Section 13. Counseling Considerations

This section contains guidance on the following types of counseling provided in MTN-011: HIV risk reduction counseling, contraception counseling, and study product adherence counseling. See Protocol Section 7 for details on when each type of counseling is required.

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, skills-building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

All counseling should be documented in participant study records. Proper documentation may be achieved through the use of counseling checklists, worksheets, and other tools, as well as counselors chart notes. To support ongoing client-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform and guide the participant's next counseling session.

13.1 HIV Counseling

Female and Male study participants must always have separate HIV counseling sessions and must also be provided the testing results individually. HIV pre-test and post-test counseling and full risk reduction counseling is required at the Screening Visit and the participant's final study visit: Visit 7b for Group 1 and Visit 9 for Group 2. Modified risk reduction counseling is required at the follow-up visits.

Referrals also should be provided when indicated. It is generally expected that detailed counselors notes will be completed in order to fully document all counseling sessions and all referrals provided.

All HIV counseling should be provided in accordance with local counseling standards and per site SOPs. Study staff that provides HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendix III. Additional information on HIV testing during screening and follow-up is provided in Sections 4 and 5 of this manual respectively; further information on interpretation of screening and follow-up test results is provided in Table 13-1.

13.1.1 Pre-Test Counseling :

Pre-Test Counseling will be done at the screening visit and the participant's last study visit: Visit 7b for Group 1 and Visit 9 for Group 2. Client-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results. Participants should be informed of when their test results will be available.

13.1.2 Risk Reduction Counseling:

Full risk reduction counseling will be conducted at the Screening Visit and the participant's last study visit. Modified risk reduction counseling should be done at all other follow-up visits. Modified risk reduction counseling for this study is referring to the fact that condoms cannot be used by study participants during their trial participation. Condoms will not be provided through the study, but the counseling session should still discuss condoms as one of the proven methods of HIV prevention. Participants should be reminded that they cannot use condoms during the time of study participation. When discussing non-use of condoms during these sessions, participants should be reminded of study participation requirements, namely contraception, monogamy, and not being infected with STIs, including HIV.

Full Risk Reduction Counseling will be done at the following study visits:

Group1	Group 2
Visits 1, 7b	Visits 1, 9

Modified Risk Reduction Counseling will be done at the following study visits:

Group1	Group 2
Visits 2a, 3a, 4a, 5a, 6a, 7a	Visits 2, 3a, 4, 6, 7a, 8

Note: For Group 1 participants, they will have modified risk reduction counseling conducted at visit 7a, and then full risk-reduction counseling at visit 7b. Counselors should review prior counseling notes from the earlier counseling session in order to minimize repetition.

Client-centered approaches should also be used when assessing participant risk for HIV infection and providing risk reduction counseling. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying his risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Referrals are expected components of risk reduction plans when indicated based on participant needs. When referrals are provided, these should be fully documented in participant study records and should be actively followed up at subsequent counseling sessions to determine whether the participant sought the services to which he was referred, what the outcome of the referral was, and whether additional referrals are needed. All such follow-up should also be fully documented in participant study records.

13.1.3 Post-Test Counseling:

Post-Test Counseling will be conducted after HIV test results are received. Counselors should provide and explain test results in a private setting per site SOPs. Male and female participants should be given results individually. Counselors should assess participant understanding of results and provide clarification and further information as necessary. Regardless of status, continued risk-reduction should be emphasized.

Table 13-1
Interpretation of HIV Tests Performed During Screening and Final Clinic Visits

Test Result	Interpretation
EIA negative	HIV-uninfected; test results indicate that you are not infected with HIV.
EIA positive or indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.
Sample 1 Western blot positive	If Screening Visit: HIV-infected; test results indicate that you are infected with HIV If Final Visit: HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes.
Sample 1 Western blot negative or indeterminate	HIV status not clear; additional testing is needed to determine your status.
Sample 2 Western blot positive	HIV-infected. Test results have confirmed that you are HIV infected.
Sample 2 Western blot negative or indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

In the event that a participant's status is confirmed as HIV-infected, they should be referred to care per site SOPs.

13.2 Contraceptive Counseling

Women must be on an effective non-barrier contraceptive method, other than a vaginal ring, for three months prior to screening and intend to continue to use this method for the remainder of the study. It is highly desirable that women not change methods during the course of their study participation. Contraception counseling is required at the following study visits:

Group1	Group 2
Visits 1, 2a, 3a, 4a, 5a, 6a, 7a	Visits 1, 2, 3a, 4, 5, 6, 7a, 8

All contraception counseling should be provided in accordance with local counseling standards. Study staff who provide contraception counseling should be trained to do so per local practice standards and should also be trained on MTN 011 specifications related to contraception.

Participants should be counseled regarding the necessity of using an effective method of birth control. Per protocol, these include birth control pills, patch, injectable hormones, subdermal implants, IUDs, female or male sterilization. For those participants who report sterilization, study staff must verify the sterilization per site SOPs; all sites are strongly encouraged to obtain credible medical records as part of their verification procedures. At Screening, Enrollment, and throughout Follow-up, contraception may be provided on site; however, sites may opt to refer participants to non-study providers for contraception. Condoms will be provided to study participants at their final clinic visit.

All contraception counseling should be provided in a client-centered manner and should guide and support each participant in maintaining adherence to her chosen effective method.

At screening and enrollment visits, contraception counseling should be provided in the context of the study eligibility criteria related to willingness to use the same effective contraceptive method that the study participant has been using for at least the last three months.

At follow-up visits, client-centered counseling should continue. Issues discussed at the previous counseling session should be reviewed and discussed with the participant as needed and the counselor should determine whether the participant has any current issues, questions, problems, or concerns with her current contraceptive method.

All contraception counseling sessions should be fully documented in participant study records. A sample contraceptive counseling worksheet is located in Appendix 13-1. For each session, sufficient information and detail should be recorded to support review and appropriate follow-up at each subsequent visit.

13.3 Study Product Adherence Counseling — Group 2 Enrollment

Only Group 2 participants will be provided study product adherence counseling at Enrollment. Prior to receiving this counseling, participants will receive their study product, be provided with product insertion instructions, and complete product insertion at the study clinic.

13.3.1 Product Use Instructions

At the enrollment visit, Group 2 participants will be provided with detailed product use and insertion instructions. Product insertion instructions will be provided based on the instructions sheets shown in SSP Section 7. In addition to verbal instructions, a copy of the illustrated instructions could be provided to each participant. Other visual aids, such as sample applicators and pelvic models, should be used as needed when providing instructions to help ensure participant understanding of proper product use.

Adequate time should be taken to thoroughly explain the product use and insertion instructions and answer any questions the participant may have; any questions or concerns raised by the participant should be documented in her study records so this information is easily available for reference at follow-up visits.

13.3.2 First Product Use Insertion

All Group 2 female study participants will complete insertion of their first dose of study product at the study clinic during their enrollment visit. Any questions or concerns that arise in the context of product insertion can be addressed by study staff at that time. If the participant has any further questions or concerns, these should be documented for future reference and addressed by study staff.

Study staff should instruct the participant to thoroughly wash her hands before and after study product insertion. Insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance.

Inability to insert the study gel is expected to be rare. For participants who have difficulty, study staff should provide further information and guidance to address the difficulty encountered. After the gel is inserted, study staff should de-brief with the participant on her experience. Any issues raised by the participant should be documented in participant study documents so the information is easily available for reference at study follow-up visits.

13.3.3 Adherence Counseling

Study product adherence counseling will be provided at the enrollment visit for Group 2 female participants per the Enrollment Adherence Counseling Checklist shown in Section Appendix 13-2. At the enrollment visit, counseling will be provided on each of the key messages listed below.

1. Apply contents of one applicator every day.
    - at approximately the same time every day
    - to avoid gel leakage, some participants may prefer to insert gel at night, before retiring or before the longest period of rest

2. If you miss a dose, apply the missed dose as soon as possible. If the next dose is due within 6 hours, the missed dose will be skipped and the next dose will be administered as originally scheduled.

3. Keep your product supplies in your possession.

4. At home, keep your product supplies in a secure dry place, out of the sun and safe from children.

5. Do not share your product and do not use other participant's product.

6. Bring all used and unused applicators to clinic visits.

7. The study staff are here to help and support you. Please contact us if you have:
    - Problems applying the gel
    - Adverse reactions or safety concerns
    - Problems keeping your gel for your use only
    - Any other problems (such as partner or family issues)

Each of the above key messages is listed on the Enrollment Adherence Counseling Checklist, together with further guidance for counselors. The formatting of the checklist may also be tailored to individual site needs; however, the key messages should not be modified at any site. Adequate time should be taken to counsel the participant on all key messages, answer any questions and address any concerns the participant may have, and work with the participant in a client-centered manner to identify operational strategies to assist her in inserting the gel. She should be encouraged to ask questions and raise issues or problems at any time.

Each counseling session should be fully documented on the Enrollment Adherence Counseling Checklist and in additional counselors' notes as needed.

13.4 Study Product Adherence Counseling — Group 2 Follow-Up visits

During follow-up, study product adherence counseling is required for Group 2 female participants at Visits 3a, 4, 6, and 8. At these visits, the client-centered counseling approach initiated at the enrollment visit should continue, per the Follow-up Adherence Counseling Checklist shown in Section Appendix 13-3. Each counseling session should include the following components:

- Assess adherence to study product use since the last counseling session based on participant report
- Discuss challenges with product use adherence
- Reinforce key adherence messages
- Document the counseling session

The formatting of the checklist may be tailored to individual site needs; however, the key adherence counseling messages should not be modified.

Further guidance for the adherence counseling session is provided below.

- Always review documentation of previous adherence counseling sessions in preparation for a new counseling session.
- At the beginning of each session, emphasize the importance of open communication about study product use.
- Use open-ended questions and probes to assess the participant's self-reported adherence since her last counseling session.
- When providing adherence counseling:
    - Ask the participant what her experience has been using the gel
    - Review and discuss with the participant any current barriers to product use.
    - When needed, review product use insertion instructions with the participant, using the illustrated instruction sheet and any other visual aids that may be helpful to ensure participant understanding of proper product use.

Fully document each counseling session. Clearly record the challenges/barriers and adherence plan and strategies discussed at each session for ease of reference at the next session, and record further details in additional counselors notes as needed.

NOTE: Adherence counseling is a required procedure for Group 2, visit 7a; however no product is being provided at this visit. Rather than product adherence counseling, the

site should focus on protocol adherence requirements, such as monogamy and prohibited practices.

13.5 Study Product Use Instructions — Groups 1 and 2 Follow-Up visits

At the following time points, female participants in Groups 1 and 2 will be provided with detailed product use instructions:

Group1	Group 2
Visits 3a, 4a, 5a, 6a, 7a	Visits 3a, 4, 6, 8

Group1 participants, at **Visit 3a**, should be informed to insert dose at the hotel approximately 1 hour prior to coitus. At **Visits 4a, 5a, and 6a**, participants will insert gel in the clinic. Group 1 participants, at **Visit 7a**, should be informed to insert the first dose at the hotel approximately 1 hour prior to coitus and approximately 1 hour after coitus. Both doses should be inserted at the hotel.

Group 2 participants, at **Visit 3a**, should be informed to insert dose at the hotel approximately 1 hour prior to coitus. At **Visit 4**, participants will insert first dose at the clinic and be provided gel to allow for insertion at home for next 5 daily doses. At **Visit 5**, participants will insert gel in the clinic (NOTE: product use instructions are not required at this visit but sites may choose to provide instructions as needed for gel insertion at clinic). At **Visit 6**, participants will insert first dose at the clinic and be provided gel to allow for insertion at home for next 6 daily doses. Participants at this visit will be instructed to return to clinic for Visit 7a approximately 72 hours after last dose of product at home. At **Visit 8**, participants will insert first dose at the clinic and be provided gel to allow for insertion at home for next 6 daily doses. Participants at this visit will be instructed to return to clinic for visit 9 approximately 72 hours after last dose of product at home.

Product insertion instructions will be provided based on the instructions sheets shown in SSP Section 7. In addition to verbal instructions, a copy of the illustrated instructions should be provided to each participant. Any questions or concerns raised by the participant should be documented in her study records so this information is easily available for reference at follow-up visits.

Appendix 13-1
Sample MTN-011 Contraceptive Worksheet

PTID: **Page:**

Visit Date			
Visit Code			
Review participant's reproductive history documentation and previous entries on this flow sheet to inform and guide contraceptive counseling provided at each visit.			
Current contraceptive method			
Contraceptive issues/questions/ concerns discussed at this visit			
Issues to follow up at next visit			
Scheduled date of next contraceptive prescription (or NA)			
Scheduled date of next contraceptive injection (or NA)			
Initials and Date			

Appendix 13-2
Enrollment Product Adherence Counseling Worksheet (Group 2 Participants)

Enrollment Product Adherence Counseling Checklist

PTID:	**Visit Date:**

❒ **De-brief with participant about her gel insertion experience**:

- Was she able to insert the gel?
- Did she have any difficulties?
- Does she have any questions?
- Does she have any concerns about using gel at home?
- Would she like any additional information or instructions?

Discuss key adherence messages and use instructions to the participant

❒ Apply contents of one applicator every day.

- at approximately the same time every day
- to avoid gel leakage, some participants may prefer to insert gel at night, before retiring or before the longest period of rest

❒ If you miss a dose, apply the missed dose as soon as possible. If the next dose is due within 6 hours, the missed dose will be skipped and the next dose will be administered as originally scheduled.

❒ Keep your product supplies in your possession.

❒ At home, keep your product supplies in a secure dry place, out of the sun and safe from children.

❒ Do not share your product and do not use other participant's product.

❒ Bring **all used and unused** applicators to clinic visits.

❒ **Provide instructions to contact study staff:**

- To report symptoms or problems she may be experiencing
- Needs additional counseling
- Has any other problems, concerns, or questions (such as partner or family issues)

_____
Staff Initials and Date

Appendix 13-3
Follow-Up Product Adherence Counseling Checklist (Group 2 Participants)

Follow Up Product Adherence Counseling Checklist

PTID:	**Visit Date:**

❒ **Discuss and assess adherence to gel insertion use since the last counseling session based on participant report. Examine the following:**

What were the participant's experiences with the gel since the last counseling session?
What are things that seem to have made inserting the gel easy or challenging?

_____

_____

_____

_____

_____

_____

_____

_____

Reinforce key adherence messages

❒ Apply contents of one applicator every day.

❒ If you miss a dose, apply the missed dose as soon as possible. If the next dose is due within 6 hours, the missed dose will be skipped and the next dose will be administered as originally scheduled.

❒ Keep your product supplies in your possession.

❒ At home, keep your product supplies in a secure dry place, out of the sun and safe from children.

❒ Do not share your product and do not use other participant's product.

❒ Bring all **used and unused** applicators to clinic visits.

❒ Provide instructions to contact study staff if you have any questions, problems or need study gel between visits.

_____
Staff Initials and Date