

MTN 017 Operational Guidance #02



Scheduled Study Exit/Termination

The purpose of this communication is to clarify the duration of participant follow-up and timing of scheduled study termination.

- Per Protocol Section 10.5, the study termination date is defined as the 7th day after the End Period 3/Final Clinic Visit (Visit Code 10.0). The AE reporting period begins at the time of randomization and ends 7 days after the End Period 3/Final Clinic Visit.

Note: A participant should not be terminated prior to the 7th day unless consent is withdrawn and the participant terminates early from the study. In the event of early termination:

- Staff should complete as many early termination visit procedures (same procedures as Visit 10.0) as permitted by the participant.
 - The termination date is based on the date the early termination visit is completed or the date the participant is considered no longer in the study (e.g., may be after all termination visit lab results are received).
 - The visit code assigned to the early termination visit should match where the participant is in his/her follow-up schedule at the time of early termination.
- Per Protocol, Section 7.3, all participants must be instructed to call-in to the clinic to report any new or worsening AEs within seven days following the Final Clinic Visit 10 (Week 26). **Sites should clearly document in the participant's binder 1) provision of these instructions, and 2) the date the participant was deemed no longer in the study (i.e., termination date).**
 - For sites that have not been instructing participants to call-in to the clinic to report any new or worsening AEs within seven days following the Final Clinic Visit 10 (Week 26), to date, please complete a Protocol Deviation Log CRF (code 99) for each occurrence and fax the forms to SCHARP as soon as possible. Please train all relevant staff at your site on this operational guidance so that required procedures and documentation are followed going forward.
 - For sites that have been correctly instructing participants to call-in any new or worsening AEs within seven days following the Final Clinic Visit 10 (Week 26), to date, but are incorrectly recording the Visit 10 date as the termination date on the Termination CRF (TM-1), please update the termination date to correspond to the actual date when termination occurred [which should be the 7th day after the Final Clinic Visit 10 (Week 26)]. Please train all relevant staff at your site on documentation requirements, per this operational guidance.

Should you have any questions about this information, feel free to contact the MTN-017 Management Team (mtn017mgmt@mtnstopshiv.org).