Appendix I: Qualitative Sub-Study Procedures

1.0 Overview of Appendix I

This appendix includes specifics on study conduct including the sources of procedural information available to HPTN 091 Qualitative sub-study site staff, data collection and storage, and reporting of adverse events (AE) and social harms.

1.1 Qualitative Sub-Study Overview

Throughout the study approximately 12 participants at each site (approximately 60 total) will be enrolled in the Qualitative Sub-study. Approximately half of participants will be of those randomized to the Immediate Intervention Arm and approximately half will be of those randomized to the Deferred Intervention Arm. Participants enrolled in the Qualitative Sub-study will be chosen based on their willingness to participate, providing consent to participate in IDIs (in-depth interviews) in the informed consent process, and their decisions on PrEP use.

IDIs will be conducted among four categories of participants:

1. TGW who accept/initiate PrEP at enrollment.
2. TGW who decline PrEP at enrollment.
3. TGW who discontinue PrEP at any point after enrollment.
4. TGW who decline PrEP at enrollment and accept PrEP at any point after enrollment.

Participants asked to participate in the Qualitative Sub-study at enrollment, meeting the requirement of categories 1 or 2, will continue to be considered in these categories regardless of their future PrEP decisions.

Participants meeting the requirement of categories 3 or 4, will be considered for participation at the visit they meet the requirement.

Approximately 30% of those enrolled in the IDI sub-study at each site should be TGW who decline PrEP at enrollment or discontinue PrEP at any time after enrollment.

The purpose of these IDIs is to better understand decision making around PrEP, experiences with PrEP use, experiences with co-located services, and acceptability of co-located services. It is also used to reflect on the whole experience of study participation and ways in which future trials could be improved.

1.2 Informed Consent

Written informed consent must be obtained from each participant prior to the conduct of the initial qualitative interview. Consent to participate in the qualitative portion of the study is collected with the informed consent for the overall study. Ensure that participants asked to participate in the IDIs have provided consent.

1.3 Scheduling the IDIs

Participants in Categories 1 and 2

IDI 1

Participants who consent to participate in the sub-study and fall into categories 1 (accept/initiate PrEP at enrollment) and 2 (decline PrEP at enrollment) will be scheduled for their first IDI at enrollment. At the Enrollment visit, the participant should be asked if they are able to stay 60-90 minutes longer to complete the first interview. If the participant is unable to stay longer at the Enrollment visit and would still like to participate in the sub-study, an additional visit can be scheduled within 30 - 60 days for the participant to return to the site for the interview. Participants in the Immediate Intervention arm that chose to initiate GAHT at the site can schedule this first IDI during their GAHT Initiation Visit. For any questions related to initiation of IDIs, please contact Tonia Poteat (tonia_poteat@med.unc.edu), Busola Akingbade (bakingbade@fhi360.org), and Kaila Gomez-Feliciano (kgomez@fhi360.org)

IDI 2

The second IDI should be scheduled to coincide with their Week 52 visit. If the participant is unable to stay 60-90 minutes after that visit, they should be scheduled within 30 days of their Week 52 visit.

IDI 3 (Final IDI)

This is the final IDI and will be scheduled to coincide with Week 78. If the participant is unable to stay 60-90 minutes after that visit, they should be scheduled within 30 days of their Week 78 visit.

Participants should receive reminders of their IDIs along with their visit reminders in the form the site has found to be most effective (email, phone calls, SMS, etc.)

Participants in Categories 3 and 4

IDI 1

Participants who consent to participating in the sub-study and fall into categories 3 (discontinues PrEP any time after enrollment) and 4 (decline PrEP at enrollment and accept PrEP any time after enrollment) will have their first IDI scheduled at the point that they meet the category description (i.e., Discontinuing or initiating PrEP after enrollment). At the visit the participant should be asked if they are able to stay 60-90 minutes longer to complete the first IDI. If the participant is unable to stay longer and would still like to participate in the sub-study an additional visit can be scheduled within 30 days for the participant to return to the site for the IDI.

Interview 2 (if applicable)

If possible, a second IDI should be scheduled with the participant. This IDI should take place at least 6 months after the first IDI and at least 6 months before Week 78 (the last visit). If a second IDI cannot be scheduled within these parameters, the participants will still be scheduled for their final IDI at Week 78.

IDI Final IDI

The final IDI should be scheduled to coincide with their Week 78 visit. If the participant is unable to stay 60-90 minutes after that visit, they should be scheduled within 30 days of the Week 78 visit.

Participants should receive reminders of their IDIs along with their visit reminders in the form the site has found to be most effective (email, phone calls, SMS, etc.)

Interviewers should schedule IDIs with enough time to complete the Summary section of the IDI guide after each IDI. This section contains pre-coded answers and summary fields for the interviewer to document findings during or immediately after the IDI. This section

will be uploaded to the site's Qualitative Sub-Study folder on Teams (Microsoft Teams) along with the final transcript (see section 1.7 of this appendix).

After completing the IDI, the assigned site staff for the IDIs should access Rev.com to upload the recordings for transcription. Each site has its own folder within Rev.com where the transcription should be placed once received. For further questions regarding Rev.com please contact Elsie Talavera (etalavera@fhi360.org) and Busola Akingbade (bakingbade@fhi360.org)

1.4 Preparing for the IDI

Prior to the IDI, the study coordinator and/or interviewer will ensure the audio recording equipment is in the room and ensure the room chosen for the IDI is private. A video recording of the IDI will not be made. No identifying information about participants, other than their PTID, will be recorded on the audio files, be recorded in notes, appear in transcripts, or on study records.

The interviewer should prepare for the IDI by ensuring they have selected the appropriate guide for the category of participant (1 – 4 above) and the sequence of IDI (1, 2, or final), reviewing the selected IDI guide, ensure the guide has all pages including the summary section, review any notes from any previous IDIs, and review the participant's CRFs. Before starting the IDI, the interviewer will verify that the correct participant is being interviewed. All other staff members should leave the room to give the participant privacy. Staff should not be entering the room while an IDI is in process.

1.5 Conduct of Qualitative IDIs

Qualitative IDIs should be conducted by staff trained in qualitative interviewing techniques. IDIs will last approximately 60-90 minutes and will be conducted in person in a private setting. If COVID-19 restrictions make in-person IDIs inadvisable, virtual IDIs may be conducted. All IDIs will be audio recorded and will be transcribed verbatim by a trained research assistant, other trained study staff, or a qualified transcriptionist/translator in compliance with applicable local requirements.

IDIs will follow the semi-structured IDI guides, with flexibility to explore probes and content that are related to study objectives but that may not specifically be in the guide. Questions are open-ended to effectively elicit information without limiting participants' responses. Open-ended questions will be followed by probes to facilitate discussion and to ensure the completeness of qualitative data.

The guides and probes may be modified during the course of the study by the study co-chairs if, for example, participants are finding a question unclear, or if it appears that topics could be explored more efficiently or effectively with a change in the guide. The

HPTN LOC will disseminate updated guides and probes to all sites when they have been approved by the study co-chairs.

1.6 Onsite Storage of Audio Files

All IDIs will be audio-recorded for transcription purposes. Once an IDI has been completed, study staff at each site will store the audio files securely in password-protected, limited-access electronic study folders. (PTID) and date of interview will be incorporated in the name of the audio file, for example as below:

091_XXXXXXXXX_MMDDYY_IDI#

In which "XXXXXXXXX" is the PTID and MMDDYY is the date of the interview, e.g. an interview that occurred on February 15, 2021would be written as 021521, and # indicates whether this is a first, second or third interview with the participant

It is noted that audio files may contain confidential and identifying information of the participant and/or other persons. It is important therefore that the audio files are stored securely and that the site keep track of any copies made (for transcription purposes, for example) and ensure that these additional copies are ultimately destroyed after use. Details of how each site will store, track, and manage their audio recordings will be described in the site's SOPs.

As of the date of this version of the SSP, DAIDS had not completely resolved guidance about the length of storage required for original audio recordings. DAIDS had provided provisional guidance that these recordings be considered source documents and that they should be stored in accordance with the longest requirement of any applicable regulations. No site should delete or erase any source documents or data without prior permission from the study sponsor.

1.7 Transcription and Translation of Audio Files

IDIs should be transcribed by trained study staff or Rev.com. Sites should ensure that any copies of the audio file sent offsite for transcription are destroyed by the transcription service after transcription or are returned to the site, in order to protect participant confidentiality. The transcription process will also include redaction of all potentially identifying or confidential information (e.g., participant names, proper names of individuals discussed during IDIs, names of potentially identifying schools, towns, organizations).
Before finalization, transcripts will be reviewed by the staff member who conducted the IDI for accuracy and redaction of all identifying or confidential information.

If necessary, transcripts will be translated into English by local bilingual study staff or a qualified translator and reviewed for translations errors or omissions.

At each step of the transcription and translation process, the site must keep a paper record of modifications to the document, including what was done, the name of the person who made or changed the document and the date of the change. Sites are expected to create

and use a log for each IDI. Details of how each site will manage and document the generation of transcripts and translation of IDIs will be described in the site's SOPs. To comply with principles of GCP and for identification, each transcript will include on each page:

In the header:

- File name

In the footer:

- 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:

091_XXXXXXXXX_MMDDYY_IDI#_VX.X

In which "XXXXXXXXX" is the PTID, MMDDYY is the date the IDI was conducted, the # indicates whether this is a first (1), second (2) or the final (F) IDI with the participant, and VX.X indicating the version of the transcript.

A transcript template is provided in Section 1.11 of this Appendix. 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.

A PDF of the final transcript will be uploaded to the site's Qualitative Sub-study folder on the study's Teams for review and analysis. A copy of the Word and PDF versions of this document will be saved on the secure drive at the site.

Once the final transcript has been 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 IDI, and the staff member making edits will save the new version of the transcript as v2.0 (091_XXXXXXXXX_MMDDYY_IDI#_ v2.0), 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 uploading it to the site's Qualitative Sub-study folder on the study's Teams.

1.8 Transcript Tracker

The process of uploading and finalizing transcripts for analysis will be documented by the site on their HPTN091_*site name*_Qual Tracker found in the site's Qualitative Sub-study folder on Teams. Site's will record the following information:

- PTID Number
- Type of guide used in the interview
- Date the interview was conducted (please format dates as MM/DD/YYYY)
- Name of the staff member that conducted the interview
- Any comments about the interview (for example: longer than expected, stopped early etc.)
- Date the Interview Summary was uploaded to Teams
- Date the transcription was completed (MM/DD/YYYY)
- Name of the staff member that transcribed the interview
- Date the transcript was uploaded to Teams (MM/DD/YYYY)
- Date the transcription was returned to the site for corrections (MM/DD/YYYY)
    - If no corrections, please put N/A
- List of corrections needed to the transcript (examples: remove identifiers, fix misspellings, correct formatting, etc.)
    - If no corrections, please put N/A
- Date corrected version of the transcript is uploaded to Teams (MM/DD/YYYY)
    - If no corrections, please put N/A
- Any comments
- File name of the final transcript

1.9 Onsite Storage of Transcripts

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

1.10 Safety Reporting

As required by DAIDS safety reporting policies, any potential reportable Adverse Event (AE) or Social Impact (SI) reported by a study participant during the IDI will be brought to the attention of the clinical staff.

In the event a suspected AE or SI is reported during the IDI, the qualitative interviewer will make note of the participant's comment(s) in the IDI notes that will be maintained in the participant files at the site.

The qualitative interviewer will alert the participant that an AE or SH will need to be reported to the clinic staff. The qualitative interviewer will then alert the clinic staff that the participant reported an AE or SI. The qualitative interviewer and the clinic staff will

document in chart notes the notification made to clinic staff (by the qualitative interviewer) and the receipt of the notice (by clinic staff).

Clinic staff will follow up with the participant to assess the AE or SI as needed and report/document on the AE log CRF and Social Impact eCRF, respectively. The qualitative interviewer will not be involved in the assessment or reporting beyond notifying the clinical site of the participant's report. The qualitative interviewer will not disclose to clinic staff the details of what was discussed during the IDI beyond the brief mention of the suspected AE or SI reported.

1.11 Transcript Template

Header of the transcript: 091_XXXXXXXXX_MMDDYY_IDI#_VX.X

PTID:	
IDI Date (MMDDYY):	
Interview Guide:	
IDI Start Time:	
IDI End Time:	
Site:	
Interviewer Name:	

Participant Information	
Assigned Study Arm:	
Participant's Category	

Interviewer text will be designated by "I:" and the participant's text will be designated by "R:" (example below).

I: I would like to start today by getting to know you. Tell me about your typical day.

R: Usually I wake up early in the morning to exercise and get ready…