Section 5. Safety and Counseling Considerations

This section contains guidance on potential social harms and unexpected safety events, as well as counseling considerations for MTN-041.

5.1. Reporting of Social Harms and Unexpected Safety Events

MTN-041 is a qualitative study which does not involve a study product nor clinical, laboratory or other procedures associated with significant risk to participants. The only anticipated risks to result from study participation are social harms and embarrassment when discussing sensitive issues. 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-041 participants.

If any UEs are reported by participants during study participation, the MTN-041 study staff, in consultation with the study coordinator/IoR, should consult with site staff to assess the UE and determine clinical management per standard of care. If needed, participants should be referred to available local resources for care. No safety events will be captured in the study database, but all action taken to address the UE, as well as any referrals, must be documented in chart notes. The MTN-041 Management Team should be notified promptly of any UEs that occur, and sites should follow local IRB requirements for reporting UEs as needed. Finally, UEs may in some cases be considered DAIDS critical events—sites should reference the current DAIDS Critical Event Policy on reporting critical events and consult their OSCO Program Officer as needed regarding critical event determination/reporting.

Social harms are defined as non-medical adverse consequences experienced by a study participant. For example, participants could be treated unfairly, experience negative repercussions in their professional or community leadership positions, or could have problems being accepted by their families, partners and/or communities. Any SH reported by participants during study participation should be fully documented in the participant file by MTN-041 staff. Social harms determined to be related to MTN-041 study participation should also be documented on the Social Harms CRF, and reported to the DAIDS Medical Officer (MO) and MTN-041 Management Team. Sites are responsible for reporting SHs to IRBs according to local requirements/timelines. 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 care, counseling and referrals for the safety of the participant as needed.

Site specific procedures for care, counseling, and referrals in the event of UEs and SHs should be outlined in site SOPs for Emergency Procedures, Participant Safety Monitoring, and Social Harms Reporting. In addition to general management and care, sites should include in this SOP procedures for handling SHs or UEs in situations requiring immediate attention, including domestic violence and suicidal ideation or behavior.

The procedures will provide clear guidelines to site staff for referring participants in these situations to the relevant institution/body and providing feedback to the MTN-041 Protocol Team.

Participants who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support, care, and referrals in accordance with all site- or study-specific SOPs. The World Health Organization (WHO) publication, *Responding to intimate partner violence and sexual violence against women*

(available at https://extranet.who.int/rhl/guidelines/responding-intimate-partner-violence-and-sexual-violence-against-women) is a useful resource that may help inform site-specific policies for responding to reports of sexual assault or other violence. Generally, responses to reports of sexual assault should include first line support—listening and offering comfort, help, and information/referrals to connect the participant to services and social support—as well as offering the participant an opportunity to provide a complete history of events, and receive relevant physical evaluations, and treatment and/or referral for any injuries. If within the capacity of the site, emergency contraceptive and STI prophylaxis/treatment should be offered. Depending on the time between the assault and presentation to the clinic (i.e. if within 72 hours), the use of PEP should also be considered. If these services cannot be provided on site, referrals should be provided. Plans for continued follow-up and care should be outlined to check in on the participant's well-being and uptake of referrals, as appropriate.

There are no additional clinical management considerations for participants enrolled in this study. Participants who express concerns with social, psychological or clinical issues will be referred for appropriate care to services available at the CRS, or at nearby partnering facilities.

5.2. Counseling Considerations

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 s/he 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. 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. 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.
- Ask the participant for his or her thoughts on what can/should be done to address the problem, including what s/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 him or her to develop a plan to try to address the problem.
- Take all possible action to try to address the problem, per the plan agreed upon with the participant.
- Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may help address the problem.
- Document a summary of the reported event, action(s) taken, and outcomes thereof, and any referrals, in signed and dated chart notes. As needed, report on Social Harms CRF and notify relevant groups as outlined in section 5.1 above.

5.3. Criteria for Early Termination of Study Participation

Participants may voluntarily withdraw from the study for any reason at any time. The IoR also may withdraw participants from the study to protect their safety and/or if they are unwilling or unable to comply with required study procedures. Participants also may be withdrawn if the study sponsors, government or regulatory authorities, including the Office for Human Research Protections (OHRP), or site IRBs/ECs terminate the study prior to its planned end date.

If the participant withdraws (voluntarily or otherwise) prior to the interview taking place, all study procedures should be discontinued immediately and the reason for withdrawal should be documented in the participant's record (e.g. chart notes). In addition, the MTN-041 Management Team should be informed.

If the participant voluntarily withdraws consent during an ongoing interview, staff should affirm the participant's right to withdraw and allow him or her to leave the FGD (or stop the IDI) per his or her request. Staff should use discretion when managing involuntary withdrawals during an ongoing FGD and take the course of action that minimizes risk of social harms or other unanticipated safety events (to both the participant being withdrawn and other FGD participants). Staff should confirm permission to maintain data already collected up until the point of participant withdrawal, and document the outcome of these conversations and any other details relevant to the withdrawal in the participant's record (e.g. chart notes, debrief report). In addition the MTN-041 management team should be notified.

In the event that participants who voluntarily withdraw from the study wish to re-join the study, they may do so if the accrual target has not yet been met, in consultation with the MTN-041 Management Team. Note that withdrawing consent and later re-joining the study requires signing a new informed consent form, and is different than needing to stop and reschedule an interview based on unforeseen circumstances (addressed in SSP Section 3.12.1).