

4. Documentation and Data Collection and Storage

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4.1 Documentation Standards

The HPTN 083-02 is a sub-study of a larger study (HPTN 083) being conducted under an Investigational New Drug (IND) authorization, and as such, it could be argued that the data produced and analyzed as part of the sub-study could be expected to require adherence to the requirements for electronic records and signatures as laid out in Title 21 of the US Government Code of Federal Regulations, Part 11 (21 CFR 11), as is the case for the main study. However, the nature of the work of conducting and analyzing qualitative interviews (the sole research activity of this sub-study) makes adherence to this standard impracticable in many aspects (a conclusion that has been reached by other study teams conducting DAIDS-funded clinical trials). As well, the fact that the data from this sub-study are not expected to be included in the main trial’s Clinical Study Report or Trial Master File suggests that adhering to such a strict standard may be not only be untenable, but unnecessary.

Although strict adherence to 21 CFR 11 standards in all aspects of study documentation for this project is not achievable, data from this qualitative study will be maintained to the highest possible quality standards. Below we describe the procedures we will follow to ensure that we are adhering to Good Documentation Procedures (GDP) at every opportunity. This includes generating source documentation that is attributable, legible, contemporaneous, original, accurate and complete (ALCOA-C) and employing paper and electronic file management and storage systems that are secure, with limited access and protection from degradation and loss.

4.2 Onsite Storage of Audio Files

All interviews will be audio-recorded for transcription purposes. Once an interview has been completed, study staff at each site will store the audio files securely in password-protected, limited-access electronic study folders. The participant’s study ID number and date of interview will be incorporated in the name of the audio file, for example as below:

HPTN083-02_XXXXXXXXXX”_DDMMYY_Recording

- Interview date
- Page number in the format Page *X* of *Y*, where *X* is the current page and *Y* is the total number of pages of the document
- The version date of the transcription reflecting the last date on which a change was made to the document.

The transcript filename should follow the following format:

HPTN083-02_XXXXXXXXXX_DDMMYY_Tscript dated_DDMMYY

In which “XXXXXXXXXX” is the PTID and DDMMYY is the date, e.g. 02FEB20. The first date will be the date of the interview and the second date is the date on which the transcript file was last altered. If it helps maintain clarity, the author of the most recent change to the document may add their initials to the filename, e.g.

HPTN083-02_847394891_02FEB20_tscript_dated_07FEB20_sbg

A transcript template and example are provided in Appendix V. Sites are encouraged to use this format but may use another as long as the same information is included as in the template. The site will retain electronic copies of all versions of the transcript referenced in the log on the secure drive at the site. These copies may be maintained in a word-processing program file.

Once the initial transcript is finalized at the site and ready to be uploaded for analysis, the person finalizing the transcript will add “version 1.0” to the version date in the footer of the transcript and will change the filename to:

HPTN083-02_XXXXXXXXXX_DDMMYY_Tscript_v.1.0

This staff member will create a PDF of this version of the transcript and will upload it for analysis to REDCap as described below. A copy of the Word and PDF versions of this document will be saved on the secure drive at the site. The site staff will print a copy of the PDF version of the document and a staff member will write on it “This is an exact copy of the PDF titled ‘HPTN083-02_XXXXXXXXXX_DDMMYY_Tscript_v.1.0’ uploaded to REDCap on [date]” and sign and date the note, certifying the print out. Site staff will file this paper copy of the transcript in the participant’s file. Alternatively, the site may use a 21 CFR 11-compliant electronic signature system to create and sign the PDF version of v.1.0 and upload this version to REDCap, storing an electronic copy on the local secured drive instead of a paper copy.

Once v.1.0 of the transcript has been downloaded from REDCap and reviewed by the analysis team, the analysis team may come back to the site with requests for corrections, for example:

- Problems such as typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data
- Sentences that are unclear
- Clarification of local terminology or context
- Inclusion of name of person or place that would identify the participant
- Requests for additional information

When the site edits the transcript to respond to these queries/requests, these changes will be documented in the Transcript Development Log for that interview, and the staff member making edits will save the new version of the transcript as v.2.0, updating the version and version date in the footer of the transcript and the version number in the filename before making a PDF copy and re-uploading to REDCap. The site will need to print off a paper copy of v.2.0, certify it, and store it in the participant's file (or use the alternative electronic procedure) as described above for v.1.0. The analysis team will maintain copies of their correspondence with the team requesting clarification/correction of transcripts on a HIPAA-compliant shared drive at Massachusetts General Hospital (MGH).

4.4 Onsite Storage of Transcripts

The transcriptions and translations of each interview will be securely stored at the site (along with original interview audio files) in a password-protected, limited-access electronic study folder.

4.5 Data Entry and Storage in REDCap

Interview transcripts will be uploaded by trained, local study staff for storage in REDCap – a secure, HIPAA-compliant database used for data capture and basic data analysis. Each transcript will be uploaded and stored in an individual participant record within the project entitled, “HPTN 083-02 Qualitative Sub Study.” The REDCap project should only be accessible to approved study staff and user rights should reflect requirements of those roles.

To Upload a New Transcript:

- ❖ Log into REDCap at <https://redcap.partners.org/redcap/> using your username and password.
- ❖ Click “My Projects” (top of screen) and then click the project entitled, “HPTN 083-02 Qualitative Sub Study.”
- ❖ Click “Add/Edit Records” (left side, underneath “Data Collection”).
- ❖ Enter the participant's study ID number next to “Enter a new or existing HPTN 083-02 Parent Study ID.” Press enter to create a new participant record.
- ❖ Click the circular bubble underneath the “Status” column, next to the data collection instrument called “Participant Information.” This will open up the “Participant Information” instrument.
- ❖ Within the “Participant Information” instrument, enter the participant's parent study step (i.e., Step 2 or Step 3), parent study group (for Step 2 participants only, i.e., “Adherent,” “Imperfectly/non-adherent,” “Discontinued product”), and HIV-seronegativity at last HIV test (i.e., Yes or No). If applicable, include any additional notes pertaining to the above participant information in the “Notes” section (optional).

- ❖ Once all data in this instrument are entered, click the drop-down menu underneath “Form Status” and change status from “Incomplete” to “Unverified.” This indicates to the study team that the data in this form have been entered, but not yet verified. (Once verified, study staff will change the form status from “Unverified” to “Complete.”)
- ❖ Click “Save &...” and then click “Save & Go To Next Form.” This will open up the next instrument to be completed within this participant record, which is called “Interview Data + File Upload.”
- ❖ Within the “Interview Data + File Upload” instrument, enter the date and time of the interview, interviewer name, study site, interview type (i.e., in person or via phone).
- ❖ Enter the date and time of the transcript file upload. Click “Upload document,” select the participant’s transcript file, click “Open,” and then click “Upload document.” Once it has been uploaded, you will see the name of the file in the instrument, to the right of “Transcript File Upload.” **All files must be in PDF format.**
- ❖ Once all data in this instrument are entered, click the drop-down menu underneath “Form Status” and change status from “Incomplete” to “Unverified.” This indicates to the study team that the data in this form have been entered, but not yet verified. (Once verified, study staff will change the form status from “Unverified” to “Complete.”)
- ❖ Click “Save & Exit Form” to exit the participant record.

To View a Previously Uploaded Transcript:

- ❖ Log into REDCap at <https://redcap.partners.org/redcap/> using your username and password.
- ❖ Click “My Projects” (top of screen) and then click the project entitled, “HPTN 083-02 Qualitative Sub Study.”
- ❖ Add/Edit Records” (left side, underneath “Data Collection”).
- ❖ Click the drop-down menu next to “Choose an existing HPTN 083-02 Parent Study ID.” Select an existing study ID number. This will take you to a participant’s existing study record.

4.6 Documenting Notes to File in REDCap

A Note to File (NTF) must be completed in REDCap for (1) events or extenuating circumstances that occur outside of the study protocol or procedures, but are not considered Adverse Events, and (2) other notes that may be relevant to the study visit. NTFs may be created to explain or contextualize any irregularities in the conduct of the study visit, and/or to provide supplementary information that the investigators reviewing

and analyzing study data may need to know.

Examples of scenarios where an NTF should be completed are:

- Participant completed the interview while under the influence of substances.
- Participant experienced a medical emergency in the middle of the study visit, and therefore had to complete the interview in two parts.

Note that the REDCap NTF function is NOT the mechanism to report Adverse Events (AEs), Serious Adverse Events (SAEs), social harms or protocol deviations (PDs) to the study team. Reporting procedures for these occurrences are provided in the study protocol and Section 5 of this SSP.

To Create a Note to File:

- ❖ Log into REDCap at <https://redcap.partners.org/redcap/> using your username and password.
- ❖ Click “My Projects” (top of screen) and then click the project entitled, “HPTN 083-02 Qualitative Sub Study.”
- ❖ Add/Edit Records” (left side, underneath “Data Collection”).
- ❖ Click the drop-down menu next to “Choose an existing HPTN 083-02 Parent Study ID.” Select an existing study ID number. This will take you to a participant’s existing study record.
- ❖ Click the circular bubble underneath the “Status” column, next to the data collection instrument called “Note to File.” This will open up the “Note to File” instrument.
- ❖ Within the “Note to File” instrument, enter the date and time of the Note to File entry, the date and time of the events described in the Note to File, the individual entering the Note to File, a description of the Note to File, and the status of the resolution (i.e., Yes, No, N/A).
- ❖ Once all data in this instrument are entered, click the drop-down menu underneath “Form Status” and change status from “Incomplete” to “Unverified.” This indicates to the study team that the data in this form have been entered, but not yet verified. (Once verified, study staff will change the form status from “Unverified” to “Complete.”)
- ❖ Click “Save & Exit Form” to exit the participant record.
- ❖ **The “Note to File” instrument is optional, and can be completed as many times as needed.**
- ❖ To enter additional Notes to File for a given participant, follow the first 4

steps above, and then click the “+” sign next to the circular bubble underneath the “Status” column, next to “Note to File.” This will open up a new “Note to File” instrument for completion.

4.7 Data Verification in REDCap

Every effort should be made to ensure accurate and complete data collection. To ensure the accuracy of all data entered into REDCap, data verification should be performed on a regular basis by a trained member of the local study team who is not directly involved in data collection, and who does not have any direct contact with study participants.

To Perform Data Verification:

In the “Participant Information” Instrument:

- ❖ Log into REDCap at <https://redcap.partners.org/redcap/> using your username and password.
- ❖ Click “My Projects” (top of screen) and then click the project entitled, “HPTN 083-02 Qualitative Sub Study.”
- ❖ Add/Edit Records” (left side, underneath “Data Collection”).
- ❖ Click the drop-down menu next to “Choose an existing HPTN 083-02 Parent Study ID.” Select an existing study ID number. This will take you to a participant’s existing study record.
- ❖ Click the circular bubble underneath the “Status” column, next to the data collection instrument called “Participant Information.” This will open up the “Participant Information” instrument.
- ❖ Review all entered data for accuracy. Correct any information that has been entered incorrectly.
- ❖ Once data have been checked, click the drop-down menu underneath “Form Status” and change status from “Unverified” to “Complete.”
- ❖ If prompted to provide a justification for making changes to the data in the instrument, write “Data verification/checking.”
- ❖ Click “Save &...” and then click “Save & Go To Next Form.”

In the “Interview Data + File Upload” Instrument:

- ❖ To perform data verification in the “Interview Data + File Upload” instrument, follow the first 4 steps above, and then click the circular bubble underneath the “Status” column, next to the data collection instrument called “Interview Data + File Upload.” This will open up the “Interview Data + File Upload” instrument.

- ❖ Review all entered data for accuracy. Confirm the interview date/time, interviewer name, interview site, and interview type. Confirm that the correct interview file was uploaded, that the file was named correctly. Correct any information that has been entered incorrectly.
- ❖ Once data have been checked, click the drop-down menu underneath “Form Status” and change status from “Unverified” to “Complete.”
- ❖ If prompted to provide a justification for making changes to the data in the instrument, write “Data verification/checking.”
- ❖ Click “Save &...” and then click “Save & Go To Next Form” or “Save & Exit Form” to exit the participant record.

In the “Note to File” Instrument:

- ❖ To perform data verification in the “Note to File” instrument, follow the first 4 steps above, and then click the circular bubble underneath the “Status” column, next to the data collection instrument called “Note to File.” This will open up the “Note to File” instrument.
- ❖ Review all entered data for accuracy. Confirm the date/time that the NTF occurred, name of the person entering the NTF, NTF description and resolution. Correct any information that has been entered incorrectly.
- ❖ Once data have been checked, click the drop-down menu underneath “Form Status” and change status from “Unverified” to “Complete.”
- ❖ If prompted to provide a justification for making changes to the data in the instrument, write “Data verification/checking.”
- ❖ When all data in a participant’s record has been verified, click “Save & Exit Form” to exit the participant record.

4.8 Data Processing and Analysis

4.8.1 Review of Transcripts

After being uploaded into the REDCap database by local study staff, the first set of transcripts will be reviewed by the behavioral science investigators (Drs. Safren and Psaros). The investigators will then schedule a supervision meeting with interviewers to provide individualized feedback on their performance and adherence to principles of qualitative interviewing.

Ongoing training and supervision of interviewers will also be provided for the duration of the study, on topics such as effective probing, asking open-ended questions, non-judgmentality, coding, and qualitative analyses (as needed). Approximately 20% of qualitative interview transcripts across all study sites will be reviewed by the investigators with site staff over the course of the study.

4.8.2 Qualitative Interview Analysis

Following the completion of data collection, Dr. Psaros will oversee the process of qualitative codebook development. The investigators will independently review the transcripts in order to generate an overarching thematic framework for data interpretation, in which major and minor themes are identified. The investigators will compare their thematic frameworks for consistency, and any discrepancies will be discussed until a resolution has been reached. Minutes from meetings where codes are discussed, agreed and revised, and copies of all versions of the codebook as it evolves will be kept on the HIPAA-compliant shared drive at MGH in an unalterable format (such as PDF) that has been digitally signed using a 21 CFR 11-compliant electronic signature system. Data will be reexamined, messages will be extracted and highlighted, and ongoing discussion between coders will allow for further theorizing and making interconnections between research questions, coding categories, and raw data. NVivo software will be used to organize data and facilitate qualitative analyses.

Site participation in the analysis phase will be encouraged. The investigators will hold training workshops on coding and other aspects of data analysis as appropriate to ensure capacity building at all study sites.

4.8.3 Descriptive Data Analysis

Descriptive data on each participant will be obtained from the parent study to facilitate grouping of qualitative data by sociodemographic variables, such as age, education, and poverty level. Differences in baseline characteristics between those who complete a qualitative interview and those who decline (or cannot be reached to complete a qualitative interview) will be examined, as well as potential differences between groups (i.e., those who were non-adherent versus imperfectly adherent, and MSM and TGW).

To enable these analyses, each site will keep a log of each main study participant approached for enrollment into this sub-study (a recruitment log). The information that must be included for each participant approached includes the following:

- Main study PTID
- Date approached to participate
- What enrollment category they were being enrolled for (Step 2, Group 1,2 or 3 or Step 3)
- Whether they enrolled or declined participation in the sub-study
- Reason for declining, if declined
- Initials of the person recording the entry in the log and date recorded
- If they enrolled, whether they completed the interview or not, and if not, reason not completed

Sites are encouraged to use the template recruitment log provided in Appendix VII, however the site may use a tool with a different format if they prefer, as long as all the same information is captured.

To comply with Good Documentation Practices, sites may either keep this log in a paper format in the secure site files or may keep it electronically. If the site chooses to keep it

electronically however, it must be kept in a 21 Part 11 compliant database or the site must create an unalterable record of the log monthly that is then saved in the site files. For example, if the site maintains the log in a spreadsheet program, a staff member should print out the spreadsheet monthly, and write on it “This is an exact copy of the HPTN 083-02 recruitment log as of *[date]*” and sign and date the note, certifying the print out and filing it in the site files. Alternatively, the site may use a 21 CFR 11-compliant electronic signature system to create and sign a PDF version of the electronic log and store it on the local secured drive instead of filing a paper copy. If maintaining a log in a spreadsheet or similar program, it may be beneficial if the file itself is password protected (e.g. in Microsoft Excel File → Protect Workbook → Encrypt with Password)