

## Section 10. Counseling Procedures

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This section contains guidance on the following types of counseling provided in MTN-030/IPM 041: HIV counseling, HIV/ STI risk reduction counseling, protocol adherence counseling, and ring use instructions.

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 the use of counseling worksheets, and/or chart notes.

Sample counseling worksheets are available on the MTN-030/IPM 041 webpage (<http://www.mtnstopshiv.org/node/7331>).

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

HIV testing is required at Screening, Enrollment, and Day 14 visits. HIV testing is performed when clinically indicated at all other visits. HIV pre-test and post-test counseling are required at visits when HIV testing is required or when performed if clinically indicated. 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 10-1 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 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.

**Table 10-1**  
**Interpretation of HIV Test Results Per Protocol Appendix II**

| <b>Test Result</b>                                   | <b>Interpretation</b>  |
|--|--|
| HIV Immunoassay negative                             | HIV-uninfected; test results indicate that you are not infected with HIV.  |
| HIV 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.   |
| Sample 1 Confirmatory Test positive                  | If Screening or Enrollment Visit: HIV-infected; test results indicate that you are infected with HIV.<br>If Follow-up Visit: HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes. |
| Sample 1 Confirmatory Test 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.   |
| 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.   |

A sample HIV counseling worksheet is available for use on the MTN-030/IPM 041 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.

## 10.2 Protocol Adherence Counseling

As safety is of the utmost importance, site staff will counsel participants to refrain from engaging in certain practices and/or using prohibited medications during the course of study participation which could potentially increase the possibility of adverse events due to agents other than the study vaginal ring.

Protocol adherence counseling is required at Enrollment, Days 7, 14, and if indicated at other visits. Per protocol sections 6.6 and 6.7, participants should be counseled accordingly:

- Several concomitant medications/practices will not be permitted. Use of antibiotic and corticosteroids are prohibited during study participation as there are potential drug-drug interactions between LNG and antibiotics and corticosteroids. Use of CYP3A inhibitors and inducers (as listed in Section 6 of this Manual) is also prohibited. These medications are not recommended because LNG and dapivirine are CYP3A substrates.
  - Note: It is important to note that single dose oral fluconazole for the treatment of vaginal fungal infections is permitted.
- Refrain from inserting non-study vaginal products or objects into the vagina, including spermicides, lubricants, contraceptive vaginal rings, douches, vaginal medications, tampons, sex toys, female condoms, diaphragms, menstrual cups, cervical caps, or other vaginal barrier method, for **24 hours prior to the Enrollment Visit and for the duration of study participation.**
- Refrain from receptive sexual activity, including penile-vaginal intercourse, anal intercourse, receptive oral intercourse, finger stimulation, for **24 hours prior to the Enrollment Visit and for the duration of study participation.**

If a participant reports a prohibited practice as listed in protocol section 6.6 or 6.7, the participant should be counseled regarding the use of alternative methods. Counseling and discussion of any issues related to protocol adherence may be documented on the

Protocol Adherence Worksheet, located on the MTN-030/IPM 041 webpage under Study Implementation Materials or other site-specific worksheet.

### 10.3 Ring Use Instructions

Participants will be provided ring use instructions at the Enrollment visit, and at other visits as needed. At enrollment, study participants will be given detailed instructions in the clinic on proper vaginal ring insertion and removal procedures. At follow up visits, these instructions should be referenced as well as exploring the participant's experience with ring use thus far.

In addition to verbal instructions, a copy of the illustrated instructions should be provided to each participant. Vaginal ring insertion instructions are available on the MTN-030/IPM 041 webpage under Study Implementation Materials. Other visual aids, such as sample vaginal rings 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 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. Site staff should help ensure participant understanding and comfort with vaginal ring use.

While reviewing instructions for inserting the ring, it is important to also discuss instructions for ring removal. The participant should be reminded that she should not remove the ring during her two-week use; however, if ring removal is needed, the below procedures should be followed:

- Before removing the ring, wash and dry your hands.
- Choose a comfortable position (can reference ring insertion instructions for illustrations of different positions).
- Put a finger into your vagina and hook it through the ring.
- Gently pull down and forward to remove the ring.
- If you will be reinserting the ring, follow the ring insertion instructions, and wash your hands when you are done.
- If you will not be reinserting the ring, place the used ring in the bag provided by clinic staff or other suitable container if the bag is not available. The participant should contact the study clinic to inform staff the ring was expelled and to receive additional guidance.
- Store the ring a safe and private area out of reach of children or other occupants of the home.
- Wash your hands.
- Bring used ring with you to the clinic during your next study visit.

After providing product insertion and removal instructions and answering any questions the participant may have, the participant will insert the vaginal ring. She may want to practice removing and inserting the ring herself as well. If she chooses to do so, removal and insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance.

After the vaginal ring is inserted, study staff should de-brief with the participant on her experience. Any issues or problems raised by the participant should be addressed by the study staff and documented in chart notes. Clinicians will check for proper ring placement. Instructions to clinicians can be found in SSP Section 7.