5. Reporting of Adverse Events, Social Harms and Protocol Deviations

5.1 Adverse Events

As noted in the HPTN 083-02 study protocol, all participants in HPTN 083-02 will also be participants in the HPTN 083 study. Any AEs reported to staff of this qualitative study (including SAEs) will therefore be reported through the main study reporting procedures described in the HPTN 083 protocol and SSP manual. Staff of this qualitative study will work with main study staff at the site (if these are not the same personnel) to ensure procedures are correctly followed and reporting achieved within required timelines. If an AE appears to be related, or potentially related, to the participant's participation the sub-study, the AE will also be reported to and reviewed by the sub-study investigators, though this is not expected in this study which consists of a single qualitative interview.

5.2 Social Harms

Similar to the process described above for AE reporting, social harms reporting in HPTN 083-02 will also take place through main study mechanisms and according to the procedures spelled out in the HPTN 083 protocol and SSP manual. Also as described for AE reporting, if staff for the sub-study and main study are not the same at a particular site, they will work together to ensure that all necessary information is conveyed to main study staff and reporting is performed according to HPTN 083 procedures. Sub-study investigators will be informed of any social harms that are or potentially are related to participation in the sub-study, though these are not expected.

5.3 Protocol Deviations

Sites must document all deviations from the protocol in participant charts or other study documents. A sub-set of deviations may be considered reportable protocol deviations and must be reported to study leadership, the HPTN LOC and the sponsor.

As outlined in the HPTN Manual of Operations, reportable protocol deviations are defined by the HPTN as individual incidents, trends or omissions that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to GCP

Examples of reportable protocol deviations are:

- Enrollment of an ineligible participant or enrollment prior to confirming eligibility. This includes situations when ineligibility is found after the fact.
- Informed consent not obtained prior to performing protocol-specified procedures.
- Breach of participant confidentiality.

Participant non-compliance with the study protocol is not considered to be a reportable protocol deviation, but should be discussed by the protocol team. Full documentation of all protocol deviations – including reportable deviations as defined above - must be maintained at the site and reported as required to the local IRB/EC.

If a site believes a deviation has occurred that would be considered reportable, the following steps should be followed:

- Contact Sam Griffith at the HPTN LOC as soon as possible (within 24 hours) but no more than 3 business days once a site becomes aware of a deviation to determine whether it constitutes a reportable protocol deviation.
- If it is confirmed that the deviation is reportable, site staff should complete the HPTN 083-02 Protocol Deviations Report Form, Appendix VI to this manual. The completed form should be printed out, hand-signed in ink by the reporting staff member and then scanned and emailed to the study's protocol deviations alias: 083-02PD@HPTN.org
- The alias will send the protocol deviation report to:
    - Protocol Chair and Co-Chair
    - LOC protocol representative
    - DAIDS Protocol Medical Officer
    - DAIDS HPTN Office of Clinical Site Oversight (OCSO) Program Officer Liaisons
- When sending the report to the alias, the site should copy the IoR, Study Coordinator, Site Regulatory Coordinator, and the site's DAIDS OCSO Program Officer on the email **(note that the site's DAIDS OCSO Program Officer is not the same as the HPTN Program Officer Liaisons).**

Note that DAIDS has a Critical Event policy that may overlap with events that are deemed to be protocol deviations by the HPTN. Sites should confirm with their DAIDS OCSO Program Officer whether a reportable deviation is also a critical event. Refer to the policy at this link: https://www.niaid.nih.gov/research/daids-clinical-research-event-reporting-safety-monitoring. The HPTN has a template available for sites to use to respond to the requirements of a critical event – it can be found at this link: https://hptn.org/resources/manual-of-operations (listed under "Other").