Section 10 – Counseling Considerations

10. Introduction

This section contains guidance on the following types of counseling provided in MTN-033: HIV Pre- /Post-Test, HIV/STI Risk Reduction, Product Adherence and Product Use Instructions, Protocol Adherence and Rectal Biopsy/Fluid Procedural Counseling. All counseling should be provided in a non-judgmental participant-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. Specific content to cover or skills to emphasize are not standardized. Rather, the process for these discussions is standardized to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time.

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 chart notes. To support ongoing participant-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. Counselors should engage in the discussion rather than focusing on taking notes. A summary of the counseling session should be written once the session is completed.

10.1 HIV Pre- /Post-Test and Risk Reduction Counseling

HIV testing is required at Screening, Enrollment and Visit 6; as such, HIV pre-test and post-test counseling is required at each visit in which HIV testing is performed. HIV pre- and post-test counseling should be provided in accordance with local counseling standards. Study staff who provide such 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 II. Information on interpretation of screening, enrollment, and follow-up test results is provided in Table 10-1 which can be referenced as needed when providing pre-test and post-test counseling.

Participant-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. Counselors should provide and explain test results in a private setting per site SOPs. Counselors should assess participant understanding of results and provide clarification and further information as necessary. Regardless of status, continued risk-reduction should be emphasized.

HIV and STI risk reduction counseling is required per protocol at Screening, Enrollment, and Visit 6. The site is required to develop and follow SOP(s) for HIV pre- and post-test counseling as well as HIV risk reduction counseling. Participant-centered approaches should be used when assessing participant risk for HIV and STI 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/her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Supported and facilitated by the counselor, the risk reduction plans identified by the participant should reflect and respond to his/her current risk assessment and should be practical, yet challenge the participant toward further risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need to be incremental. For participants whose risk reduction barriers change over time (e.g., due to a partner change), risk reduction plans may need to change over time. Importantly, all risk reduction plans should be agreed upon by the participant and should be documented in the participant's study records, with a copy made available to the participant if he/she wishes.

At each counseling session, the risk factors and risk reduction plans identified at the previous sessions should be reviewed and discussed with the participant to determine:

- What was the participant's experience since the last session?
- Was the participant able to carry out strategies and plans?
- What were the outcomes?

Risk reduction plans identified and agreed upon with the participant at the current session should then build on experience since the last session:

- Successful strategies should be continued
- Additional strategies may be identified to achieve further risk reduction
- Alternative strategies may be identified if strategies tried since the last session were not successful

Risk reduction counseling sessions should also offer skills building to the participant when indicated, e.g., on how to use condoms, how to discuss sensitive issues with partners and other influential persons. HIV/STI risk reduction counseling for partners should always be offered, either as an individual session or as a couple's session.

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 s/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 and/or on applicable counseling worksheets.

A sample HIV Pre/Post Test and Risk Reduction Counseling Worksheet is posted on the MTN-033 webpage (http://www.mtnstopshiv.org/node/7332). This worksheet provides a guide to the minimum requirements for HIV testing and counseling sessions and may be tailored for use. It also incorporates a structure that counselors may find helpful for documenting current risk factors and barriers, experiences with risk reduction since the last session, and risk reduction plans until the next session.

Table 10-1 Interpretation of HIV Test Results Per Protocol Appendix II	
Sample 1 Immunoassay negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Sample 1 Immunoassay 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. No additional blood collection is needed for this testing. Provide estimated turnaround time for results.
Sample 1 Confirmatory Test positive	**If Screening or Enrollment Visit**: HIV-infected; test results indicate that you are infected with HIV. You are not eligible for enrollment in this study. Provide counselling and referrals for HIV positive participants per site SOPs. **If during study follow-up**: HIV-infected; test results indicate that you are infected with HIV. Additional testing may be needed for study purposes and to see how your body is responding to the virus. This additional testing will be done from a new blood sample. It is common for HIV research studies to do additional testing in this situation, and unusual for this testing to show a different result. Provide counseling and estimated turnaround time for results.
Sample 1 Confirmatory Test 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. Consult the LC for specific testing and counseling guidance.
Sample 2 Confirmatory Test positive	HIV-infected. Test results have confirmed that you are HIV infected. Provide counselling and referrals for HIV positive participants per site SOPs. Counsel participant that regular study visits will discontinue at this time.
Sample 2 Confirmatory Test 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. Consult the LC for specific testing and counseling guidance.

10.2 Product Use Instructions

Participants will be provided product/device use instructions counseling at Visits 3 and 5. In addition to verbal instructions, visual aids such as sample applicators or coital simulation device, could be used as needed when providing instructions to help ensure participant understanding of proper use. Adequate time should be taken to thoroughly explain the use instructions and answer any questions the participant may have. Any questions or concerns raised by the participant should be documented in his/her study records so this information is easily available for reference at follow-up visits. Use instructions are available on the MTN-033 Study Implementation Materials webpage.

10.3 Protocol Adherence Counseling

Protocol adherence counseling is required at each scheduled study visits. As safety is of the utmost importance, site staff will counsel participants to refrain from using prohibited medications and engaging in certain practices during the course of study participation.

10.3.1 Prohibited Medications Counseling

Per protocol, participants should be counseled to refrain from using the following for the entire duration of study participation:

- Anticoagulants
- Aspirin (greater than 81mg/day)
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Other drugs associated with increased likelihood of bleeding
- Perianally applied topical steroids and other rectally-administered medications, including products containing N-9
- CYP3A inducer(s) and/or inhibitor(s)* (as specified in SSP Section 6)
- Hormone-replacement therapy in tablet, patch, injectable, or gel form*

**Use of these medications will result in permanent discontinuation of study product.*

At the discretion of the IoR/designee, a participant may be permanently discontinued for reported use of the following prohibited medications:

- Anticoagulant medications
- Aspirin (greater than 81 mg/day)
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Drugs that are associated with increased risk of bleeding

Should a participant report taking any of the medications noted above or perianally applied topical steroids and other rectally-administered medications including products containing N-9 within 72 hours prior to a PK sample collection, the visit should be rescheduled if within the visit window. If it is determined that rescheduling the visit within the window is not possible, the visit may proceed at IoR discretion after proper participant counseling has occurred. If desired, the IoR may request rapid PSRT consultation to assist in making the determination as to whether or not to proceed with the visit at that time or to reschedule as an interim visit. If the decision is made to reschedule as an interim visit, any missed procedures (including biopsy collection) should be performed during the interim visit.

10.3.2 Prohibited Practices Counseling

Participants should be counseled abstain from inserting any non-study products into the rectum for 72 hours prior to and following clinic visits. Participants should also be counseled to abstain from the following for 72 hours before and after biopsy collection: receptive anal intercourse (RAI), receptive oral anogenital stimulation (i.e. rimming), rectal stimulation via fingers, as well as the insertion of any non-study products into the rectum. Should a participant report such practices within 72 hours prior to dispensation of product and a PK sample collection, dispensation of product and biopsy collection will be performed at IoR discretion. Participants should be counseled that engaging in these practices or using any of the above products while in the study may make the gel work differently. These products and practices could irritate the rectum and increase the risk of side effects.

10.4 Rectal Biopsies and Fluid Collection Counseling

Participants will undergo collection of rectal biopsies and fluid for PK, PD, biomarker and mucosal safety analysis. At visits in which samples are collected, study staff will explain what procedures will be performed at the visit and what to expect.

Participants will be counseled that a rectal biopsy is a procedure to remove a small piece of rectal tissue (about the size of a grain of rice) for examination. Inform the participant that approximately 7-10 biopsies will be collected. In addition, participants will be informed that in preparation for this procedure they will receive an enema in order to empty their bowels completely. This will allow the clinician a clear view of the rectum. After the enema, a lubricated flexible sigmoidoscope is placed into the rectum. Site staff should explain to participants what a flexible sigmoidoscope is and its purpose. A picture of the flexible sigmoidoscope is recommended during counseling for reference. Participants should be counseled that they may experience some cramping or mild discomfort during the procedure, and they may feel an urge to have a bowel movement as this sensation occurs as the instrument is placed into the rectum.