2. Site Activation Processes and Requirements

2.1   Overview of Activation Process

HPTN 083-02 is being conducted by the HIV Prevention Trials Network and is a sub-study of HPTN 083, in which all HPTN 083-02 sites are participating. The Network-level requirements and procedures for site activation, as described in the HPTN Manual of Operations, and with which the sites are already familiar from HPTN 083, apply to HPTN 083-02. Information about activation to HPTN 083-02 is included in the study protocol. Additional information is provided below.

To summarize the process, to be activated to the HPTN 083-02 study, sites must first obtain approval of the protocol, informed consent forms and other required materials locally from their Institutional Review Board (IRB) or Ethics Committee (EC) and any other applicable local regulatory entity. Note that for the US sites of the study, IRB review will need to transition to a single, central IRB contracted by the HPTN per NIH policies; the HPTN Leadership and Operations Center (LOC) will communicate with the US sites about completing this transition. Sites will then submit required materials to the Division of AIDS (DAIDS) Regulatory Support Center (RSC) for review. In parallel with this process, the site will complete the other elements listed on the "HPTN 083-02 Qualitative Sub-Study Site Activation Checklist" (see Appendix I and below). Once all requirements on the checklist have been completed, including RSC approval, the Investigator of Record (IoR) will sign the checklist and it will be sent to the HPTN LOC representative for the study. The site IoR and the HPTN LOC representative will have a phone call to review the checklist. Once the LOC representative has confirmed that all checklist items have been completed, the LOC representative will request site activation from HPTN leadership and DAIDS. Upon receipt of activation approval, the LOC representative will send an activation notice to the site on behalf of the study leadership. The site may begin enrollment of participants only after receiving this notice.

2.2   Study-Specific Requirements for Site Activation

The following list documents the steps that must be completed before a site will be activated to the HPTN 083-02 protocol:
- IRB/EC approval for the HPTN 083-02 Sub-Study
- Approval for the HPTN 083-02 Sub-Study by any other applicable national or local regulatory authorities
- Staff hired/assigned to execute qualitative interviews, with documentation in regulatory file of appropriate education, training and experience, to include:
  - CV

- o GCP training
- o HSP training
- o Study-specific training from the main HPTN 083 trial, including study design, AE, social harm reporting and relevant SSP manual sections
- o Qualitative interview training, including 083-02 specific training
- o Training or self-study of the HPTN 083-02 Study Specific Procedures Manual (SSP)
- o Completed Delegation of Duties Log (using current DAIDS Delegation of Duties Log template)
- SOPs in place for conduct and recording of confidential interviews, confidential storage of recordings, transcript generation, confidential storage and transmission of transcripts, and, as applicable, translation of transcripts.
- Current and prior versions of the HPTN 083-02 SSP manual on file at the site
- Equipment in place and operational for recording of qualitative interviews.
- Protocol registration approval has been received from the DAIDS Regulatory Support Center (RSC)
- IoR has signed the protocol signature page and it is on file at the site

2.3   Interviewer Training and Early Transcript Review

Per protocol, HPTN 083-02 site staff who will be performing qualitative interviews will receive study-specific interview training from a study co-chair.

To ensure interview quality, the study co-chairs will review the transcripts from each interviewer's first two interviews before the interviewer is allowed to conduct any further interviews. The site is encouraged, therefore, to produce these transcripts quickly after the interviews are conducted and forward them for review to minimize delays. If the co-chairs identify any concerning issues or trends in early transcripts, it may be necessary for the interviewer to receive additional training and/or for co-chairs to continue to review this interviewer's transcripts until any issues have been addressed.