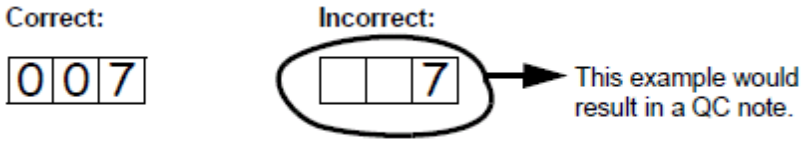
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

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:

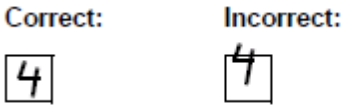
- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

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



- 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:



- 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.

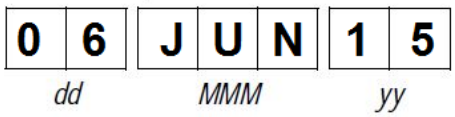
4. How to Record Dates

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.

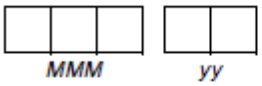
The month field must be filled in with the three-letter abbreviation *in English*. Abbreviations are shown in the table below.

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**

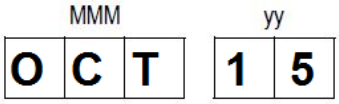
For example, June 6, 2015 is recorded as:



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:



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



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.

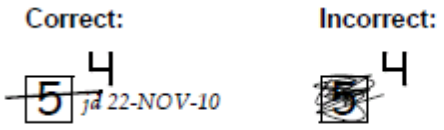
It is important to make these changes to the original CRF—***never*** copy data onto a new form. After making the change, the CRF *must* be re-sent to RTI.

Note: If a correction or addition is made to one page of a multiple-page CRF, re-upload all pages. 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.

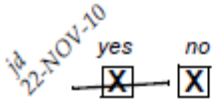
Whenever an entry on a CRF is changed, do the following:

- 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:



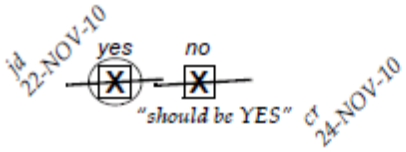
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:

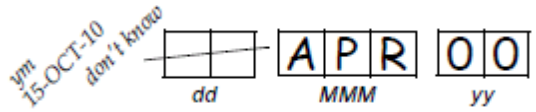


The standards above must ***always*** be followed whenever a CRF is changed, clarified, or amended, even if the change is made ***before*** the CRF is uploaded for the first time.

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), “MISSING”, 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.