

MTN-042 Protocol Counseling Guide

Instructions: Protocol counseling is required at all in-person study visits starting at enrollment. 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, 2-week, 4-week, and Bi-weekly Visits (Any visits before pregnancy outcome)

- 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.
 - If PEP is used, study product will be temporarily held. 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.
- If labor starts (i.e. contractions, water breaks or labor induced), or the participant reaches 41 and 6/7 weeks gestation (*provide date based on visit calendar tool*), stop product use and contact clinic as soon as possible. Bring used vaginal ring (in zip bag) 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 prenatal care, she should still attend all appointments with her local prenatal care provider.

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 or delivers at a facility not previously contacted by the site as this guide will provide important information about her study participation. Offer any additional educational resources as appropriate (e.g. study factsheets).

Post-Pregnancy Outcome (PPO) Visit

- **MOTHER:** 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).
- **MOTHER:** For entire study:
 - Refrain from using non-study vaginal products spermicides, lubricants, contraceptive VRs, douches, vaginal medications
 - Refrain from using non-study PrEP.
 - If PEP is used, study product will be temporarily held. 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 mother and/or infant use of any prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations.
- 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 postnatal or well-baby care, she should still attend all appointments with her local postnatal care provider, and attend recommended well-baby visits.

6-Week PPO Visit

- Remind participant this is her last study visit, but her baby will continue in the study until they are 1 year old. Ensure participant and infant return for 6-month and 12-month follow-up visits, and to contact site staff with any locator information changes.
- For the duration of infant's participation, inform study staff of infant use of any prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations.
- Provide next scheduled visit date for infant, and remind participant of importance of bringing her baby to all remaining study visits. Provide clinic contact card, as needed, and request that participant contact clinic if she cannot make her baby's appointment or if she has any other concerns or questions.
- Remind participant that study visits do not replace routine well-baby care, she should still bring her baby to all recommended well-baby visits