**MTN-043 Protocol Counseling Guide**

**Instructions:** Protocol counseling is required at study visits starting at enrollment through the PUEV. Find the visit below that corresponds to the visit the participant is completing today and review elements of protocol counseling required at that timepoint. Participants should be encouraged to inform study staff if they have not been able to follow any guidelines. Document any questions or issues on the relevant visit checklist, or in chart notes.

**Enrollment, Weeks 1 & 2, Month 1 & 2 (i.e., visits before PUEV)**

Review the following guidance with the participant:

* For 24 hours prior to study visits:
* Abstain inserting any non-study objects into the vagina (including tampons, pessaries, sex toys, female condoms, diaphragms, menstrual cups, cervical caps or any other vaginal barrier method, etc.
  + Stay sexually abstinent i.e. no receptive intercourse (vaginal, anal, oral and finger stimulation).
* For entire study:
  + Refrain from using non-study vaginal products (including spermicides, lubricants, contraceptive VRs, douches, vaginal medications)
  + Refrain from using non-study PrEP or PEP. If PEP or PrEP is used, study product will be discontinued. Participants should use PEP if they have a known or potential HIV exposure during the study, as soon as possible and within 72 hours of exposure.
* Inform study staff of use of any prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations.
* Bring any used or unused vaginal ring(s) or remaining pills back to clinic.

Provide next scheduled visit date, and remind participant of importance of attending all study visits. Provide clinic contact card, as needed, and request that participant contact clinic if she cannot make her appointment or if she has any other concerns or questions.

Remind participant that study visits do not replace routine well-baby or postnatal care. Ensure that she and her infant are linked to appropriate community-based health care providers and encourage them to attend all appointments with local care providers.

As appropriate, offer participant a copy of the relevant Provider Guide. Instruct the participant to keep this sheet with her in case she sees a provider not previously contacted by the site as this guide will provide important information about her and her infant’s study participation. Offer any additional educational resources as appropriate (e.g. study factsheets).

**Additional Protocol Counseling to Provide at PUEV**

* Remind participant she will stop study product at this visit, but that she and her baby have one more appointment in about 2 weeks *[provide scheduled date]* which will be their final visit.