MTN-036
Counseling Considerations

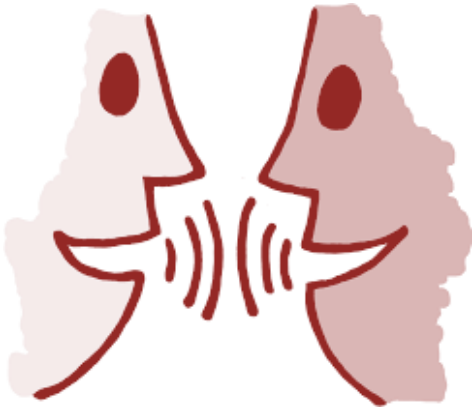
Study-Specific Training | 11 Sept 2017

Overview

- HIV Pre/Post Test
- HIV and STI Risk Reduction
- Contraceptive
- Product Use Instructions
- Protocol Adherence
- Additional Counseling Materials

Counseling Techniques

- Utilize Participant-Centered Approaches
- Non-judgmental
- Collaborative partnership
- Respectful of the participants' ability to choose
- Encompasses more listening and eliciting than telling
- Tailored to participants' needs which change over time



HIV Pre- and Post-Test and Risk Reduction Counseling

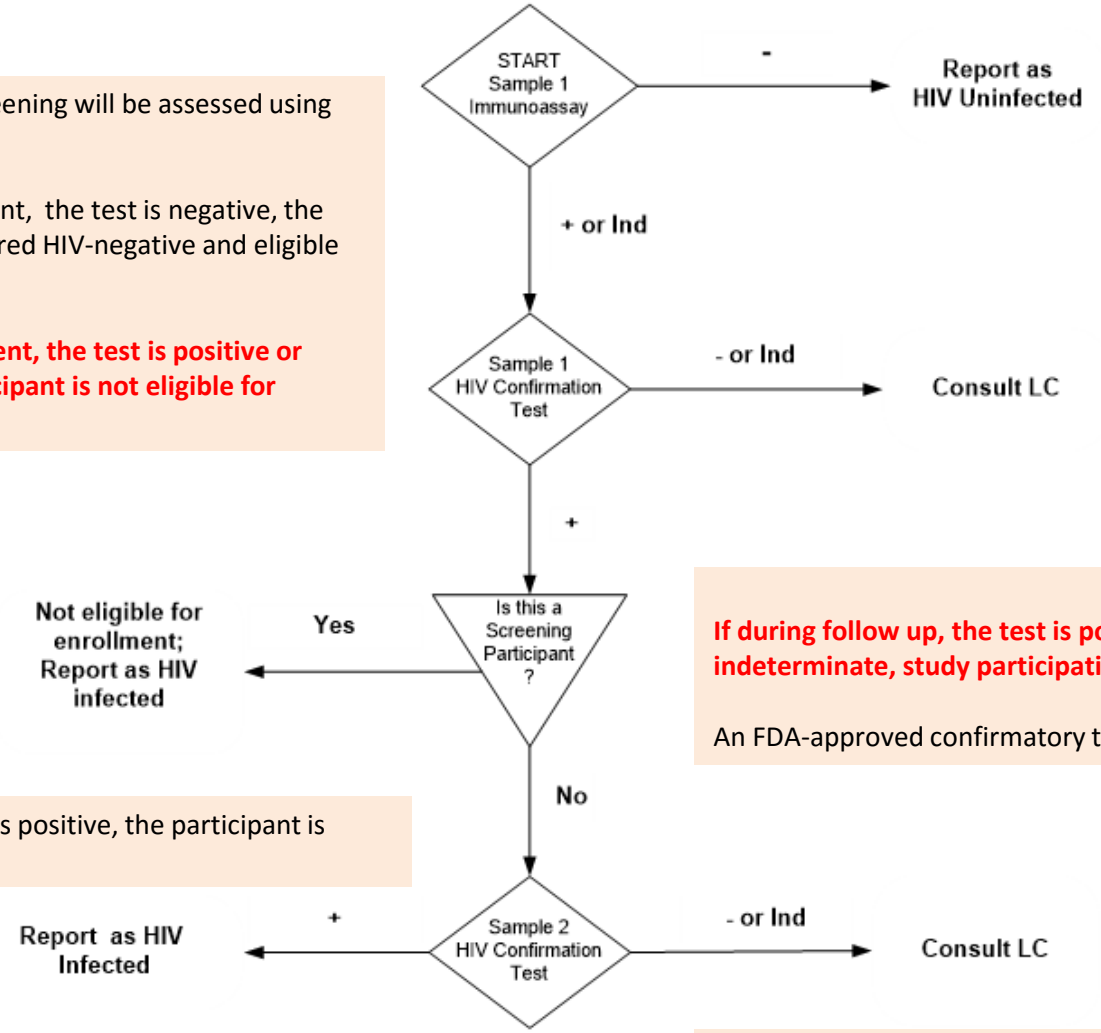
- HIV testing is required at :
  - Screening
  - Enrollment
  - Visit 10/ PUEV
  - All other visits, if clinically indicated
- HIV pre-test and post-test is provided in conjunction with HIV testing
- HIV/STI risk reduction counseling required at same visits

APPENDIX II: ALGORITHM FOR HIV TESTING FOR SCREENING AND ENROLLED PARTICIPANTS

HIV infection status at screening will be assessed using an FDA-approved HIV test

If at Screening or Enrollment, the test is negative, the participant will be considered HIV-negative and eligible enrollment.

If at Screening or Enrollment, the test is positive or indeterminate , this participant is not eligible for enrollment.



If during follow up, the test is positive or indeterminate, study participation will be discontinued.

An FDA-approved confirmatory test must be performed.

If the confirmatory test is positive, the participant is considered HIV-positive.

If the confirmatory test is negative or indeterminate, contact the LC for guidance. Additional testing is required.

Ind: Indeterminate test results
LC: Laboratory Center

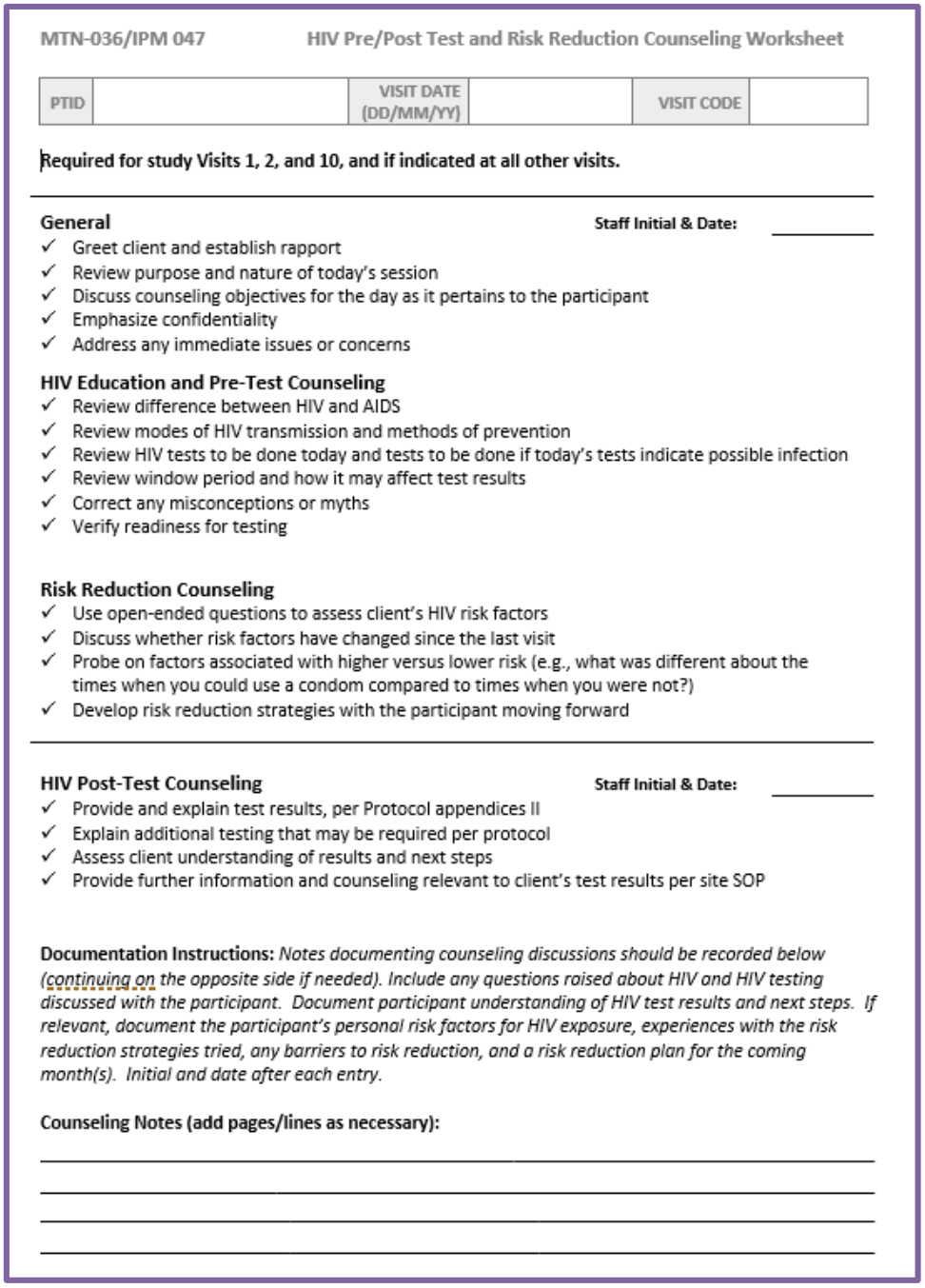
In the event of an HIV positive result…

- Refer participants to local care and treatment services
- Provide additional counseling and other support services, as needed
- Discontinue screening attempt, or follow-up visits, and terminate participant from the study
- Offer additional laboratory testing (HIV RNA and HIV drug resistance testing) at the discretion of IoR and MTN LC

STI/HIV Risk Reduction Counseling

- Assess knowledge of relevant information
- Ensure readiness for HIV testing and understanding of test results
- Dispel any misconceptions
- Re-emphasize confidentiality
- Emphasize risk-reduction (identification of risk factors/barriers to risk reduction and strategies/action plans to try to address)
- Offer skills building (e.g. how to use condoms, discuss sensitive issues with partners/others)

- Worksheet provides an overview of the minimum requirements expected for each HIV testing and risk reduction counseling session
- Assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, ensure participant understanding of test results
- Guides the participant in identifying risk factors, barriers to risk reduction and developing strategies and action plans to reduce/eliminate risk



MTN-036/IPM 047 HIV Pre/Post Test and Risk Reduction Counseling Worksheet

PTID		VISIT DATE (DD/MM/YY)		VISIT CODE	

Required for study Visits 1, 2, and 10, and if indicated at all other visits.

General **Staff Initial & Date:** _____

- ✓ Greet client and establish rapport
- ✓ Review purpose and nature of today's session
- ✓ Discuss counseling objectives for the day as it pertains to the participant
- ✓ Emphasize confidentiality
- ✓ Address any immediate issues or concerns

HIV Education and Pre-Test Counseling

- ✓ Review difference between HIV and AIDS
- ✓ Review modes of HIV transmission and methods of prevention
- ✓ Review HIV tests to be done today and tests to be done if today's tests indicate possible infection
- ✓ Review window period and how it may affect test results
- ✓ Correct any misconceptions or myths
- ✓ Verify readiness for testing

Risk Reduction Counseling

- ✓ Use open-ended questions to assess client's HIV risk factors
- ✓ Discuss whether risk factors have changed since the last visit
- ✓ Probe on factors associated with higher versus lower risk (e.g., what was different about the times when you could use a condom compared to times when you were not?)
- ✓ Develop risk reduction strategies with the participant moving forward

HIV Post-Test Counseling **Staff Initial & Date:** _____

- ✓ Provide and explain test results, per Protocol appendices II
- ✓ Explain additional testing that may be required per protocol
- ✓ Assess client understanding of results and next steps
- ✓ Provide further information and counseling relevant to client's test results per site SOP

Documentation Instructions: *Notes documenting counseling discussions should be recorded below (continuing on the opposite side if needed). Include any questions raised about HIV and HIV testing discussed with the participant. Document participant understanding of HIV test results and next steps. If relevant, document the participant's personal risk factors for HIV exposure, experiences with the risk reduction strategies tried, any barriers to risk reduction, and a risk reduction plan for the coming month(s). Initial and date after each entry.*

Counseling Notes (add pages/lines as necessary):

_____

_____

_____

_____

HIV/STI Risk Reduction Counseling Considerations

- Will you incorporate risk-reduction counseling before or after the test results are given?
- Will the same person conduct pre- and post-test and risk reduction counseling?
- What kinds of questions might you ask to assess participant understanding?
- How will you avoid repetition during follow up counseling sessions?

Contraceptive Counseling

- Required starting at Screening through Visit 10/PUEV
- At screening:
  - Intended to assess eligibility criteria (per participant report)
  - Provide rationale for contraceptive requirement and obtain accurate information about use
  - Confirms pregnancy intentions and willingness to use an effective contraceptive method
  - Discuss which methods are acceptable for study purposes and emphasize that women who cannot commit to using one of these methods for the duration of the study should not enroll

Contraceptive Counseling

- During follow-up:
  - Counseling may be abbreviated
  - Issues discussed at the previous session should be reviewed
  - Determine if the participant has any issues with current method
  - If participant decides to stop contraceptive use, they may remain in the study, and continue using study product

PTID		Visit Code		Staff Initial & Date	

Contraceptive Counseling

At screening, review protocol contraception requirements as well as the participant's current contraceptive method(s) and/or preferences, and any questions she may have.

At enrollment and all follow-up visits, ask the participant if she has any questions or concerns, confirm current contraceptive method(s), and ensure participant has adequate contraceptive coverage until her next visit.

Current contraceptive method: _____

Is this a change from the previous visit?

☐ N/A (Screening visit)

☐ No

☐ Yes. Explain change:

_____

_____

_____

Status of next contraceptive prescription:

☐ N/A

☐ Prescription refill/renewal or injection needed by _____ (Date).

Any contraceptive information/issues/questions/ concerns discussed at this visit?

☐ No

☐ Yes. Describe discussion, indicated counseling provided, and note issues to follow-up at next visit:

_____

_____

_____

_____

_____

_____

In the event of a positive pregnancy test result…

- Participant will be referred to local health care services and may return to the research clinic for additional counseling, as needed
- Follow-up visits will be discontinued and the participant will be terminated from the study
- Optional Procedure:
  - Participants who become pregnant while on study product may be offered enrollment in MTN-016*

Product Use Counseling

- Product use instructions should be reviewed at the Enrollment Visit and all visits through Visit 10/PUEV as needed
- Provide copy of illustrated instructions to each participant in the event the ring is removed/expulsed and the participant needs to reinsert it at home
  - Page 1: VR Use Instructions
  - Page 2: VR Important Information
- For participants who have difficulty inserting the VR, study staff should provide further information and guidance to address the difficulty encountered.
  - After guidance is provided, the participant should try again to insert the VR. If unable, study staff may insert the VR for the participant.

VAGINAL RING INSERTION INSTRUCTIONS

1. 

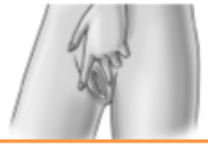
   Wash your hands with soap and dry them on a clean cloth.

2. 

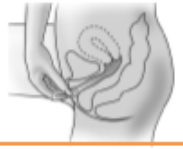
   Get in the position that is most comfortable for you to insert the ring.

3. 

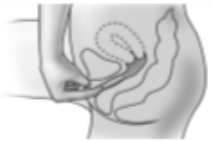
   Hold and press the sides of the ring together. You may find it easier to insert the ring if you twist it into the shape of the number '8'.

4. 

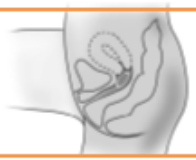
   Use your other hand to hold open the folds of skin around your vagina.

5. 

   Place the tip of the ring in the vaginal opening and then use your finger to push the folded ring gently into your vagina.

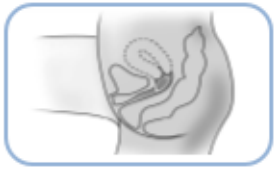
6. 

   Push it up towards your lower back as far as you can. If the ring feels uncomfortable, it is probably not inserted far enough into your vagina. Use your finger to push the ring up as far as you can into your vagina.

7. 

   The ring should now be in your upper vagina. Wash your hands when you are done. If you have trouble, contact the clinic or come in for assistance.

VAGINAL RING IMPORTANT INFORMATION



Leave ring inserted, all day, every day: The ring should be kept inserted at all times, including bathing.

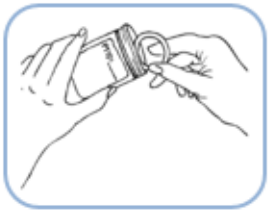
If the ring falls or is taken out:

Somewhere clean: Try to reinsert the ring as soon as possible. If you cannot reinsert it right away, place the ring in the bag provided to you. Before you reinsert, rinse the ring in clean water (no soap permitted) and follow the insertion instructions on the other side.

Somewhere dirty (such as the toilet or the ground): Do NOT reinsert the ring. Instead, place it in the bag provided to you and contact the clinic as soon as possible (do not rinse before putting it in the bag).

Avoid and Abstain: Certain vaginal products, devices, and practices are prohibited during all of study participation or at specific time points before and after clinic visits. See the Study Adherence Guidelines handout for detailed information on this topic.

Do not Share: Insert only the ring assigned to you and do not share your ring with other women.



Storage: If the ring is removed and is not reinserted, place the ring in the bag provided to you and return it to the study clinic at your next visit (do not rinse the ring before putting it in the bag).

Transport: When returning an uninserted ring to the clinic, keep the bag with the ring inside it with you at all times to avoid loss.

Questions or Concerns: The study staff are here to help and support you. Please contact us between visits with any questions or concerns. [site to insert contact information]

Protocol Adherence Counseling

- Required at every scheduled study visit, per protocol; content may be targeted towards participants' need, given frequency of the sessions
- Worksheet provided to guide and document counseling session
- Study Adherence Guideline sheet provided to aid in provision of counseling
  - Given to take home at Enrollment
  - Reviewed/offered at every visit follow-up visit through Visit 10/PUEV
    - Focuses on explaining prohibited medications and practices participants should refrain from engaging in during the course of study participation

PTID		Visit Code		Staff Initial & Date	

Use this worksheet to guide and document protocol adherence counseling, which encompasses protocol adherence, product use, and contraceptive counseling. Contraceptive counseling should begin at the screening visit, and protocol adherence and product use counseling should begin at the enrollment visit.

For all follow-up visits (V2-11), all three components of protocol counseling must be provided and documented, but may be abbreviated and content tailored to participant needs. Staff should review the participant's Protocol Counseling Worksheet from the previous visit to determine the level of counseling needed and issues to revisit.

Protocol Adherence and Product Use Counseling

☐ N/A (Protocol Adherence/Product Use Counseling not required at Screening Visit)

At enrollment, thoroughly review the Study Adherence Guidelines sheet and the Vaginal Ring Insertion Instructions/Important Information sheet with the participant and give her a copy to reference at home.

At enrollment and all follow-up visits, ask the participant if she has any questions and review any medications, non-study products, and practices that the participant should refrain from before the next visit. Offer copies of the Study Adherence Guidelines at each visit.

☐ Study Adherence Guidelines reviewed and discussed
☐ Vaginal Ring Insertion Instructions/Important Information sheet reviewed and discussed

Any protocol adherence issues/questions/concerns discussed at this visit?
☐ None reported
☐ Yes. Describe discussion, indicated counseling provided, and note issues to follow-up at next visit:

_____

_____

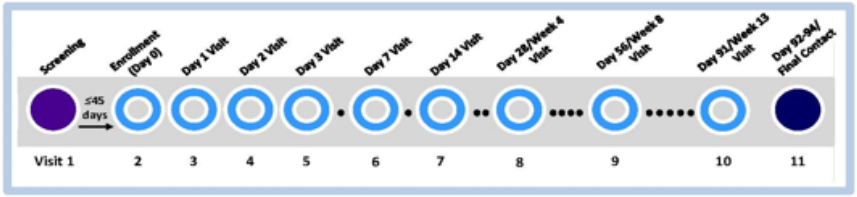
_____

MTN-036 Study Adherence Guidelines

Following all study instructions and requirements is important to ensure your safety as a participant and the validity of the study. Please review this document carefully and keep available for reference at home.

✓ **Attend all Study Visits as Scheduled**

It is important for you to come to every study visit. If you cannot come to the visit, please tell the study staff as soon as possible so that the visit can be rescheduled.



✓ **Use an effective contraceptive method**

You must use an effective contraceptive method for the entire duration of the study. Effective methods include sterilization, hormonal methods (expect contraceptive rings), IUDs, and abstinence from penile-vaginal intercourse.

✓ **Adhere to vaginal ring use instructions**

Be aware of the instructions for inserting, wearing, and removing the vaginal ring provided by the study staff.

✓ **Refrain from certain activities from during specified periods of time, as follows:**

Duration of study participation beginning 24 hours before the enrollment visit

- Inserting any objects into your vagina, including:
  - Sex toys
  - Female condoms
  - Diaphragms
  - Menstrual cups
  - Cervical caps or any other vaginal barrier method
- Using any vaginal products, including:
  - Spermicides
  - Lubricants
  - Contraceptive VRs
  - Douches
  - Vaginal medications
  - Vaginal moisturizers
- Taking specific medications*, such as
  - Anticoagulants or blood thinners (such as heparin, Lovenox®, warfarin, Plavix® [clopidogrel bisulfate)
  - Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)

72 hours before each clinic visit	72 hours before and after each biopsy visit (Day 28, Day 91)

- Engaging in receptive vaginal sexual practices, including:
  - Penile-vaginal intercourse
  - Receptive oral intercourse
  - Finger stimulation
- Taking Aspirin (greater than 81 mg)
- Vaginal Sexual Practices

24 hours before each clinic visit
Tampon use

**Let the clinic know if you start taking any medication so they can check to make sure the study products will not interfere with how your medication works.*

If you have any questions or concerns about the study adherence guidelines, contact the following study staff:

<Study Staff contact info>

Documentation

- All counseling activities (including but not limited to participant questions, risk reduction strategies, action plans, etc.) should be recorded on the worksheet and/or in chart notes to support review and appropriate follow up at subsequent visits
- Documentation should be sufficient and detailed enough to inform and guide subsequent counseling sessions
- Be sure to engage in the discussion rather than focusing on taking notes
- Summarize the session once complete