Counseling Considerations

MTN 005
Study-Specific Training
Overview

- Contraceptive Counseling
- HIV pre- and post-test counseling
- STI/HIV risk reduction counseling
- Seroconversion counseling
- Study product
- Protocol adherence counseling
- Documentation
Contraceptive Counseling

- According to Protocol Section 5.3, women must be using an effective method of birth control throughout the study:
  - Hormonal contraceptives
  - IUD
  - Study provided male condoms
  - Sterilization (participant or her male partner)
Contraceptive Counseling

- Guide and support the participant in making the best choice for her and in maintaining adherence to an effective method.

- The participant’s pregnancy intentions should also be assessed.
Contraceptive Counseling

- Are contraceptives offered at your clinical sites?
  - Which ones?

- Where do you refer potential participants for contraceptives?

- If participants begin oral contraceptives when they begin the study, be conscience of the cause of potential adverse events, particularly spotting.
Questions?
HIV Pre- and Post-Test Counseling

- HIV testing will occur at the Screening and 16-Week/ Study Termination visit, and when clinically indicated.

- HIV pre- and post-test counseling will occur in conjunction with a participant’s HIV test.

  - Client-centered approach to assess participant knowledge, dispel misconceptions, ensure readiness for testing and understanding of results
STI/HIV Risk Reduction Counseling

- STI/HIV risk reduction counseling is required at every study visit
  - Client-centered approach utilizing open-ended questions, probe for further information, guide participant in identifying her risk factors and barriers to risk reduction
  - Strategize, action plan to address barriers
STI/HIV Risk Reduction Counseling

- Condoms should be offered at every visit
- Who at your site is responsible for risk reduction counseling?
Seroconversion Counseling

- In the event of a seroconversion, site staff can refer to the MTN-005 SOP that describes HIV treatment and care
  - This may simply be procedures for providing appropriate referrals to local care facilities
  - Post-test counseling for HIV testing should also include support and appropriate referrals

What is standard for your site?
Protocol Adherence Counseling

- Participants must agree to abstain from non-study vaginal products and practices:
  - Spermicides
  - Diaphragms
  - Vaginal antibiotic or antifungal medication
  - Sex toys
  - Lubricants or condoms that contain silicone
  - Menstrual cup and douching
Study Product Adherence Counseling

- At Enrollment, 4-Week and 8-Week visits (IVR group only):
  - Product use instructions
  - Study product use counseling

- SSP Section 15.3 and the Adherence Counseling checklists outline the key messages for study product adherence counseling.
### Counseling Checklist

**Section Appendix 12-2b**
Enrollment, 4-Week and 8-Week Follow-up Visit Counseling Checklist

<table>
<thead>
<tr>
<th>HIV Risk Reduction Counseling</th>
<th>Product Use Adherence Counseling</th>
<th>Contraceptive Counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform HIV risk reduction counseling per site SOPs.</td>
<td>Wash your hands thoroughly before and after study product insertion and/or removal.</td>
<td>What method of contraception are you currently using?</td>
</tr>
<tr>
<td>Offer condoms.</td>
<td>Try not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.</td>
<td>Have you experienced any problems with your current form of contraception?</td>
</tr>
<tr>
<td></td>
<td>If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If you have any problems putting the ring back in your vagina, call or come to the clinic.</td>
<td>Do you plan to continue using this method throughout study participation?</td>
</tr>
<tr>
<td></td>
<td>Contact study staff if you have any questions or need another study vaginal ring between visits.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The study staff are here to help and support you. Please contact us if you have:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problems inserting the vaginal ring</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Any other problems (such as partner or family issues)</td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**

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**Signature/Date:** ________________  
**Signature/Date:** ________________  
**Signature/Date:** ________________
Documentation

- All *counseling* activities should be documented in chart notes and/or visit checklists.
- These will not be documented on case reports forms.
Questions?