

LETTER OF AMENDMENT #01 TO:

MTN-032

Assessment of ASPIRE and HOPE Adherence

Version 1.0, dated 20 August 2015

**DAIDS Protocol #12058
A Non-IND Study**

Date of Letter of Amendment: 26 October 2015

Site Instruction

The following information impacts the MTN-032 study and must be forwarded to your Institutional Review Board (IRB)/Ethics Committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation. The following information impacts the sample informed consent. Your IRB/EC will be responsible for determining the process of informing participants of the contents of this Letter of Amendment (LoA).

Implementation

Upon receiving final IRB/EC and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. DAIDS sites are still required to submit a LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). DAIDS sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. A LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

Summary of Revisions

This LoA does not impact the overall design or the study visit schedule for MTN-032. The primary purpose of this LoA is to allow for audio-recordings to serve as source documentation for qualitative evaluations. Qualitative data processing details will be included in the SSP.

Text to be deleted is noted by ~~strike through~~ and text to be added is noted below in **bold**.

Detailed Listing of Revisions

1. The following revision has been made to the third sentence in the paragraph after the topics list on Section 7.3.2, *In-Depth Interviews (IDIs) and Focus Group Discussions (FGDs)*:

Interviews and discussion sessions will be audio-recorded ~~and transcribed and translated into English (if applicable)~~.

2. The following revision has been made to the second sentence in Section 10.5, *Data and Study Monitoring Procedures*:

Qualitative data will be audio-recorded, ~~transcribed, translated~~ **processed** and coded for thematic analyses, using NVivo or a similar qualitative software.

3. The following revision has been made to the third bullet in Section 10.6.2, *Qualitative Analysis – Data Sources*, to indicate that the local language audio files are to be designated as source documents:

- ~~Transcripts from a~~ Audio-recorded IDIs and FGDs

4. The following revision has been made to the first sentence after the data source list in Section 10.6.2, *Qualitative Analysis – Data Sources*:

Qualitative data will be audio-recorded, ~~transcribed, translated~~ **processed**, and coded for thematic analyses, using NVivo or a similar qualitative software.

5. The following revision has been made to the fourth sentence in Section 10.6.2, *Qualitative Analysis – Qualitative Analysis Overview*:

Qualitative data will be audio-recorded, ~~transcribed, translated~~ **processed**, and coded for qualitative analyses, using NVivo or a similar qualitative software.

6. The following revision has been made to the fifth sentence in Section 11.1, *Data Management Responsibilities*:

~~Audio files and transcriptions of interviews and group discussions~~ **files** generated in the field will be electronically transferred to RTI International using a secure File Transfer Protocol (FTP) site, where they will be uploaded and managed using a qualitative software package.

7. The following revision has been made to the eighth sentence in Section 11.1, *Data Management Responsibilities*:

~~Original language and translated~~ **Transcripts** will be transferred to RTI International as they are completed.

8. The following revision has been made to the fourth paragraph in Section 11.2, *Source Documents and Access to Source Documents*, to remove text indicating that the local language audio files would be destroyed after being transcribed and after confirmation of database lock:

~~Audio files will be transcribed and destroyed once the QC process is complete and the data coordinating center at RTI International confirms that the database is locked for analysis. The site IoR or designee will be responsible for ensuring that these files have been destroyed.~~

9. The following revisions have been made to the eleventh and twelfth sentences in Section 13.6, *Participant Confidentiality*, to remove text indicating that the local language audio files would be destroyed:

All digital audio files will be stored on password-protected computers. ~~Audio files will be transcribed. Please see SSP for guidance regarding audio file destruction.~~

10. The following revision has been made to the twelfth sentence in *APPENDIX I: SCREENING AND ENROLLMENT SAMPLE INFORMED CONSENT FORM - PHASE I (ASPIRE) PARTICIPANTS – Risks and/or Discomforts*, to remove text indicating that the local language audio files would be destroyed after being transcribed and after confirmation of database lock:

~~The voice recordings will be destroyed as soon as the audio recording has been typed and all responses are verified.~~

11. The following revision has been made to the twelfth sentence in *APPENDIX II: SCREENING AND ENROLLMENT SAMPLE INFORMED CONSENT FORM - PHASE II (HOPE) PARTICIPANTS – Risks and/or Discomforts*, to remove text indicating that the local language audio files would be destroyed after being transcribed and after confirmation of database lock:

~~The voice recordings will be destroyed as soon as the audio recording has been typed and all responses are verified.~~

The above information will be incorporated into the next version of the protocol at a later time if it is amended.