

# VOICE-C Data Management Manual

The purpose of this manual is to provide guidance on the qualitative data flow and management of the transcripts, field notes and debriefing reports for the VOICE-C interviews (In-Depth Interviews, Focus Group Discussions, and Ethnographic Interviews). Additionally, the manual provides information needed to successfully complete, enter and submit case report forms (CRFs) to the Data coordinating Center (RTI) for the VOICE-C study. For questions about this manual or about general data collection policies, procedures, or materials, please contact Elizabeth (Liz) Montgomery ([emontgomery@rti.org](mailto:emontgomery@rti.org)) and Miriam Hartmann ([mhartmann@rti.org](mailto:mhartmann@rti.org)).

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### Qualitative and Quantitative Data Overview

VOICE-C is a qualitative research study whose primary purpose is to collect qualitative interview data from participants. These data will be captured during In-Depth Interviews (IDI), Focus Group Discussions (FGDs); and Ethnographic Interviews (EI) and transcribed verbatim (or in expanded field notes in the case of EI) into Word documents that will be uploaded into a qualitative software database called NVivo 8. Also, field notes will be taken by VOICE-C staff attending events such as community meetings and gatherings/educational sessions for male partners of VOICE participants. In addition to these transcripts and notes, debriefing reports that summarize each IDI and FGD will be entered and managed in a Microsoft Access database.

Quantitative data that document the enrollment and termination status and the demographic characteristics of these participants, as well as any occurrences of Social Harms, will be captured on the following Case Report Forms (CRFs): Demographic Form (DEM), Termination Form (TF), Social Harms Form (SH), Enrollment Status Form for Group 1 (ESF\_G1), Enrollment Status Form for Group 2 (ESF\_G2), Enrollment Status Form for Group 3 (ESF\_G3), and Enrollment Status Form for Group 4 (ESF\_G4). These CRF data will be managed in the CPro software system.

#### 1. Quantitative Data:

This section of the manual describes the process for capturing, entering, verifying, transmitting and Quality Control (QC) of CRF data.

##### 1.1. CRF General Guidelines for Capturing Data

Based on Good Clinical Practices (GCP), follow the guidelines below when completing CRFs:

- Read carefully and follow all the form instructions printed on the back of each form;
- 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 use cursive or script writing as it can be difficult to read;
- Write numbers as large as possible while staying within the boundaries of the boxes;
- Record data on the front of the CRFs only;
- Record written text responses on the lines provided. If additional space is needed, continue writing the response in the margin;
- Mark only one response except when given explicit instructions to **mark all that apply**;
- A response is required for every item unless instructed otherwise by a skip pattern.

Note: The site staff member who initially completes the form must record his/her initials and date in the space provided at the bottom right-hand corner for the DEM, TF and SH form or at the end of each section for the ESF for Groups 1-4 form.

### Interviewing Techniques

The CRFs have form instructions printed on the back of each CRF page which provides specific guidance on how to administer the forms. At the top of the form instructions, information is provided about the form's purpose as well as general instructions for the Interviewer to communicate to the participant. Below these instructions, there are item-specific instructions for all questions that warrant further description. Information provided includes additional detail on how the Interviewer should record information, the meaning of a question, and other question-specific details to facilitate a clearer understanding of the question.

In addition to the guidance in the form instructions, below are general interview tips and techniques.

### **Welcoming the Participant**

When a new participant arrives at the clinic, always make the participant feel comfortable. Introduce yourself and create a rapport with the participant to make him/her feel comfortable. Let the participant know you will be talking about personal and sensitive topics as part of the visit. Read all instructions as they appear on the forms.

### **Asking Sensitive Questions**

Your level of comfort with asking sensitive questions will affect the participant's level of answering the questions. Ask questions in a confident and supportive manner.

### **Pacing the Interview**

Every participant is different. Some will answer questions very quickly while others may have to think longer or change their responses after giving more thought. Always account for this variability when doing an interview. Read items slowly. Let the participant finish thinking before you record the answer and move to the next item.

### **Reading Items Aloud**

Read the entire question word for word to the participant. Vary your voice so you don't sound automated. Avoid re-phrasing as this could lead to inconsistent interpretations of content. Unless explicitly instructed, do not read out the answer options unless the participant is struggling to answer or needs prodding.

### **Checking your Work**

During an interview, it is important to use the form instructions. Make sure the participant understands what you are asking and responds accordingly. Record all reported information on the forms. After the interview and while the participant is still there, review the forms for accuracy and completeness so you can complete any item that may have been missed. Once the participant has left the interview, any items identified as missing must be left as is and considered "missing data". Because interviewer-administered CRFs are considered source documents (with the participant being the source of the data), missing items cannot be completed once the participant leaves the clinic or interview venue. The exception for which data can be completed at a later visit, is for variables on the DEM Form that do not change over time (e.g. DEM Form, item 3, date of birth).

#### **1.2. Recording Data on the CRF form**

Data should be hand-written on the CRFs by the Interviewer at the sites. There are several response formats to questions: categorical, numeric, dates, multiple answer format and open-ended (textual).

##### **1.2.1. Recording Categorical responses on the CRF:**

Mark the appropriate box with an X. Only record one response per question. For example, on the DEM Form, for item 6 which asks 'what is the language most spoken at home', if the participant reports that it is SeSotho, mark the corresponding box with an X.

<sub>2</sub> SeSotho

##### **1.2.2. Recording Numerical responses on the CRF:**

Some questions include boxes for recording a numeric response. The following instructions should be followed when recording numeric responses:

Right justify all numbers and fill in any boxes with leading zeroes.

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

Correct:

0	7
---	---

Incorrect:

	7
--	---

Write the number(s) as large as possible while staying within the boundaries of the box on the CRF hardcopy.

### 1.2.3. How to Record Dates on the CRF

All dates are recorded in the format ddMMMy, where dd is the day, yy is the year, and MMM is the month. The dd and yy are numeric and MMM is alphabetic. Refer to **VOICE SSP Manual Section 14.2.4** for instructions on how to record dates.

### 1.2.4. Recording responses to Multiple-Answer Questions on the CRF:

When instructed, participant can provide multiple answers to a specific question. Mark all the appropriate boxes with an X. These items will be identified with a '**mark all that apply**' instruction.

For example, in the ESF for Groups 2, 3 and 4, the participant is asked what languages s/he is comfortable using for data collection and the instructions indicate '**mark all that apply.**' The participant will then be prompted to answer all languages. If needed, the Interviewer will provide the participant with the response options: IsiZulu, SeSotho, English, Other (specify). The Interviewer should mark an X next to every language response the participant provides. If s/he lists 1 or more languages not listed as an option, mark the **Other, specify** box with an X and list ALL other languages provided by the participant.

### 1.2.5. Recording textual responses on the CRF:

Some questions are open-ended or require the interviewer to specify a response. The interviewer should write the participant's response verbatim, if possible. If the response is too long, the interviewer should summarize the response.

### 1.2.6. How to Handle Missing and Unknown Data

If the answer to an item is missing (MSG), not available (NA), or if the participant refuses to answer (REF), the interviewer should make a written notation corresponding to the codes above (MSG, NA, REF) in the margin next to the item on the CRF and the response boxes should be left blank. This procedure should be followed for any type of question on the CRF forms. A skip pattern is the **only** valid reason to leave a response blank without any margin notation on the CRF.

## 1.3. Correcting Data on the CRF form

Once all data has been written, the CRF should undergo a review process. Immediately following the completion of the form, the Interviewer checks the form to make sure it is complete and accurately entered. Then, the form is given for review to a second staff member (according to the site's internal QC process and Data Management SOP). This second reviewer then reviews the form by the end of the day to check for inconsistencies or incomplete information. If anything is incomplete, the designated staff reviews the form with the Interviewer to fill out the information and document a brief explanation in the comment's section of the form as to why something wasn't filled out. All comments should be documented with staff initials and date.

#### 1.4. CRF Data Entry Instructions for CSPro Database

Once CRF data have been internally QC'ed, they should be double data-entered into a CSPro database at the site. Instructions for running the CSPro software system and beginning the data entry process can be found in **Appendix A**. Staff should enter data from CRFs into the CSPro database that corresponds to that form. If the response type is categorical, numeric (including dates), or multiple answers, a numeric value should be entered into the database. If the response type is open-ended or textual, text should be entered verbatim in the corresponding database field, as described below.

##### 1.4.1. How to Enter a Categorical Response

When entering a categorical response into the CSPro database, look at the subscript next to the box marked with the X on the CRF. Enter the corresponding subscript number into the CSPro database.

For example, on the DEM Form, for item 6 which asks 'what is the language most spoken at home', if SeSotho is marked with an X, record 2 into the CSPro database (as 2 is the response's corresponding subscript).

<sub>2</sub> SeSotho

##### 1.4.2. How to Enter a Numeric Response

Some questions include boxes for recording a numeric response. The following instructions should be followed when entering numeric responses into the CSPro database:

Right justify all numbers when entering numeric responses in the database, and fill in any boxes with leading 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 two response boxes are provided in the database:

Correct:

Incorrect: this example would result in a QC

##### 1.4.3. How to Handle Missing and Unknown Data

If the answer to an item on the CRF is missing (MSG), not available (NA), or if the participant refuses to answer (REF), the interviewer will make a written notation as instructed above (MSG, NA, REF) in the margin next to the item on the CRF. The corresponding field should be left blank in the CSPro Database, by keying through with the 'Enter' key.

The CSPro database does not have built in skip patterns and therefore, when entering a response which necessitates a skip pattern on the CRF, the data entry staff should manually advance to the appropriate field by pressing the "Enter" key.

For step-by-step instructions on how to enter a data from a CRF into CSPro, refer to **Appendix A**.

### 1.5. CRF Double Data Entry

CRFs should first be entered manually in a main database called 'main', and then a second time in a verification database called 'verify' by a different staff person. The purpose of double data entry is to minimize data entry errors by verifying the consistency of entries from two individuals entering the same form. See **Appendix A** for detailed instructions on how to enter data in the main and verification database, and run a verification report.

#### 1.5.1. Comparing Doubly-entered Data in CSPro

After CRF data has been entered into the corresponding CRF's 2 databases (main and verification), a staff member designated by the site (see Data Management SOP) should run an auto-generated verification report which will detail the inconsistencies and errors between the two databases, question by question. For inconsistencies between the 2 databases, the sites should refer to the hardcopy CRF and determine which database contains the correct response and correct the other manually and re-save. If neither database reflects the response listed on the CRF, both databases need to be manually updated with the correct information and re-saved until all discrepancies are resolved. For instruction on how to make corrections in CSPro, and save the corrections refer to **Appendix A**.

Once site verification processes are complete and the main database is considered clean, the Data files should be uploaded to the FTP site as described in **Appendix A** and the FTP Log should be updated.

#### 1.5.2. FTP file Transferring, Opening and Modifying

For information on FTP file transferring, opening, saving and modifying, please refer to **Appendix B**.

#### 1.5.3. Frequency of data entry, and uploading of files to FTP site

For the above described data entry process, there is **1 week** turnaround time to complete the following steps:

- Double data entry of CRF data into CSPro databases;
- Create a CRF Log and Data Files
- Run QC checks through an automated Double Data-Entry Verification process;
- Revise CRF Log and Data Files and CRFs if needed
- Upload the updated CRF Log and Data File to the FTP site for RTI review

#### 1.6. RTI QC and site response and documentation of queries:

Once RTI receives the CRF Log and Data Files, an auto-generated SAS report will be run to further detect errors such as out of range data as well as inconsistent PTIDs and/or group assignments or missing data. A Query report listing all errors will be generated and sent to the sites (see **Appendix C** for sample Query report) within **1 week** of receipt of the CRF Log and Data Files. Upon receipt, the sites then have **1 week** to do the following:

- Make necessary data entry corrections/ modifications based on the Query Report to the 1) CSPro database(s) and/or; 2) CRFs;
- Respond item by item in the Query report as to how each QC was addressed and resolved and provide staff initials and date for each item on the report. Notation made on the printed QC reports should be clear and conform to GCP standards. Query Reports should be printed and filed at the sites.

The annotated Query Reports with notes that address each issue should then be scanned and sent back to RTI via the FTP server or email attachment. RTI will verify that each item has been addressed, or will request the site to further follow up with any issue. Once every issue is resolved and the data is considered 'clean' by the sites and RTI, updated/corrected data files should be uploaded to the FTP site.

NOTE: Query notes on weekly Query reports will recur until updated/corrected files are uploaded to the FTP site. Therefore, it is important that the site upload to the FTP site diligently.

For questions regarding the CRF data entry and QC procedures, please contact Helen Cheng ([hcheng@rti.org](mailto:hcheng@rti.org)) and Katharine Rivett ([krivett@rti.org](mailto:krivett@rti.org)).

## 2. Qualitative Data

This section of the manual describes the process for capturing, transcribing, transmitting and QC'ing qualitative data, including transcripts from **interviews (IDI, FGD), EI field notes, Debriefing Reports and Field Notes from male partner meetings or community events.** .

### 2.1. Qualitative Interview Techniques<sup>1</sup>

In addition to the general interview techniques described above in Section 1.1 that apply to all types of interviews (i.e. welcoming, pacing, being sensitive), below are techniques specific for the IDI, FGD and EIs.

#### 2.1.1. IDI Techniques

##### **Maintain Confidentiality**

Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned the interview. This is especially important when interviewing people about their sexual behaviors.

##### **Influencing Responses**

It is especially important to be on guard against asking leading questions. Leading questions are those that imply a value judgment on your part. This can bias the responses that you will obtain because if the participant disagrees with you, they may be reluctant to state it.

*biased question: "I know that most smart people in this community always use condoms, don't they?"*

*Better phrasing: "I have heard some people in this community say that most smart people use a condom, and others say that they know smart people who don't use condoms. What do you think?"*

##### **Probe for Depth**

As much as possible ask follow up questions and probe for a deeper understanding of what the participant is saying. Examples of probing phrases might be: "Why?" "How did you feel when that happened?" "Did you do that?" "What do you think?" "What happened then?" "Can you tell me more?" "I'm not sure I understand." Such probing also may require extra patience on the part of the interviewer.

*Example: Can you tell me more about why you didn't feel you could ask him to use a condom?*

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<sup>1</sup> The Qualitative Interview Techniques section is adapted from the following reference: Mack, Natasha, Cynthia Woodsong, Kathleen MacQueen, Greg Guest and Emily Namey. Qualitative Research Methods: A Data Collector's Field Guide. RTP, NC: Family Health International, 2005.

### **If Uncertain, Verify Responses**

When you want to be sure that you have heard clearly what the participant said or that the information is accurate, rather than asking them to repeat their response, you can reflect the answer back to the participant.

*Example: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?*

### **Do Not Respond to Questions**

If the participant asks you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think.

*Example: Well, I was hoping you could help me understand what people in this community say about how you catch the HIV virus.*

### **Be Patient**

It is not necessary to be asking questions every minute. Creating pauses can permit the participant to think more deeply about the topic. Don't be afraid to wait quietly while they think about a response or further probe, but be reassuring in your body language so the participant knows you are genuinely interested in what she/he has to say.

### **Do Not Interrupt Participant's Work**

The participant is doing a favor to answer the questions. If the participant must interrupt the interview to attend to a child, a customer, a neighbor, use this time productively to review your notes and think about what else you would like to ask.

### **Handle Time Wisely**

Always note the time when the interview begins and ends. As you begin the interview, evaluate how much time you may have with this participant and what are realistic goals for asking questions from the interview guide. Ideally, the interview will flow like a conversation rather than a series of questions and answers.

### **Be Truthful**

In obtaining informed consent or in responding to questions from participants during the interview, provide brief, truthful answers about the objectives of the study, the likely benefit to the community.

### **Moderate Tone of Voice**

During the interview, use a moderate, friendly tone of voice.

### **Moderate Body Language**

Be sensitive to your participant's body language and aware of your own. Avoid body language that may send the signal that they are giving "correct" answers, or are wasting your time.

## **2.1.2. FGD Techniques**

The primary responsibility for the flow of each focus group session rests with the facilitator. Facilitators should keep the following "do and don't" list in mind.

<b><u>A good facilitator does:</u></b>	<b><u>A good facilitator doesn't:</u></b>
Show flexibility	Dictate the course of discussion
Show sensitivity	Lose control over the conversation
Have a sense of humor	Judge comments or be an "Expert"
Link group ideas together	Inform or educate <u>during</u> the group
Encourage everyone to participate	Lead a Question and Answer session

### **Asking Questions and Probing**

The goal of the facilitator during the focus group session is twofold: (1) to create a natural discussion in which the facilitator participates very little, i.e., she/he should "disappear," (2) to unobtrusively steer the discussion through all the important questions in the guide and at a pace which will allow for all topics to be adequately covered. Much of what happens in the focus group will rely on the facilitator's ability to monitor the tone and the group and make quick judgments about when, how and if to reenter the conversation as the discussion progresses.

To the extent possible, the discussion should flow in the order presented in the applicable guide. However, the facilitator should be prepared for things to be mentioned out of order, and she/he should not ask participants to stick with the established sequence if it would be disruptive. It is helpful to tick questions off on the guide as they are discussed, in the event that the discussion "gets ahead of itself." Then, when it is appropriate, the facilitator can return to the questions that were skipped.

### **Tips for Facilitators:**

- **Be prepared.** Have everything you need to conduct the focus group with you and in order. Get all your materials together. Make sure flipcharts and additional tools needed are prepared. (See IDI, FGD and EI visit checklists).
- **Introduce yourself individually** as participants gather. Make small talk. Thank participants for coming.
- **Limit the amount of time you talk** once the session begins. Attempt to get a question on the floor and let the participants kick it around with limited direction from you.
- **Steer the conversation** mainly by asking for experiences, thoughts or definitions. Ask people not only to talk about themselves, but to talk about what others like them think, say or do.
- **Try to include as many participants as possible.** You may refer to an individual if the current conversation relates to something that individual has said earlier in the discussion. For example, *What you are describing sounds very similar to (or very different from) what Martha was talking about earlier. What do you think about this Beverly?*
- **Do not force responses by using leading questions** or by paraphrasing what participants have said. Instead, use neutral probes or repeat what the participants say in their own words.
- **Do not use evaluative comments** like "good" or "That's interesting." Do provide positive enforcement by looking interested, saying uh-huh, or asking a follow-up question. Make sure that you **provide consistent enforcement for all comments** (unless you are trying to steer conversation

elsewhere). Comments such as "I see" and neutral probes such as *"Any other thoughts about this?"* and *"Who else has some ideas about this?"* are acceptable. Questions may also be addressed to the group: *"What do you [the group] think about what [name] just said?"*

### **Tips for Note-Takers:**

- **Be prepared.** Have everything you need to conduct the focus group with you and in order.
- Even if you are audio recording the group, it is important to remember that **if the recording fails your notes will be the only documentation** of what occurred during the group. Make sure you have a sufficient number of tapes handy, or sufficient memory in your digital recorder. Check the tapes and recorder before the group begins. Record the time and date and the archival number prior to beginning the group.
- It is the **note-taker's responsibility** to note observational details such as: body language, interruptions, silent agreement, indications of group mood, irony or contradictory statements when the meaning is opposite of what is said.
- It is the note-taker's responsibility to **capture well-said quotes**, word for word if possible.

### **2.1.3. Ethnographic Interview Techniques**

Ethnography is process of learning the meaning of the world through the eyes of another. Thus one does not merely describe the cultural practices of another individual or group (with an outsider or "-etic" perspective), but studies and aims to understand and learn how life is perceived by that individual/culture from an insider or ("-emic") perspective.

Flow of interview and techniques are similar to that of IDI. While in-depth ethnographic research is beyond the scope of this study, EI field notes should include observational notes about the environment and context from the interviewer that represent what she is learning from the participant.  
Update after training.

## **2.2. Qualitative Data Capture**

### **2.2.1. Audio-recording**

The IDI and FGD should be audio recorded. Audio recordings will be transcribed and translated into English (word file "transcripts"). See SSP Section 19.11.11 as well as DM SOP Section 7.3 for audio recording details.

Once the audio file is copied onto the FTP site, RTI will transfer the file onto a local drive and burn onto a password protected CD for RTI documentation.

### **2.2.2. Debriefing Reports**

#### **2.2.2.1. IDI and FGD Debriefing Reports and Transmission**

Immediately following the IDI and FGD, the facilitator and note-taker will need to review and expand the notes they have taken during the interview on the guides themselves (and additional pages if used). Then these hand-written notes will be entered electronically into an ACCESS database and will constitute the content of the "Debriefing Report" for each interview. In addition to summary responses corresponding to each FGD or IDI question, the Debriefing Report Access database will also capture basic statistics and summary notes about each interview session. A hard copy of the Debriefing Reports should be filed in a secure site location as specified in the Data Management SOP.

Detailed instructions on how to enter the Debriefing Report information into the Access database is provided in **Appendix D**.

### **2.2.2.2. Debriefing Report Quality Control**

After the Debriefing Report is entered into Access, it will be reviewed for accuracy and completeness by the site, after which it is considered final. Once final, it is transferred to the FTP site for RTI review, during which the following occurs:

- Verify that each Debriefing Report is listed on the most recent FTP log
- At RTI, the report will be read and reviewed by Data team members and queries will be listed on a Query Report within **1 week** of receipt of the Access files. The following are examples of queries:
  - Typos that lead to ambiguous meaning: e.g. “sore the medication” vs. “store the medication”
  - Sentences that don't make sense
  - Clarification of local terms used
- Upon receipt, the sites then have **1 week** to do the following:
- The Debriefing QC Reports are sent **weekly** to the site. Within a **week**, the site is asked to correct or clarify any problems identified in the QC Report directly in the Access database and confirm the status (e.g. 'done', 'corrected', 'not needed', etc) of each query and whether it resulted in a change in the database.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated Data Team member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made on the Access database and the notes are updated on the Query Report.
- Once RTI finds no additional issues, the Debriefing Report is considered fully clean and final and is emailed to the VOICE-C Protocol Team.

A sample Debriefing QC Report is included in **Appendix E**.

NOTE: Queries will recur until the modified Access database is uploaded to the FTP server and/or the change is properly documented on the QC report.

### **2.2.3. IDI and FGD Transcripts**

#### **2.2.3.1. Transcript Flow**

IDI and FGD transcripts will be finalized, quality controlled and transmitted to RTI through the following steps: 1) the interviews will be audio-recorded; 2) from the audio file, the interview will then be transcribed by an external provider; 3) the transcript will then be translated internally by RHRU; 4) 10% of all transcribed texts will be submitted to a different external provider and translated. These translated texts will be compared to the internal translations; 5) once transcripts are fully reviewed and approved by the sites, they are emailed to RTI for review. Note that both the local language transcripts as well as translated English transcripts will be uploaded.

For IDI and FGD data flow, see **Appendix 2** in the DM SOP.

#### **2.2.3.2. Transcript Quality Control**

Once a transcript (or field notes) is emailed to RTI, the following should occur:

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- Each transcript is then reviewed by a member of RTI's Data Team. Problems such as typos, confusing terms or missing /potentially incorrect data are written in comment bubbles attached to the appropriate text. The site then responds to all comments through either comment responses and/or changes directly in the transcript noted by brackets.
- RTI-reviewed transcripts will be emailed to the site within two approximate weeks of transcript receipt. The site is asked to correct or clarify any problems identified in the comment bubbles within two weeks of receipt of the reviewed transcript.
- Once the revised transcript is circulated through email, an RTI Data staff member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made.
- Once RTI finds no additional issues, the transcript (or notes) is considered fully clean and final. At this point, the transcript is uploaded into Nvivo 8 for qualitative data coding and analysis.

Note: If a change is made to a transcript but the updates are not emailed to RTI, the change will **not** be correctly received by RTI. Therefore, it is very important that the site email all revised transcript files to RTI diligently until deemed final.

### **2.2.4. Ethnographic Interview Field Notes**

Because the EI is not audio-recorded, the field notes that are uploaded on the FTP site are not verbatim transcripts of the session, but rather observations and overall session notes. EI Field Notes undergo a 1 step translation process at the site. During the first EI, a description of the household composition should be recorded on the "Household Composition Table" created by the study. At all subsequent visits, the table should capture any changes (or additional information) captured in the 'Changes to Household Table' section.

After the Note-Taker reviews the EI Field Notes to ensure all important information is thoroughly completed, the EI Field Notes should be uploaded and subsequently QCed in the same manner as described above in the **Transcript Quality Control** section for the IDI and FGDs.

The EI Household Composition Tables will also be uploaded to the FTP site, undergo QC, and once final, imported to Nvivo for analysis.

### **2.2.5. Male Involvement Meeting and Community Event Field Notes Reports**

Prior to and during the VOICE trial, men will be invited to participate in meetings to learn more about the trial as well as VOICE-C sub-study as well as their involvement in the sub-study. The men will be encouraged to network with other men and share information about the trial and discuss strategies for involving male partners. VOICE and VOICE-C staff will work together coordinating efforts with male involvement activities. For more detail, refer to the MTN003 Male Involvement SOP. Additional community-based activities that are either directly or indirectly related to VOICE will also occur.

The same template that will be used A sample field note report used for male involvement meetings is located at **Appendix G**.

## VOICE-C

### 3. Study Databases

A VOICE-C Database Summary table (Quantitative and Qualitative) is listed below:

VOICE-C data are entered into one of three database systems. CRFs are entered into CPro databases; Debriefing Reports are entered into Access databases, and interview transcripts from FGDs and IDIs and Field Notes from EIs and community events are entered (uploaded) in an NVivo database. Procedures are outlined below for each of these database applications.

Database Type	Forms	Database Names*	Procedures
CPro	CRFs	DEM ESF_G1 ESF_G2 ESF_G3 ESF_G4 TF	<ol style="list-style-type: none"> <li>1. Enter data into two databases (MAIN and VERIFY)</li> <li>2. Check on double data entry</li> <li>3. Export MAIN data file to local machine</li> <li>4. Complete FTP log</li> <li>5. Upload files to FTP server</li> <li>6. Resolve queries identified by RTI</li> </ol>
Access	FGD and IDI Debriefing Reports	FGD_G1 FGD_G2 FGD_G3 FGD_G4 IDI_G1 IDI_G1	<ol style="list-style-type: none"> <li>1. Enter data into database</li> <li>2. Complete FTP log</li> <li>3. Upload files to FTP server</li> <li>4. Resolve queries identified by RTI</li> </ol>
NVivo	FGD and IDI Interview Transcripts; Field Notes from EI and Community Events	VOICE-C	<ol style="list-style-type: none"> <li>1. Interview transcribed &amp; translated verbatim or field notes expanded in Word document.</li> <li>2. Complete FTP log</li> <li>3. Upload files to FTP server</li> <li>4. Resolve queries identified by RTI</li> <li>5. Final documents imported into NVivo</li> </ol>

### 4. Study Specific Data Reporting Information

#### Reporting Requirements

The MTN SMC will conduct periodic reviews of study progress including rates of participant accrual. These reviews will take place every 12 months or as needed.

SMC reports will be provided to the MTN SMC committee approximately every 12 months and these reports will be prepared by RTI International.

## 5. APPENDIX A: CPro STEP-BY-STEP DATABASE ENTRY INSTRUCTIONS

The following instructions provide a step-by-step guide to data entry of a CRF into its corresponding CPro database, using the ESF Group 2 form as an example. If entering data into other CPro databases, substitute the form name for ESF\_G2 where appropriate below.

Location of files:

All ESF\_G2 files are located in the folder: **C:\VOICE-C\DataEntry\CPro\ESF\_G2**.

You can open this folder by clicking on the shortcut on the Desktop named “Shortcut to VOICE-C CPro databases” and then opening the ESF\_G2 folder. This folder contains four shortcuts and four subfolders. The subfolder ‘database’ contains files that site staff should **not** access. Modifying these files will affect the performance of the databases.

### 5.1. ENTERING DATA

Data should be entered within one week of form completion.

#### 5.1.1. Data entry into MAIN database.

- Open database by double clicking on the shortcut in the ESF\_G2 folder named: **ESF\_G2\_MAIN.pff**
- Type your initials. Click ‘OK’.
- Click on ‘add’ button at the top left side of the screen 
- Enter first form.
- Enter VOICE-C PTID as written on the CRF (paper form).

**Note for ESF forms for ineligible participants:** If a pre-selected VOICE-C participant is ineligible, then a PTID from the ineligible series should be used on hard copy and electronic data. The ineligible series of PTIDs is formatted as X900, where ‘X’ represents the Study Group number, 9 signifies that the participant is ineligible, and the last 2 digits proceed in sequential order. For example, for Group 1 participants, the first ineligible case should be assigned a PTID of 1901, the second should be 1902, and so on.

ESF Group (ESF_GX)	PTIDs
1	1901, 1902,...
2	2901, 2902,...
3	3901, 3902,...
4	4901, 4902,...

- After entering value, press the Enter or Tab key to proceed to next field. If you would like to move to a previous field, press the Shift and Tab key at the same time.

**Note:** Do **not** use a mouse to move from field to field.

- If value is blank on form, leave field blank on database by pressing the Enter or Tab key.

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- If error message appears, reenter value. If error message instructs you to press F8, do so and then reenter value.
- If you are having difficulty modifying a value in the field, move the cursor to left most position in the box and press delete until all characters have been cleared, then re-enter the correct data.
- Make sure to enter version # of form (including decimal place) at the bottom of every form regardless of whether the form is complete.
- When entering the version number, the decimal place needs to be entered in addition to the numerical values. Therefore, 3 fields must be entered. For example, if the version is 1.0, the “1”, “.” and “0” all must be entered before saving.
- Press ‘Enter’ and click on ‘Yes’ to accept the record. This is an important step because this saves the case and any changes that you have made.

**Note: Keying in the version number followed by pressing the Enter key must be completed in order to SAVE all work.** This applies to when data is originally entered as well as to when any changes are made.

- Enter all forms.
- Click on ‘Stop’ button  after entering all forms.
- Close window by clicking on X in top right corner.

### **5.1.2. Data entry into VERIFY database.**

Note: The staff member who enters into the VERIFY database should not be the same person who entered data into the MAIN database.

- Open database by double clicking on the shortcut in the ESF\_G2 folder named: **ESF\_G2\_VERIFY.pff**
- Type your initials.
- Click on ‘Add’ button  at the top left side of the screen.
- Enter all forms (as per instructions for the instructions above for Main database).
- Click on ‘Stop’ button  after entering all forms.
- Close window by clicking on X in top right corner.

\*\*\*\*\*

### **5.1.3. Entering Section 2 (Screening 2 and Enrollment Data) Data**

Because the ESF\_G2 form may be filled out at two visits, you may enter form data into the database on different days. To locate a partially completed record, open the MAIN and VERIFY databases as described above. Instead of clicking on the ‘add’ button, locate the VOICE-C PTID on the left-hand column and double click on the PTID. Prior to entering Section 2 data, confirm that the PTIDs written on the paper form and the PTID shown on the top of the ‘Data Entry Screen 2’ match.

## **5.2. CHECKING DOUBLE DATA ENTRY**

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To check on double data entry and resolve discrepancies, compare the MAIN and VERIFY databases by following these steps:

- Produce discrepancy report by double clicking on shortcut in ESF\_G2 folder named: **ESF\_G2.cmp.pff**.
- If discrepancy report is generated, print report.  
-> **If no discrepancies are found, STOP HERE.**
- Close report window by clicking on X in top right corner.
- Open both the MAIN and VERIFY databases.
- For each discrepancy on the list, identify which value has been incorrectly keyed. (Note that “Inp” entries refer to MAIN database values and ‘Out’ entries refer to VERIFY database values.) Correct the value in the appropriate database by double clicking on the relevant VOICE-C PTID in the left column and correcting the field. Be sure to check data file name at top of window to ensure that you are correcting the appropriate database (whether MAIN or VERIFY). Mark each item on discrepancy report (e.g., with a check) after resolving in the appropriate database.
- After all discrepancies have been addressed, close both databases.
- Rerun discrepancy report to ensure that discrepancies have been resolved by double clicking on shortcut named **ESF\_G2.cmp.pff**. If discrepancy report is generated, print and resolve. Repeat this process until no discrepancy report is generated.
- File discrepancy report(s) in the appropriate binder as specified in site Data Management SOP.

### 5.3. EXPORTING DATA FROM CSPRO

On the **Thursday** of each week in which data has been entered into the database, export data from the CPro system by following these steps:

- Double click on shortcut in ESF\_G2 folder named: **ESF\_G2.exf.pff**.
- Close CPro Text Viewer and CSExport windows by clicking on X in top right corner.
- Two files will be exported to the ‘exported files’ subfolder in the ESF\_G2 folder. They are named ESF\_G2.sas and ESF\_G2.dat and will overwrite the previous .sas and .dat files.

### 5.4. COMPLETING FTP LOG

After entering or modifying information in the CPro databases, update the FTP log. The FTP should be updated weekly to capture all ongoing FTP upload activity. This log should be emailed to Katharine Rivett ([krivett@rti.org](mailto:krivett@rti.org)) at the end of every week.

### 5.5. UPLOADING FILES

#### 5.5.1. Schedule for Uploading

Exported .sas and .dat files should be uploaded to RTI FTP server each **Thursday**. Site staff should e-mail Katharine Rivett ([krivett@rti.org](mailto:krivett@rti.org)) the weekly FTP report to inform that data has been uploaded. If no records have been entered in a week, site staff should not upload database and should notify Katharine Rivett by e-mail message by Friday that no data has been entered that week.

#### 5.5.2. Uploading to FTP Server

- -Open FTP window and connect to RTI FTP server using the following information:
  - o Host: ftp.rti.org

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- Username: VOICE-C
- Password: mtn003cpass!
- Port: 22
- Click on the QuickConnect button.
- On left-hand window, type location of exported files in 'Local site' box:  
**C:\VOICE-C\DataEntry\CSPPro\ESF\_G2\exported files**. Press Enter key.
- On right-hand window, type location of directory that you will upload to in 'Remote site' box:  
**/VOICE-C/Data/CSPPro/ESF\_G2**. Press Enter key.
- Transfer current version of exported files by dragging ESF\_G2.sas and ESF\_G2.dat from left-hand window to right-hand window.
- After files have been transferred, right click on file names on the right-hand window and click on 'Rename'. Append today's date to file name such that files are named ESF\_G2\_ddMMMyy.sas and ESF\_G2\_ddMMMyy.dat.
- Transfer current version of FTP log by typing location of FTP log in 'Local site' box:  
**C:\VOICE-C\DataEntry\CSPPro\ESF\_G2\FTP log** and dragging file (FTPlog\_ESF\_G2.xls) to right-hand window.
- After spreadsheet has been transferred, right click on spreadsheet file name on the right-hand window and click on 'Rename'. Append today's date to file name such that file is named FTPLog\_ESF\_G2\_ddMMMyy.xls.
- Check that three files have been transferred to FTP server and dated appropriately. If so, you may close the FTP window by clicking on the X in the top right-hand corner.

### 5.6. QUERY RESOLUTION

A designated site staff person will receive a list of queries by e-mail identifying missing or discrepant data from RTI the week following an FTP upload. Reports will list the VOICE-C PTID as well as describe the issue associated with the PTID. Queries should be resolved within the week and database changes should be made by the end of the week. To address queries:

- Correct error or complete missing information on CRF. Incorrect values (if any) should be crossed out and correct values written beside the erroneous value. Staff member should write initials and date next to the change. (This may be unnecessary if issue is a result of a data entry error.)
- Locate record by opening databases and double clicking on PTID in left-hand column. After making changes to a record, remember to save the change to the record by moving cursor to **version** field, pressing the Enter key, and clicking on 'Yes' to accept changes.
- Follow above instructions to:
  - Change record in MAIN database
  - Change record in VERIFY database
  - Compare two databases
  - Export data
  - Upload exported .sas and .dat and log to FTP server
- FTP Log: If in a given week, the site makes changes to the database(s) to address queries but did not enter **new** records into the database, the site should still fill out the FTP log to indicate that it has uploaded data to the FTP server. This entry will be blank aside from the fourth column. If site staff do enter new records, it should not add an extra line to the FTP log to reflect query resolution changes to the database.

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- Query List: Complete three columns on the query list indicating action taken, staff initials, and date of action. Query list will be named: QueryList\_ESF\_G2\_ddMMMyy.rtf and will contain the date on which the query list is sent to the site. After query lists have been updated by site, save by appending the site staff initials (e.g. AAA) to the file name such that file will be named: QueryList\_ESF\_G2\_ddMMMyyAAA.rtf. Query lists may be saved in the 'query lists' subfolder in the ESF\_G2 folder.
- Upload updated query list to FTP for RTI review.

## 6. APPENDIX B: CHEAT SHEET for FTP FILE TRANSFERING, OPENING AND MODIFYING

Here is a cheat sheet of procedures for navigating the FTP site:

Enter the FTP site through filezilla. If filezilla is downloaded, go to Start => Programs => FTP filezilla client => filezilla. If filezilla and FTP is not downloaded, email Katharine Rivett ([krivett@rti.org](mailto:krivett@rti.org)) for download instructions.

Once on the FTP site, connect through entering the following information:

- o Host: ftp.rti.org
  - o Username: VOICE-C
  - o Password: mtn003cpass!
  - o Port: 22
- Click on the QuickConnect button.

Note: Once you log-in once, for all future sessions, there is a log-in shortcut. Click the gray arrow to the right of the QuickConnect button and select the address listed. This will automatically connect you to the FTP site without having to enter all of the log-in information.

The **left-hand side** of the screen shows the 'local site' or the local drives on your computer.

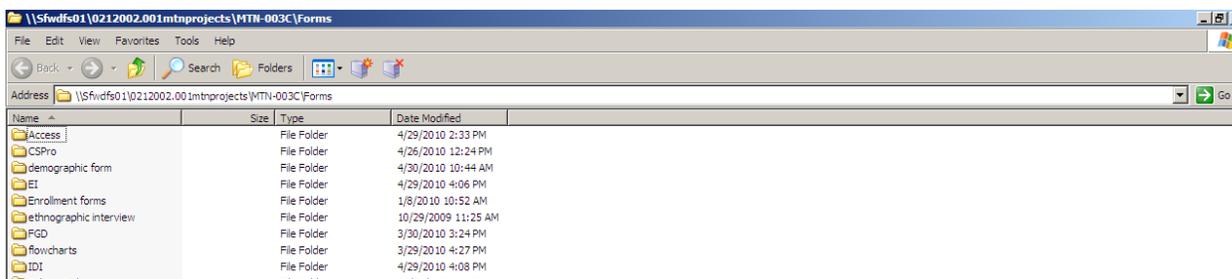
The **right-hand side** shows the 'remote site' or FTP site.

### To view the correct FTP folders (right-hand side of the FTP site):

Double click on the VOICE-C folder. Within that, double click data and then double click either CSPro, Access or Transcript depending on what file you need to access and/or transfer.

### To view the file from your local computer (left-hand side of the FTP site):

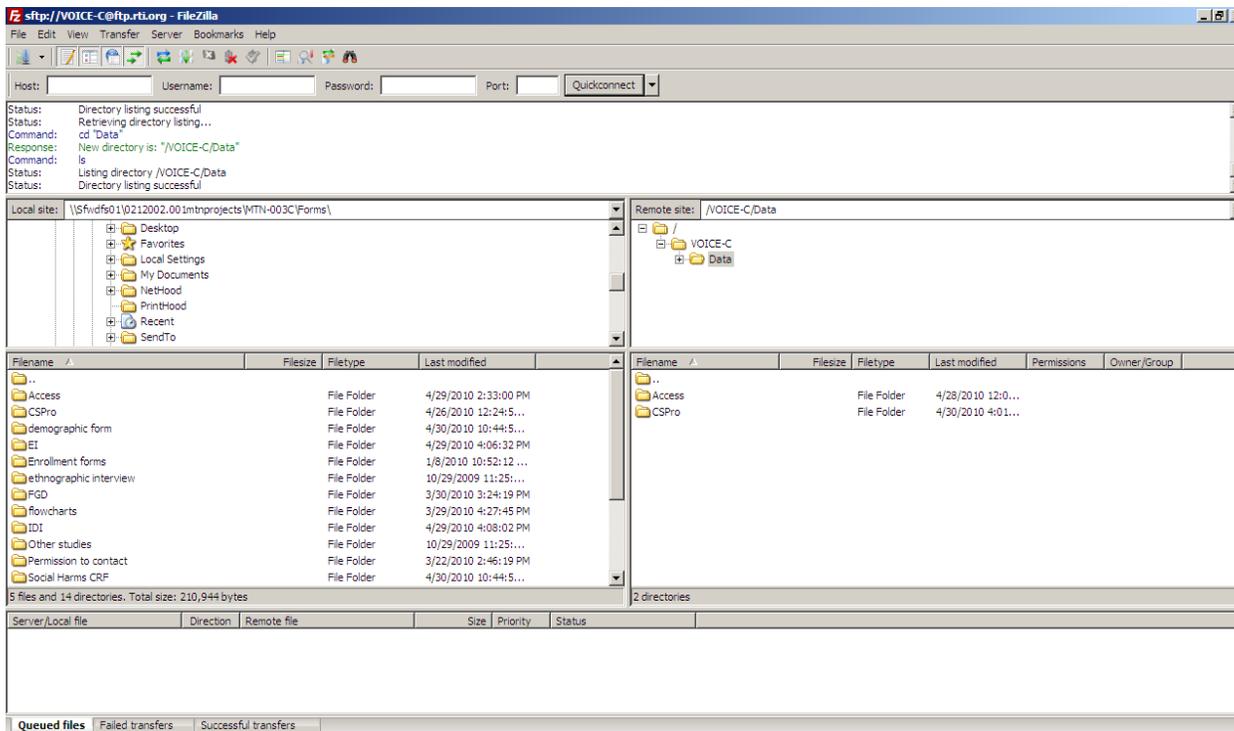
Go to the location of the folder in your computer. Then go to the toolbar up top that lists the name of the file and copy and paste the address line into 'Local Site' address line in the FTP site.



### To Transfer a document from one's local computer folders to the FTP site:

Make sure the 'Local Site' on the left-hand side has the correct address to access the file you need to upload. Make sure the 'Remote Site' on the right-hand side has the folder opened for the location in which you want to transfer the document to on the FTP server.

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Once the left hand and right hand side are properly set-up, click on the file on the left side side that you want to transfer and drag it to the right-hand side of the screen.

Alternatively, another way of transferring a file from the left-hand to the right-hand side of the screen is to double click on the file.

Note that when you transfer a file, it doesn't become removed from your local files, but rather a copy of it is made on the FTP server.

**To Open a document on the FTP site:** Open up the VOICE-C folder. Put your cursor on the document you wish to open. Right click and select "View/edit" and the document will open.

**To Modify a document on the FTP site:** Once the correct document is open, make changes as needed, document the changes (on the QQC Report), initial the document on the top left corner, and save the updated file per the instructions in the above sections: CRF File-Naming, Debriefing Report File-Naming or Transcript File-Naming.

**To Save a document on the FTP site:** when a document on the FTP site is opened and changes are made, the file must be saved to the user's local computer and then be transferred onto the FTP site.

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**7. APPENDIX C: SAMPLE QUERY REPORT for ESF\_G2 (CSPRO Query Report)**

Based upon database: ESF\_G2\_15JUN10.dat and ESF\_G2\_15JUN10.sas

Report Generated on: 18JUN10

			Completed by site staff			Completed by RTI staff
Query #	Voice-C PTID	Issue	Action Taken	Staff Initials	Action Date (ddMMMyy)	Issue Resolved (ddMMMyy)
1	1111	If q1 = 'yes' then female partner's VOICE-C PTID must be completed				
2	1111	If q5 = 'no' then q8 must = 'Not all met'				
3	1111	If q11 = 'no' then q12 should be completed				
4	1111	Second page VOICE-C PTID missing				
5	2222	q2 is missing				
6	2222	q3 is missing				
7	2222	q4 is missing				
8	2222	q5 is missing				

## 8. APPENDIX D: STEP-BY-STEP INSTRUCTIONS FOR ENTERING DEBRIEFING REPORTS INTO ACCESS

These instructions provide a step-by-step guide for entering data from an interview guide into the Debriefing Report interface in Access, using the FGD Group 3 as an example. If entering data into other Access databases, substitute guide name for FGD\_G3 where appropriate.

Location of files:

All FGD\_G3 files are located in the folder: **C:\VOICE-C\DataEntry\Access\FGD\_G3**.

You can open this folder by clicking on the shortcut on the Desktop named "Shortcut to VOICE-C Access databases" and then opening the FGD\_G3 folder. This folder contains one database file (FGD\_G3.mdb) and two subfolders.

### 8.1. ENTERING DATA AND PRINTING DEBRIEFING REPORTS

Data should be entered within one week of FGD session.

#### Getting Started

- Open Access data entry screen by double clicking on **FGD\_G3.mdb** in the FGD\_G3 folder.
- Maximize screen size by clicking on the maximize icon  in the top right-hand corner.

#### Page 1 Data:

- Create a new record by clicking on the asterisk button  in the bottom left-hand corner.
- Enter the interview date in the ddMMMy format (e.g. 15May10). Then press the Tab key to move to the next field.
- Enter the three-digit interview number from the top right-hand corner (e.g. 301 which is Group 3's first FGD).
- Enter the initials of the facilitator.
- Enter the initials of the note taker.
- Enter the venue.
- For language, mark all languages the interview was spoken in as some may be in more than 1 language. Use the **mouse** to select each language.
- For number of participants, enter the number who attended the interview session
- Then enter staff initials and date as recorded on the bottom right side of Page 1 of the guide

#### Page 2 through end of the form:

(e.g. in the example of Group 3 FGD, it is Page 2-11):

- Enter interview date and FGD number.
- Enter the summary comments as recorded in the right-hand column of the guide for each respective question. If nothing was recorded, leave the data field blank.
- For questions that also have middle column for a checked response (e.g. Question 4 of the Group 3 FGD guide), select the response from the drop-down menu to the left of the question.
  - o -For example, for Question 4 of the Group 3 FGD, there is a Question 4: Community Attitude. Click on the gray box with a downward arrow to access the dropdown menu options and select the response marked in the guide.
- Don't forget to include the post-interview section summary notes as well as checked response questions.

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- Once all information is entered for the FGD, enter your initials in the field at the bottom right of the screen.
- After all FGD records have been entered, you may close the window by clicking on the X in the top right-hand corner. Note that all changes to the database are saved automatically. Keyer should check that information has been accurately entered prior to exiting the database.

### Navigating between records

In the bottom left-hand corner of the Access screen, it says '**Record**' along with a field box with a number as well as left and right arrows. This is for navigating between FGD 'records' or interviews/sessions. To move to next record, click on right arrow. To move to previous record, click on left arrow.

### Printing Debriefing Report

To print a debriefing report showing all fields from each record in the database, maximize the Navigation Pane on the left-hand side of the screen. Click on the downward facing arrow and select 'Report' from the menu. Double click on **FGD\_G3 Debriefing Report** to display the report. Press Ctrl+P to print the document. If you would like to print specific records only (for example, the record that you just entered), you may use the Print Preview feature to identify the relevant page numbers and restrict your Print Range to the pages containing your record of interest. After printing, you may close the Debriefing Report screen by clicking on the X in the top right-hand corner of the report window.

(These printing instructions pertain to Access 2007. Instructions will differ slightly for Access 2003.)

## **8.2. COMPLETING FTP LOG**

After entering new information to the Access databases, update the FTP log. This FTP log should be updated weekly and emailed to Katharine Rivett (krivett@rti.org).

## **8.3. UPLOADING FILES**

### Schedule for Uploading

Access databases should be uploaded to FTP server each Thursday. Site staff will e-mail Katharine Rivett (krivett@rti.org) the weekly FTP report to inform that data has been uploaded. If no records have been entered in a week, site staff will not upload database and will notify Katharine Rivett by e-mail message by Friday that no data has been entered that week.

### Uploading to FTP Server

- Open FTP window and connect to RTI FTP server using the following information:
  - o Host: ftp.rti.org
  - o Username: VOICE-C
  - o Password: mtn003cpass!
  - o Port: 22
- Click on the QuickConnect button.
- On left-hand window, type location of database in 'Local site' box:
  - **C:\VOICE-C\DataEntry\Access\FGD\_G3.**
- On right-hand window, type location of directory that you will upload to in 'Remote site' box:
  - **/VOICE-C/Data/Access/FGD\_G3.**
- Transfer current version of database by dragging file (FGD\_G3.mdb) from left-hand window to right-hand window. It may take a few minutes for the file to transfer.

- After database has been transferred, right click on database file name on the right-hand window and click on 'Rename'. Append today's date to file name such that file is named FGD\_G3\_ddMMMyy.mdb.
- Transfer current version of FTP log by typing location of FTP log in 'Local site' box:  
**C:\VOICE-C\DataEntry\Access\FGD\_G3\FTP log** and dragging file (FTPLog\_FGD\_G3.xls) from left-hand window to right-hand window.
- After spreadsheet has been transferred, right click on spreadsheet file name on the right-hand window and click on 'Rename'. Append today's date to file name such that file is named FTPLog\_FGD\_G3\_ddMMMyy.xls.
- Check that both files have been transferred to FTP server and dated appropriately. If so, you may close the FTP window by clicking on the X in the top right-hand corner.

#### 8.4. QUERY RESOLUTION

Site staff person will receive a list of queries by e-mail identifying missing or discrepant data from RTI the week following an FTP upload. Reports will list the FGD group # as well as describe the issue. Queries should be resolved within the week and database changes should be made by the end of the week. To address queries:

- Correct error or complete missing information on FGD hand-written debriefing report. Incorrect value (if any) should be crossed out and correct value written beside the erroneous value. Staff member should write initials and date next to the change. (Changes to FGD debriefing report may be unnecessary if issue is a result of a data entry error.)
- Open database and use right arrows to locate the relevant FGD record.
- Follow above instructions to:
  - o Change record in Access database
  - o Upload Access database and log to FTP server
- FTP Log: If in a given week, you make changes to the database to address queries but did not enter **new** records into the database, you should still fill out the FTP log to indicate that you have uploaded data to the FTP server. This entry will be blank aside from the fourth column. If you do enter new records, you do not need to add an extra line to the FTP log to reflect query resolution changes to the database.
- Query List: Complete three columns on the query list indicating action taken, staff initials, and date of action. Query list will be named: QueryList\_FGD\_G3\_ddMMMyy.xls and will contain the date on which the query list is sent to the site. After query lists have been updated by site, save by appending the site staff initials (e.g. AAA) to the file name such that file will be named: QueryList\_FGD\_G3\_ddMMMyyAAA.xls. Query lists may be saved in the 'query lists' subfolder in the FGD\_G3 folder.
- Upload revised query list to FTP site for RTI review.

**9. APPENDIX E: SAMPLE QUERY REPORT FOR DEBRIEFING REPORT**

Based upon database: FGD\_G3\_27APR10.mdb

Report Generated on: 30APR10

				Completed by site staff			Completed by RTI staff
Query #	FGD Group #	Question Name/#	Issue	Action Taken	Staff Initials	Action Date (ddMMMyy)	Issue Resolved (ddMMMyy)
1	301	Facilitator Initials	Missing				
2	301	Question 1	Text reads "Community is considered saf by most members." Please clarify 'saf'.				

**10. APPENDIX F: FTP LOG – CRFs, Debriefing Reports, Transcripts and EI Notes** (see next page for FTP Log completion instructions)

Database or document Identifier	VOICE C PTID (CRFs) or Visit Code (Transcripts, Debriefing Reports, Notes)	Date Uploaded to FTP Server (ddMMMyy)	Document/file name(s)
<b>Examples:</b>			
DEM db	2119, 1447	7-Oct-10	DEM_7OCT10.sas and DEM_07OCT10.dat; DEM_7OCT10.sas and DEM_7OCT10.sas
FGD_G3 Debriefing Report db	FGD_301	14-Oct-10	FGD_G3_14OCT10.mdb
FGD_G3	301	4-Nov-10	FGD_301__English_04NOV10.doc
<b>Actual Log:</b>			

**FTP Log Completion Instructions**

**General Instructions:** The FTP Log is to be completed weekly, at the end of each work week. This will be a running log of all new documents uploaded to the FTP site. It will verify what versions have been uploaded and when. Therefore, the FTP Log should be updated weekly and emailed to Katharine Rivett at RTI: [krivett@rti.org](mailto:krivett@rti.org). This log should capture all new database (db) entry and documents. For databases, provide an FTP Log entry for every new record created (e.g. CRFs) or interview (e.g. Debriefing Reports). For Word documents (e.g. transcripts), provide an FTP Log entry every time a new document version is created (e.g. original transcripts as well as modified or updated transcripts).

**Column 1: Document Identifier:** Provide the name and type of report being uploaded from the following options: CRFs, Transcripts, Debriefing Reports, and EI Notes. Here are a few sample entries: DEM db, TF db, ESF\_G1 Debriefing Report db, IDI\_G2 transcript, FGD\_G3 transcript, etc

**Column 2: VOICE C PTID or Visit Code -** For the CRFs, enter the respective VOICE C PTID. If more than 1 record or entry has occurred during the week, enter all of the respective records. For example, if two DEM forms were completed, enter the PTIDs for all two DEM forms in the same field. See example. For all other documents, enter the Visit Code from this list in the VOICE-C SSP:

**Table 19-3 VOICE-C Visit Codes**

Participant Group	Modality	Visit Code
<b>Group 1</b>	<b>IDIs</b>	<b>IDI_101 – IDI_130</b>
	<b>EIs</b>	<b>EI_101a – EI_130a</b> <b>EI_101b – EI_130b</b> <b>EI_101c – EI_1130c</b> <b>EI_101d – EI_130d</b>
	<b>FGDs</b>	<b>FGD_101 – FGD_108</b>
<b>Group 2</b>	<b>IDIs</b>	<b>IDI_201 – IDI_212</b>
	<b>FGDs</b>	<b>FGD_201 – FGD_204</b>
<b>Group 3</b>	<b>FGDs</b>	<b>FGD_301 – FGD_305</b>
<b>Group 4</b>	<b>FGDs</b>	<b>FGD_401 – FGD_404</b>

**Column 3: Date Uploaded to FTP Server:** This date reflects the specific date in which the document or files was uploaded to the FTP server. Depending on whether the site uploads all documents on one day per week or on an 'as completed' basis throughout the week, the dates for every week will either fall on the same day as or fall within one week of each FTP Log update.

**Column 4: Document file/name:** The document/file names should follow the extensions provided in the examples at the top of the FTP log. There is an example for each 'type' of document. The date of the file should match the date uploaded in the 3rd column of this report. For reports in which more than 1 file is generated (e.g. with CRFs, 2 files [.sas and .dat] are generated) upload both files and include them in the same line entry. Whenever a Word document (e.g. for transcripts) is modified, it must be saved as a new version and date and re-uploaded to FTP and entered into the FTP log.

## APPENDIX G: INSTRUCTION FOR TRANSCRIPT COMPLETION AND QUERY RESOLUTION

### 10.1. PREPARING TRANSCRIPTS (and EI Field Notes)

After FGD or IDI session, audio file is burned onto a CD and saved in preparation for transcription.

#### Getting Started:

The **FGD transcript** Word document should contain the following information at the top of Page 1:

FGD identifier: FGD\_101  
DATE: 08 Sept 2010  
VENUE: RHRU  
Number of Participants: 11  
FACILITATOR: [name or initials inserted]  
NOTETAKER: [name or initials inserted]  
TRANSCRIPTIONIST: [name or initials inserted]  
TRANSLATOR: name or initials inserted]  
REVIEWER: [name or initials inserted]  
ADD INTERVIEW LANGUAGE

#### TRANSCRIPT KEY

[ ]: Facilitator comments and clarifications  
"xxx": Facilitator quoting someone, not a translation  
'xxx' participant quoting someone  
XXX: names of people mentioned  
???: questionable accuracy  
... pause/silence

The **IDI transcript** word document should contain the following information at the top of Page 1:

VISIT CODE / IDENTIFIER: IDI\_101  
SITE: RHRU  
DATE: 17 NOV 10  
INTERVIEWER: [name or initials inserted]  
TRANSCRIPTIONIST: [name or initials inserted]  
TRANSLATOR [name or initials inserted]  
REVIEWER: [name or initials inserted]  
INTERVIEW LANGUAGE: SESOTHO

#### TRANSCRIPT KEY:

[ ]: Interviewer comments and clarifications  
"xxx": Interviewer quoting someone, not a translation  
'xxx' participant quoting someone  
XXX: names of people mentioned  
???: questionable accuracy  
... pause/silence

The **EI notes** will be done on a Field Notes form.

### Completing Transcripts:

The audio-file should be transcribed verbatim in Word documents for the FGD and IDIs. The EI Field Notes should be expanded upon immediately after the interview, and later transcribed in Word.

#### 10.2. Transcription and Translation Process

The interviews should be audio-recorded, transcribed, translated, quality controlled and uploaded to the FTP through the following steps:

- From audio file, the interview should be transcribed verbatim by an external provider fluent in the interview language;
- The transcript should then be translated into English internally by the site;
- 10% of all transcribed texts (and a larger percentage initially) should additionally be translated separately by a second external provider to verify consistency.
- The translations should be compared by the IoR or a member of the Protocol Team. Any discrepancies should be resolved through consensus, and the final version transferred to the FTP site for RTI review.

Note: For each FGD and IDI, the English and local language transcripts should both be transferred to via the FTP server to RTI. However, the English transcript is the version RTI will review and query.

##### 10.2.1. Transcript File-Naming:

Transcripts should be saved the following way: visit code\_language\_date.

The date refers to the date in which the transcript was completed.

For example, the (English) transcript for Group 1's first FGD session would be saved as:

**FGD\_101\_\_English\_16AUG10. doc**

When changes are made and the document is revised, it should be re-saved the identical way except with the new revision date replacing the previous date. Note: For document changes, the staff should provide his/her initials at the top of the document. If there are multiple revisions, each staff initial should be included along with date. The example below is for the FGD detailed above in Appendix G. In this example, it has undergone 4 revisions from site staff.

Staff Initials/date for document changes: FTM 4JUN10, BM 16JUN10, SS 3JUL10, SS 8JUL10

FGD identifier: FGD\_101  
DATE: 08 Sept 2010  
VENUE: RHRU  
Number of Participants: 11  
FACILITATOR: [name or initials inserted]

VOICE-C

NOTETAKER: [name or initials inserted]  
TRANSCRIPTIONIST: [name or initials inserted]  
TRANSLATOR: name or initials inserted]  
REVIEWER: [name or initials inserted]  
ADD INTERVIEW LANGUAGE

For saving modified transcripts, if all changes were made to the transcript as of 27 Sept 2010, the transcript would be re-saved as the following: **FGD\_101\_\_English\_27SEP10. doc** and emailed to RTI.