

Section 11. Counseling Procedures

Section 11. Counseling Procedures	1
11.1 HIV pre- and post-test Counseling, and HIV/STI Risk Reduction Counseling	1
11.2 Protocol Counseling	2
11.2.1 Product Use Counseling	2
11.2.1 Contraceptive Counseling.....	3
11.2.3 Protocol Adherence Counseling	3

This section contains guidance on the following types of counseling provided in MTN-037: HIV pre- and post-test counseling, HIV/STI risk reduction counseling, and protocol counseling (inclusive of protocol adherence, product use, and contraceptive 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-037 webpage.

11.1 HIV pre- and post-test Counseling, and HIV/STI Risk Reduction Counseling

HIV pre- and post-test and HIV/STI risk reduction counseling are required at visits when HIV testing is conducted. HIV testing is required at Screening, Enrollment, and Visit 8, and if clinically indicated at the final contact (Visit 9). Referrals should be provided when indicated. Sites are required to develop and follow SOPs for HIV testing and counseling considerations.

All HIV counseling should be provided in accordance with local counseling standards and 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. Further information on interpretation of screening and follow-up test results is provided in Table 11-1 below. This informational resource should be referenced as needed when providing pre-test and post-counseling.

Client-centered approaches should be used to assess participant knowledge of relevant information, dispel misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results. Information should be provided in a manner that is respectful and interactive. Participants should be informed of when their test results will be available. 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.

As a component of HIV counseling, participant-centered approaches should be used when assessing participant risk for HIV/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 reported risk factors and barriers. Risk reduction counseling should also offer skills-building to the participant when indicated, e.g., how to discuss sensitive issues with partners and other influential persons.

	Test Result	Interpretation
HIV Immunoassay	negative	<u>HIV-uninfected</u> ; test results indicate that you are not infected with HIV.
	positive or indeterminate	<u>HIV status not clear</u> ; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.
Sample 1 Confirmatory Test	positive	<i>If Screening or Enrollment Visit:</i> <u>HIV-infected</u> ; 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] <i>If Follow-up Visit:</i> <u>HIV-infected</u> ; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes.
	negative or indeterminate	<u>HIV status not clear</u> ; additional testing is needed to determine your status.
Sample 2 Confirmatory Test	positive	<u>HIV-infected</u> . Test results have confirmed that you are HIV infected. Regular study visits will discontinue 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)	<u>HIV status not clear</u> ; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

A sample HIV Pre- and Post-Test and STI Risk Reduction counseling worksheet is available for use on the MTN-037 webpage under Study Implementation Materials. This worksheet provides a guide to the minimum requirements for HIV testing and counseling sessions; this worksheet may be tailored for use at each study site.

11.2 Protocol Counseling

Protocol counseling for MTN-037 includes three components:

- Product Use Counseling
- Contraceptive Counseling (for female participants)
- Protocol Adherence Counseling

A sample Protocol Counseling Worksheet that can be used to guide and document each component of protocol counseling is available on the MTN-037 webpage under Study Implementation Materials. Sites may use this worksheet as-is or tailor it for use. If preferable, sites may choose to use a site-specific counseling worksheet.

11.2.1 Product Use Counseling

Given administration of study product use will be done in-clinic by site staff, participants will be provided verbally with an explanation of product use/administration. Site staff should explain each step (beginning with replacement of the cap of the Luer-Lok™ syringe with the rectal tip, to rectal insertion, and application). Staff should take as much time as needed to ensure the participant is comfortable and 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, 5, and 7) and documented on the Protocol Counseling Worksheet or in chart notes.

11.2.1 Contraceptive Counseling

Contraceptive counseling for female participants is required at all study visits from Screening through Visit 8a, and if indicated at the final contact (Visit 9). When performed at the screening and enrollment visits, contraceptive counseling should be provided in the context of assessing study eligibility criteria. Per MTN-037 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, she should not enroll in the study.

Effective methods include:

- hormonal methods (except contraceptive ring)
- Intrauterine device (IUD) inserted at least 42 days prior to Enrollment (but not past the maximum length of recommended usage according to package instructions)
- Sterilization of participant or partner at least 42 days prior to Enrollment
- Self-identifies as having sex with women exclusively

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 her current contraceptive method.

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 she 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-037 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.

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.

11.2.3 Protocol Adherence Counseling

Protocol Adherence counseling is required at all study visits from Enrollment through Visit 8a, and if indicated at the final contact (Visit 9). During follow-up, protocol adherence counseling can be abbreviated based on each individual participant's needs.

The MTN-037 Study Adherence Guidelines document has been created to help guide study staff through the required elements of this counseling. This resource should be referenced during the counseling session and participants should be offered a copy to take home (note that although protocol adherence counseling is not required at screening, sites should consider providing a copy of the Study Adherence Guidelines during or after the informed consent session). During protocol adherence counseling, study staff should begin with a review of the study visit schedule and any retention challenges the participant may be facing. As safety is of the utmost importance, site staff will also counsel participants to refrain from engaging in certain practices and/or using prohibited medications at certain points throughout study participation, as outlined on the Study Adherence Guidelines document. Engaging in these prohibited practices or taking any

of the prohibited medications could potentially increase the possibility of adverse events or compromise the results of the study.

At enrollment, if a participant shares that s/he has engaged in any of the practices or used any of the products or medications that are prohibited during the 72 hours prior to enrollment, the visit should be rescheduled and the counselor should review the protocol requirements with him/her. During follow-up, if any prohibited practices or medications are reported by the participant, document them in counseling notes and on the appropriate CRFs. Note that protocol deviation reporting may be a required component of this documentation. Counseling should include a review of the protocol requirements and a conversation with the participant about a plan moving forward (e.g. is it possible for him/her to avoid the behavior, product, or medication in the future? What would help? What are challenges?).

The Protocol Counseling Worksheet provides a guide to the minimum requirements for protocol adherence counseling sessions and provides a place for documenting these sessions. Alternatively, the session can be documented in chart notes.