3. Conduct of Study Visits

3.1 Overview

HPTN 083-02 participants will attend a total of one study visit, consisting of an in-depth, qualitative interview with a member of the study team. Following completion of their interview, participants will be reimbursed an amount that is consistent with IRB standards for the given context (usually the equivalent of $15-25 USD).

3.2 Informed Consent

Written informed consent must be obtained from each participant prior to conduct of the qualitative interview. Each site is responsible for developing a study informed consent form (ICF) for local use, based on the template in **Error! Reference source not found.** of the study protocol, which describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation. The study site also is responsible for translating the template form into local languages and verifying the accuracy of the translation by performing an independent back-translation.

Literate participants will document their provision of informed consent by signing the ICF. Non-literate participants will be asked to document their informed consent by marking their ICFs (e.g., with an X, thumbprint, or other mark) in the presence of a literate third-party witness. (Further details regarding DAIDS requirements for documenting the informed consent process with both literate and non-literate participants are provided in the DAIDS Standard Operating Procedure for Source Documentation.) Any other local IRB/EC requirements for obtaining informed consent from non-literate persons also will be followed.

Participants will be provided with a copy of their signed ICF if they are willing to receive it. Original, signed copies of each participant's ICF will be securely stored o`nsite; all measures taken to protect confidentiality for the parent study will be followed in HPTN 083-02.

During the international COVID-19 emergency, sites may choose to obtain consent remotely in accordance with guidelines put forward by DAIDS, NIH Office of Human Research Protections (OHRP), U.S. Food and Drug Administration (FDA) and European Medicines Authority (EMA). The HPTN has archived the guidance promulgated by these entities in response to the 2020 COVID-19 epidemic on the HPTN.org website at:

https://www.hptn.org/news-and-events/announcements/hptn-covid-19-resource-center

Sites wishing to obtain consent remotely must draft or modify a local standard operating procedure (SOP) to describe the process that will be used. This procedure must include the following elements:

- How the identity of the potential participant will be confirmed and documented. All participants in this sub-study are by definition participants in the main 083 study, so one option for determining identity might be to have the participant confirm personally identifying information recorded on the main study locator form that would not be likely to be known by others. An initialed, dated progress note describing how identity was confirmed prior to consent procedures would be one way to document this process.
- How the participant will receive a printed or electronic copy of the written consent form before initiating the informed consent process and how they can continue to access this form after consent has been obtained. Options for this might include mailing two copies of a paper copy to the participant (one for them to return to the site, one for them to keep), emailing it, providing it through a web-based application, sending it as an attachment to a text message, etc.
- Whether the remote consent approach will be used for participants who are illiterate or will have a legally authorized representative consent on their behalf, and if so, how such participants will be accommodated.
- How the staff member will ensure that the consent discussion can take place confidentially at both the participant's and the staff member's locations.
- How the staff member and potential participant will review the consent elements, answer questions and assess understanding. It is expected this would be by telephone call or web-based chat/video chat.
- How documentation of consent by the participant and staff member will be accomplished. It is expected that this may be through handwritten signature, through an on-line application for consent or for obtaining electronic signatures, or potentially through a witnessed, oral consent process if approved by the IRB/EC. Sites are reminded that because HPTN 083-02 is being conducted under an IND, any electronic systems used for obtaining consent or obtaining electronic signature must comply with the requirements of the U.S. Code of Federal Regulations 21 CFR Part 11.
- How the informed consent process for each participant will be documented in study files and made available for review by monitors, auditors and inspectors.

Once a site has determined the system(s) they will use to conduct remote consent, and has written or modified their SOP(s) to describe the remote consent procedure, the SOP(s) will be forwarded to the HPTN 083-02 Clinical Research Manager (CRM) at the HPTN LOC who review the SOP in light of the pertinent guidelines. Sites must also obtain approval from applicable IRB(s)/EC(s) for the proposed change in consent procedures and this approval must be documented in the site records. The proposed approach to obtaining remote consent must meet all applicable regulations including OHRP, 45 CFR 46, ICH, FDA, EMA and local and institutional policies and procedures. The site may begin conducting remote consent once confirmation to proceed from the LOC has been received and IRB/EC approval has been obtained.

3.3 Conduct of Qualitative Interviews

Qualitative interviews will last approximately 30-60 minutes and will be conducted either via phone/internet or in person in a private setting. All interviews will be recorded with an audio recorder and will be transcribed (and translated, if necessary) by a trained research assistant, other trained study staff, or a qualified transcriptionist/translator in compliance with applicable local requirements, such as the US Health Insurance Portability and Accountability Act (HIPAA).

Interviews will follow a semi-structured interview guide, 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 most effectively elicit information without biasing participants' responses. The guide will begin with potentially less sensitive topics and end with more sensitive topics in order to facilitate rapport. Open-ended questions will be followed by probes to facilitate discussion and to ensure the completeness of qualitative data.

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

The interview guide and probes are found in Appendix II of this SSP.