Section 6. Counseling Considerations

6. Introduction

This section contains guidance on the following types of counseling provided in MTN-039:

- HIV Pre-/Post-Test Counseling
- HIV/STI Risk Reduction Counseling
- Contraceptive Counseling
- Study Product Counseling
- Protocol Adherence Counseling
- Biopsy Procedural Counseling
- Rectal Biopsy/Fluid Procedural Counseling

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. Because of this, specific content to cover, or skills to emphasize, are not standardized. Rather, the process for these discussions is to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time. To support continuity in the ongoing client-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform subsequent counseling sessions. Sites are encouraged to use flags or alert notes in participant study charts to highlight issues requiring follow-up at subsequent visits.

All counseling and referrals should be documented in participant study records per site SOPs. Proper documentation may be achieved through use of counseling worksheets, and/or chart notes.

Sample counseling worksheets are available on the MTN-039 webpage.

6.1 HIV Pre- /Post-Test Counseling

HIV testing is required at Screening, Enrollment and Visit 10. HIV pre-test and post-test counseling is required at each visit at which HIV testing is performed. The sample HIV/STI Risk Reduction Counseling Worksheet available on the MTN website provides a guide to the minimum requirements for HIV and risk reduction counseling sessions; this worksheet may be tailored for use at all study sites.

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide 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 II.

Information on interpretation of screening, enrollment, and follow-up test results is provided in Table 6-1 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.

Table 6-1
Interpretation of HIV Test Results Per Protocol Appendix II

	Test Result	Interpretation
HIV Immunoassay	negative	HIV-uninfected; test results indicate that you are not infected with HIV.
	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 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, but additional counseling and referrals for care are available [provide per site SOPs] *If Follow-up Visit:* HIV-infected; test results indicate that you are infected with HIV, however additional testing is needed for study purposes.
	negative or indeterminate	HIV status not clear; additional testing is needed to determine your status.
Sample 2 Confirmatory Test	positive	HIV-infected; test results have confirmed that you are HIV infected. You will be exited from the study at this time, but additional counseling and referrals for care are available [provide per site SOPs]
	negative or indeterminate (the participant may have already been given positive clinical lab results)	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

6.2 HIV/STI Risk Reduction Counseling

Risk reduction counseling is required per protocol at Screening, Enrollment and all other visits as indicated. Sites are 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 their 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 their 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.

The sample HIV/STI Risk Reduction Counseling Worksheet posted on the MTN-039 website (http://www.mtnstopshiv.org) 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.

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.

6.3 Contraceptive Counseling

Contraceptive counseling for female participants is required at all study visits from Screening through Visit 10, as needed. When performed at the Screening and Enrollment visits, contraceptive counseling should be provided in the context of assessing study eligibility criteria. Per MTN-039 inclusion criteria, a potential participant must be using an effective method of contraception at enrollment and agree to use an effective method of contraception throughout the duration of study participation. Counseling provided at these visits should explain which methods are acceptable for study purposes and emphasize that if the participant cannot commit to using one of these methods during study follow-up, the participant should not enroll in the study.

Effective methods include:

- hormonal methods (except contraceptive ring)
- Intrauterine device (IUD) inserted at least 30 days prior to Enrollment (but not past the maximum length of recommended usage according to package instructions)
- Sterilization (of participant or partner, as defined in SOPs)
- Sexually abstinent as defined by abstaining from penile-vaginal intercourse for 90 days prior to Enrollment and intending to remain abstinent for the duration of study

participation; this includes having sex exclusively with individuals assigned female sex at birth

During follow-up visits, client-centered counseling should continue, but may be abbreviated. 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 the current contraceptive method being used.

Some participants may wish to discontinue use of a contraceptive method during follow-up. In these cases, counselors should explore the participant's reasons for this and determine if other options would be acceptable to her. If no other options are acceptable, the participant may remain in the study, and continue using study product, even if the participant discontinues contraceptive use. However, the possibility of resuming contraceptive use should be re-visited at each subsequent visit to determine whether the participant's circumstances may have changed.

Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-039 protocol specifications related to contraception. Contraception may be provided on-site, however sites may opt to refer participants to non-study providers for contraception. All sites are strongly encouraged to obtain credible medical records as part of their verification procedures for participant reported contraceptive methods. Starting at enrollment, staff should monitor when a new contraceptive prescription i.e. new pill prescription, Depo injection, IUD, is needed and should actively review this information at every follow-up visit to ensure that adequate contraceptive coverage is available for the duration of study participation. Expiration/replacement of a currently prescribed contraceptive can be documented on the counseling worksheet, in chart notes, or other site-specific form.

All contraceptive counseling sessions should be fully documented in participant study records. For each session, sufficient information and detail should be recorded to support review and appropriate follow-up at each subsequent visit. Staff members providing the contraceptive counseling can document details of each session on the Protocol Counseling Worksheet, a site-specific counseling worksheet, or in chart notes.

6.4 Product Use Counseling

As administration of the rectal inserts will be done in-clinic by site staff, participants will be provided verbally with an explanation of product use/administration, as well as provided a copy of the *MTN-039 Rectal Insert Guide*, which provides on overview of the study product administration procedures, to follow along while in the clinic. Site staff should explain each step. Staff should take as much time as needed to ensure the participant is comfortable and that all questions or concerns have been addressed prior to and after insertion. This discussion should be done in conjunction with each study product dose administration (Visits 3 and 7) and documented on the Protocol Counseling Worksheet or in chart notes.

6.5 Protocol Adherence Counseling

Protocol adherence counseling is required at Screening, Enrollment and Visits 3- 10. As safety is of the utmost importance, site staff will counsel participants to refrain from using prohibited medications and engaging in certain practices during study participation.

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

- Rectally-administered medications and products, including any containing N-9
- Anticoagulants or blood thinners**
- Strong/moderate CYP3A inducers/inhibitors**
- NSAIDs (nonsteroidal anti-inflammatory drugs) *
- Aspirin (over 81 mg per day) *

- PrEP (approved or other investigational oral Truvada) **
- PEP **

** Within 72 hours **prior to** and **following** a tissue sample collection visit*
Reported use of these medications will result in permanent discontinuation of study product and termination from the study.

Participants should also be counseled to refrain from engaging in the following **72 hours (3 days) prior to and following each clinic visit**:

- Receptive anal intercourse (RAI)
- Receptive oral intercourse
- Receptive anal or genital stimulation
- Insertion of any non-study products or objects into the rectum, including:
  - Fingers
  - Rectal medications
  - Enemas
  - Lubricants
  - Sex toys (such as dildos, anal plugs, etc.)

Female participants are also asked to abstain from the above as well as the following activities **72 hours (3 days) prior to clinic visits**:

- Receptive vaginal intercourse
- Insertion of any non-study products or objects into the vagina, including:
  - Fingers
  - Spermicides
  - Vaginal medications (including hormones)
  - Vaginal douches
  - Lubricants or vaginal moisturizers
  - Sex toys (such as vibrators, dildos, etc.)

Note: Participants should also be asked to refrain from using tampons 24 hours prior to clinic visits.

Participants should be counseled that engaging in these practices or using any of the above products while in the study may make the insert work differently. These products and practices could irritate the rectum or vagina and increase the risk of side effects.

If a participant reports use of aspirin (greater than 81 mg) and other non-steroidal anti-inflammatory drugs (NSAIDS) or any other drugs associated with increased bleeding prior to biopsy collection, samples may still be collected per IoR discretion. Participants should be counseled regarding potential risks of biopsy collection and documentation of this counseling and added risk should be included in the participant binder.

Each counseling session should be fully documented in chart notes and/or using the Protocol Counseling Worksheet.

6.6 Biopsy Procedural Counseling

Participants will undergo collection of rectal biopsies and fluid for PK, PD, and biomarker 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. Approximately 15-22 biopsies will be collected at any

given time point. Participants will be informed that they will perform an at-home enema prior to their dosing visits (Visits 3 and 7). At enrollment (all participants), on the day of dosing (all participants), and during the 48-hour post-dose for Group 1 and the 72-hours post-dose for Group 2 (when assigned to have rectal tissues samples collected), they will have a rectal enema performed in the clinic prior to each rectal biopsy procedure and sigmoidoscopy. This will serve to empty the bowels completely and allow the clinician a clear view of the rectum. Then 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.