Section 11. Safety Monitoring and Reporting

MTN-016 is an observational study involving no investigational products or procedures associated with significant risk to participants. Therefore, few safety concerns are expected as a result of study participation. Nonetheless, the site Investigator of Record (IoR) is responsible for continuous close safety monitoring of all study participants and for alerting the Protocol Team if any unexpected concerns arise.

Note: Participants co-enrolled in MTN-016 and a parent protocol will have adverse events (AEs), serious adverse events (SAEs) and Expedited Adverse Events (EAEs) considered reportable in the parent protocol reported via the safety reporting system utilized by the parent protocol.

11.1 Unanticipated Problems Related to Study Participation

The IoR must identify any unanticipated problems considered possibly, probably, or definitely related to study procedures and/or participation. Any problem not listed as a possible risk in the study informed consent form should be considered unanticipated. In the event that any such problems are identified, the IoR will report the problem to the DAIDS Medical Officer (Jeanna Piper; piperj@niaid.nih.gov or fax: 301-402-3684) at the same time that he/she reports the problem to the site institutional review boards and/or ethics committees (IRBs/ECs), per IRB/EC policies and the requirements of 45 CFR 46. For purposes of determining reportability to the DAIDS Medical Officer, the following definitions should be applied at all sites:

Definitely not related: The problem is clearly explained by another cause not related to study participation. Do not report to DAIDS.

Probably not related: A potential relationship between the problem and study participation/procedures could exist (i.e. the possibility cannot be excluded), but the problem is most likely, explained by causes other than study participation/procedures. Do not report to DAIDS.

Possibly related: Problem and study participation/procedures are reasonably related in time, and the problem could be explained equally well by causes other than study participation/procedures. Report to DAIDS.

Probably related: Problem and study participation/procedures are reasonably related in time, and the problem is more likely explained by study participation/procedures than by other causes. Report to DAIDS.

Definitely related: Problem and study participation/procedures are related in time, and a direct association can be demonstrated with study participation/procedures. Report to DAIDS.

11.2 Social Harms

Participants in MTN-016 may experience social harms — non-medical adverse consequences — as a result of their participation in the study. For example, participants could experience difficulties in their personal relationships with partners, family members, and friends. They also could experience stigma or discrimination from family members and members of their community. In the event that any social harms occur, study staff should fully document the issues or problems in chart notes, record on relevant MTN-016 and parent protocol CRFs, and make every effort to facilitate their resolution as described in this section. Note that if the social harm is associated with an AE per the parent protocol, the AE will need to be reported via the safety reporting system utilized by the parent protocol.

The following are suggested strategies for responding to social harms that may be adapted and tailored to best meet participant needs at each site:

- When first responding to an issue or problem, actively listen to the participant's description of the problem and ask questions to elicit as much detail as possible about the problem, including the participant's perception of the severity of the problem. Record all pertinent details in signed and dated chart notes.

- Ask the participant to articulate her thoughts on what can/should be done to address the problem, including what she would like study staff to do in response to the problem (if anything).

- Discuss with the participant any additional or alternative strategies that you might suggest to address the problem and collaborate with her to develop a plan to try to address the problem. Document the plan in signed and dated chart notes.

- Take all possible action to try to address the problem, per the plan agreed upon with the participant. Document all action taken, and outcomes thereof, in signed and dated chart notes.

- Follow all problems to resolution or stabilization. Also report the issue or problem to all responsible IRBs/ECs, if required per IRB/EC guidelines.

- Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may be able to help address the problem.

- Consult the MTN-016 Protocol Team for further input and guidance as needed.