

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 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:

Not related: There is not a reasonable possibility that the AE is related to participation in MTN-016. Do not report to the DAIDS Medical Officer.

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Refer to the MTN-016 protocol, section 8 for further description of the assessment of safety.

11.1.1 Infant Safety Event Log form – For Use by VOICE Sites Only

In order to capture infant safety data that will be used for comparisons in MTN-018 B and MTN-018C, an additional CRF has been created for use beginning 2 September 2011. This form is completed ONLY for infants of mothers enrolled from the VOICE study. Sites should print their own forms, available on the MTN-016 Atlas webpage in the CRF portion of the materials, within the Infant Individual CRFs section.

Sites should review the instructions on the back of the form. Note that only safety events that meet the following criteria will be reported on this form:

- Life-threatening event
- Persistent or significant disability/incapacity
- Hospitalization
- Death

Any events which DO NOT meet the above criteria will be documented in chart notes and on the Infant Medical History Log form, but NOT on the Infant Safety Event form.

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.