

Section 10. Counseling Procedures

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This section contains guidance on the following types of counseling provided in MTN-029/IPM 039: HIV counseling, breast milk production maintenance, ring use adherence counseling, and protocol adherence 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 the use of counseling worksheets, and/or chart notes.

Sample counseling worksheets are available on the MTN-029/IPM 039 website.

10.1 HIV Counseling

HIV testing is required at Screening. It is also required at Enrollment if more than 30 days have passed since the screening visit. 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**

Test Result	Interpretation
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. If Final 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-029/IPM 039 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 Breast Milk Counseling

10.2.1 Breast Milk Production Maintenance Counseling

Breast milk production maintenance counseling is performed at screening, if indicated. The MTN-029/IPM 039 screening to enrollment window is up to 56 days, so counseling on breast milk production maintenance may be important for participants to ensure adequate breast milk production at enrollment, and throughout study duration. All breast milk production maintenance counseling should be provided in accordance with local counseling standards.

If needed, a breast pump will be provided to participants at the Enrollment Visit once they enroll in the study. However, as part of breast milk production maintenance counseling at the screening visit, it will be important to review the use of a breast pump and determine if the participant has any concerns or difficulties in its use. Participants will be encouraged to continue breastfeeding their infants, if applicable, use their own breast pump device, or manually express milk during the screening period to maintain an adequate supply. Participants will provide breast milk samples at both screening and enrollment to ensure supply is adequate for study participation. Participants must be able to express at least one ounce of breastmilk to be considered eligible.

Breast milk production maintenance counseling, and any concerns or questions the participant may have, should be documented on a counseling worksheet or in chart

notes. A sample counseling worksheet is available for use on the MTN-029/IPM 039 webpage under Study Implementation Materials.

10.2.2 Breast Milk Collection and Storage Counseling

Counseling on breast milk at-home collection and storage will be conducted at the Enrollment visit, Day 1, Day 7, and if indicated at Day 14. If needed, a breast pump will be provided to participants at the Enrollment Visit. Additional supplies to be provided to participants for at home milk collection are listed in Section 5.4.1 of this manual. Participants will be instructed to express milk a minimum of twice a day for 5 days, during the first week of at-home collection, and a minimum of twice a day for 6 days during the second week of at-home collection. As per Clarification Memo #01, participants will be providing a breastmilk sample in the clinic at study visit Days 1, 7, and 14; however they should also collect one additional sample at home on these days to ensure a minimum collection of 2 samples per day. Participants will also be instructed to express milk a minimum of twice a day on Day 15 (between the Day 14 and Day 16 visits). Note: if the participant is only able to complete her final visit on Day 17 or Day 18, she should continue to collect 2 samples each day until her visit date.

When collecting the samples, there is no time requirement between sample collection, however participants should be instructed to allow for a sufficient amount of time between pumping sessions to ensure an adequate amount of milk supply. If participants express milk more than twice per day, they should discard the remaining milk.

Site staff will review the following instructions at required visits:

1. Express milk from one or both breasts until the milk stops flowing. Use a clean container to collect the sample.
2. GENTLY swirl the container(s) of breast milk. DO NOT SHAKE. If milk was expressed from both breasts, combine into one container and gently swirl once more.
3. Using the provided dropper, place approximately 2 mLs of breast milk into 2 of the small tubes provided. And leftover breastmilk should be discarded.
4. Write the COLLECTION DATE and COLLECTION TIME on the provided labels. Also record the date and time on the breastmilk collection log.
5. Place one label on each of the tubes.
6. Immediately place labeled tubes in your freezer, away from the door or sides.
7. After the first week, you should have a total of 20 small tubes in your freezer. After the second week, you should have a total of 24 small tubes in your freezer. And in between the last two study visits, you should have 4 small tubes in your freezer (unless your visit is postponed for any reason, in which case you should have 8 small tubes per day of at home collection). Bring all tubes with you to your next study visit using the cooler and ice packs provided to you.

Provision of the breast milk collection and storage instructions may be documented on the sample counseling worksheet available on the MTN-029/IPM 039 webpage under Study Implementation Materials. Any concerns or questions the participant may have should be documented in chart notes or on the counseling worksheet itself.

10.3 Ring Use Adherence Counseling

Participants will be provided ring use instructions and adherence counseling for the first time at the Enrollment visit. Ring use adherence counseling will also be provided at the Day 1 and Day 7 visits. 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-029/IPM

039 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.

A Ring Use Counseling worksheet is available for use on the MTN-029/IPM 039 Study Implementation Materials webpage. This worksheet provides a guide to the minimum requirements for product use counseling sessions; this worksheet may be tailored for use. Discussion points and participant questions should also be noted on the worksheet and/or in chart notes.

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, rinse the ring and place the used ring in the bag provided by clinic staff or other suitable container if the bag is not available. 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, study staff will insert the vaginal ring in the participant. The participant 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. The clinician must do the final insertion of the ring after the participant has practiced.

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 on the ring use adherence worksheet and/or in chart notes. Clinicians will check for proper ring placement. Instructions to clinicians can be found in SSP Section 7.

10.4 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 1, 7, and if indicated, day 14 visits. Per protocol section 6.6, participants should be counseled to avoid the following practices:

- Refrain from using non-study provided or approved vaginal products or objects during study participation, including spermicides, lubricants, contraceptive vaginal rings, douches, vaginal medications, etc.
- Refrain from inserting non-study vaginal objects into the vagina, including tampons, sex toys, female condoms, diaphragms, menstrual cups, cervical caps, or other vaginal barrier method, for 24 hours prior to each scheduled visit.
- Refrain from receptive sexual activity, including penile-vaginal intercourse, anal intercourse, receptive oral intercourse, finger stimulation, for 24 hours prior to each scheduled visit.

Should the participant report that she has engaged in any of the above, this should be documented on the Vaginal Practices and Sexual Practices Assessment CRFs.

If a participant reports a prohibited practice as listed in protocol section 6.6, 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-029/IPM 039 webpage under Study Implementation Materials or other site-specific worksheet.

10.5 Contraception Counseling

Contraception counseling is only performed if indicated throughout study duration. If contraception counseling is done, all counseling should be provided in accordance with local counseling standards.

If performed at screening and enrollment visits, contraception counseling should be provided in the context of assessing study eligibility criteria. Per MTN-029/IPM 039 inclusion criteria, a potential participant must agree to use an effective method of contraception at enrollment and throughout the duration of her participation. Counseling provided at these visits should explain which methods are acceptable for study purposes and emphasize that if she 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 for the contraceptive ring
- IUD inserted at least 28 days prior to enrollment
- Engages in sex exclusively with women
- Sterilization (of participant or partner)
- Sexually abstinent for the past 90 days

During follow-up visits, client-centered counseling should continue if needed. 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 contraception counseling should be trained to do so per local practice standards and should also be trained on MTN-029-IPM 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.

All contraception 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. Detailed counselors notes or counseling worksheets should be used to document counseling sessions.