Section 8. Co-Enrollment Considerations

All participants in MTN-016 will be or will have been enrolled in another microbicide study. Provided in the remainder of this section is guidance related to the conduct and documentation of MTN-016 visits and procedures for women who are co-enrolled in multiple MTN protocols.

8.1 Co-Enrollment with MTN Parent Protocols

The management team encourages sites to think about ways to streamline visits and reduce participant visit burden as much as possible for participants who are completing MTN-016 visits concurrently with parent protocol follow-up visits. One way to streamline visits may be to conductMTN-016 and parent study visits on the same day, however this may not be the preferred approach for all participants at all sites. Reserving specific days of the week or times of the day for MTN-016 visits may be another option for reducing visit length. Sites should discuss all options for visit scheduling with participants and accommodate participant requests as much as possible, so as to maximize enrollment and retention in the study. Site staff should also be mindful that some participants may find combined visits too time-consuming and/or may prefer separate visits to prevent stigma. In the event that MTN-016 visits are scheduled on the same day as parent study visits, completion of the parent study visits should take priority if time or other factors do not allow for both study visits to be completed on the same day.

Using the procedure listings in Section 7 of the MTN-016 protocol as a guide, the remainder of this section provides guidance on the conduct and documentation of MTN-016 procedures for co-enrolled participants. Please contact the study management teams with any questions related to interpretation of, or compliance with, both parent study and MTN-016 protocols. Please also refer to Section 3 of this manual for more information on MTN-016 documentation requirements.

Informed consent	This procedure is specific to MTN-016. Conduct and document per the MTN-016 protocol, SSP Manual, and SOPs.
Review parent study records to confirm pregnancy	This procedure is specific to MTN-016. Conduct and document per the MTN-016 protocol, SSP Manual, and SOPs.
Eligibility determination	This procedure is specific to MTN-016. Conduct and document this procedure per the MTN-016 protocol, SSP Manual, and SOPs.
Assign participant ID	This procedure is specific to MTN-016. Conduct and document per the MTN-016 protocol, SSP Manual, and SOPs. A master participant/PTID log should be maintained in a secure location, listing all protocols in which participants are involved.
Update locator information	Sites may choose to maintain one centralized locator form, which is updated for both MTN-016 and the parent protocol during the period that the participant is co-enrolled. Upon exit from the parent protocol, a certified copy of the locator should be made to archive with the parent protocol study records. The centralized locator

	should then be maintained as part of MTN-016 follow-up. Alternatively, sites may opt to maintain two locator forms (one for each study) or to prepare a certified copy of the parent study locator form in the MTN-016 study record. Full descriptions of the site process should be documented in the site SOP(s).
Schedule next visit	Review the target dates and allowable visit windows for both the parent study and MTN-016 when scheduling visit dates with the participant. Schedule visits to minimize duplication of procedures across studies when possible.
Reimbursement	Site SOPs should specify how reimbursement will be handled when MTN-016 visits are conducted on the same day as parent study visits. Reimburse participants per site SOPs and any applicable IRB/EC specifications.
Obtain/update medical history	Medical history information is typically collected at parent protocol and MTN-016 visits. Sites may file certified copies of the parent study medical history form in the MTN-016 study record. Full descriptions of the site process should be documented in the site SOP(s). Note, clinical events identified in MTN-016 may be considered AEs in the parent study. Document and report AEs per the parent study protocol, SSP Manual, and SOPs. Prepare and file certified copies of MTN-016 source documents as needed to document the AEs in the parent study record.
Obtain/update pregnancy report and history	Sites may file certified copies of the parent study pregnancy report and history form in the MTN-016 study record. Full descriptions of the site process should be documented in the site SOP(s).
Obtain pregnancy outcome data	More detailed information regarding the pregnancy outcome is collected on MTN-016. **Therefore, sites may NOT make certified copies of parent protocol pregnancy outcome form as documentation**. Sites must instead obtain certified copies of medical records to complete pregnancy outcome forms for MTN-016.
Obtain/update genetic screening history	This procedure is specific to MTN-016. Conduct and document this procedure per the MTN-016 protocol, SSP Manual, and SOPs.
Obtain/update medication history	Concomitant medication information is typically collected at all parent study visits and MTN-016 visits. Sites may file certified copies of the parent study concomitant medications log in the MTN-016 study record and collect participant updates

	during each 016 visit. Full descriptions of the site process should be documented in the site SOP(s).

8.2 Co-Enrollment with Non-MTN Parent Protocols

As of the version date of this section, there are no firm plans in place for women to be enrolled to MTN-016 from a non-MTN parent protocol. This section will be expanded in the event that this changes.