

Section 6. Safety and Counseling Considerations

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6. Introduction

This section contains guidance on potential social harms and unexpected safety events, as well as counseling considerations for MTN-032.

6.1 Reporting of Social Harms and Unexpected Safety Events

MTN-032 is a qualitative study with no clinical procedures and no investigational products. Nonetheless, it is necessary to make provisions for the identification and proper reporting of unexpected safety events/concerns (UE) and social harms (SH) as reported by all MTN-032 participants.

If any UEs are reported by participants during study participation, the MTN-032 study staff, in consultation with the study coordinator/IoR, should contact clinical staff within the site to assess the UE and determine clinical management per standard of care. If needed, participants should be referred to available resources within the area for care. All procedures to address the UE, as well as any referrals, must be documented in participants' study files.

Any social harm reported by participants during study participation, should be fully documented in the participant file by the MTN-032 staff, and social harms related specifically to the MTN-032 study documented on the Social Harms CRF. Study staff should use as much detail as possible to describe the event, including a full description of the event, severity of the event, action taken, approximate onset and resolution dates. Every effort will be made by study staff to provide appropriate referrals as needed. Every effort will also be made to provide appropriate care, counseling, and referrals to participants presenting a social harm after the study.

Each site will provide listings of social harms related to MTN-032 participation that are reported by study participants to the MTN-032 Management Team at a minimum of every month, and per any applicable DAIDS requirements. Any social harm related to MTN-032 that results in an adverse event should be reported within three days of site awareness. Additionally, sites will develop a Participant Safety Monitoring SOP for emergency procedures to be used in situations of social harm and when situations that require immediate attention are identified, including domestic violence, suicidal ideation or behavior. The procedures will provide clear guidelines for MTN-032 researchers to refer participants in these situations to the relevant institution/body.

Sites are to report social harms up to 30 days after study participation, should site staff become aware of any.

6.2 Counseling Considerations

As specified above, participants may experience social harms as a result of participation in MTN-032. If a social harm is reported by a participant every effort will be made by MTN-032 study staff to provide referrals to appropriate resources to ensure the safety of the participant.

Prior to study initiation, study staff teams at each site should discuss as a group, and with community representatives, what issues and problems are most likely to be encountered by participants at their site, and should agree upon how these issues and problems should be handled if reported. Roles and responsibilities should be defined for all staff members, such that each staff member is aware of what actions he/she can appropriately take, and what actions should be referred to other members of the team. During study implementation, staff teams at each site should continue to discuss actual participant experiences, successful and unsuccessful response strategies, and other lessons learned among themselves and with community representatives. Based on these discussions and lessons learned, procedures for responding to issues and problems should be reassessed and updated as needed throughout the study.

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

- When first responding to an issue or problem, discuss with the participant referral to a site counselor. Ensure that other than information related to the social harm, no personal information will be shared with the counselor. Counselors should follow procedures already established for the site when addressing and counseling for social harms. The counselor should 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 for his or her thoughts on what can/should be done to address the problem, including what she or he 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. Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may be able to help address the problem.
- If the reported social harm is associated with an AE, document the AE on the study file and report to the MTN-032 operations team. Also report the issue or problem to all IRBs/ECs responsible for oversight of MTN-032, if required per IRB/EC guidelines.

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. All counseling and referrals should be documented in participant study records per site SOPs.