SCREENING AND ENROLLMENT CONSIDERATIONS

MTN-036/ IPM 047 STUDY-SPECIFIC TRAINING
# SCREENING AND ENROLLMENT VISITS

<table>
<thead>
<tr>
<th>Screening/Visit 1</th>
<th>Enrollment/Visit 2 – Day 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Eligibility Criteria initially assessed</td>
<td>• Eligibility Criteria Confirmed</td>
</tr>
<tr>
<td>• Multiple visits, if needed (Split visit)</td>
<td>• No split visit permitted</td>
</tr>
<tr>
<td>• One re-screen attempt permitted</td>
<td>• Start study product use</td>
</tr>
<tr>
<td></td>
<td>• Long visit for PK collection</td>
</tr>
</tbody>
</table>

*not to coincide with participant’s menses

45 day window
## ADMINISTRATIVE PROCEDURES

<table>
<thead>
<tr>
<th>Screening Visit</th>
<th>Procedure</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial collection per site SOP</td>
<td>Locator Information collection</td>
<td>Review/update per site SOP</td>
</tr>
<tr>
<td>Conduct process: read, assess, confirm, document</td>
<td>Informed Consent</td>
<td>Review/ reconfirm</td>
</tr>
<tr>
<td>Initial assignment: Complete S&amp;E Log; PTID Name Linkage Log</td>
<td>PTID assignment</td>
<td>Use same PTID; Update S&amp;E Log</td>
</tr>
<tr>
<td>Collect via Demographic CRF</td>
<td>Demographic Information</td>
<td>N/A</td>
</tr>
<tr>
<td>Initial assessment: Age, co-enrollment, Screening Behavioral Eligibility</td>
<td>Eligibility Assessment</td>
<td>Confirmation: Co-enrollment, Enrollment Behavioral Eligibility</td>
</tr>
<tr>
<td>N/A</td>
<td>Study Arm Randomization</td>
<td>Via Medidata; after final eligibility sign-off</td>
</tr>
<tr>
<td>For Enrollment; within 45-days</td>
<td>Next Visit Schedule</td>
<td>Visit 3/ Day 1 (next day)</td>
</tr>
<tr>
<td>Per site SOP</td>
<td>Reimbursement Provision</td>
<td>Per Site SOP</td>
</tr>
</tbody>
</table>
**Informed Consent**

**Complete 1st part of coversheet**

**Read ICF**

**Assess Comprehension**

**Complete 2nd part of Coversheet**

---

**ICF/Name**

**ICF Discussion Date** (MM/DD/YYYY)

**ICF Version Number**

**Is the person of legal age to provide independent informed consent for research?**

- Yes
- No (STOP. Participant is not eligible for MTN-036).

**Can the person read and understand English?**

- Yes
- No (STOP. Participant is not eligible for MTN-026).

**Start time (OBSERV) of IC process/discussion**

---

**Complete after IC discussion**

**Was all information required to make an informed decision provided in a language that was understandable?**

- Yes
- No ➔ Explain in Notes/Comments below.

**Were all questions answered?**

- Yes
- No ➔ Explain in Notes/Comments below.

**Was comprehension assessed and did the participant demonstrate understanding of all information required to make an informed decision?**

- Yes
- No ➔ Explain in Notes/Comments below.

**Was the participant given adequate time/opportunity to consider all options in a setting free of coercion and undue influence before making an informed decision?**

- Yes
- No ➔ Explain in Notes/Comments below.

**Did the participant choose to provide written informed consent?**

- Yes
- No

**Was a copy of the consent form offered to and accepted by the participant?**

- Yes
- No ➔ Offer alternative form of study contact information to participant.

**End time (OBSERV) of IC process/discussion**

**"No study visit procedures took place prior to obtaining informed consent"**

- Yes
- No ➔ Intext of staff person obtaining consent.

**Notes/Comments:**

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**Study staff person completing informed consent process/discussion (and this coversheet):**

(Printed Name) [Signature]

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**MTN-036/ IPM 047**

**Informed Consent Comprehension Assessment (OPEN ENDED)**

**Open-Ended Question/Statement**

**Required Points of Comprehension**

**Assessed (✓)**

**Comments (Enter code or notes):**

1. **Please tell me your understanding of the purpose of the study.**
   - Testing how study drug [dose/placebo] enters and exits the body; and testing safety of ring in three different doses (drug amount/duration used).
   - Women will be randomly assigned to their group and cannot choose which one they are in.
   - One group will receive a VR for monthly use and the other two will receive theVR to wear continuously for 12 weeks.

2. **Tell me what you understand about the three different groups in the study.**
   - Wear one of these rings for a total of 18 weeks.
   - Have physical and pelvic exams and cervical biopsies. Provide blood, vaginal fluid, rectal fluid, and urine for testing.
   - Agree not to put anything in the vagina for the duration of the study. Agree to abstain from receptive vaginal sexual practices and tampon use for certain times periods prior to study visits.

3. **What are the possible risks for participants in the study?**
   - Pain or discomfort in genital area or other side effects, discomfort from exams or blood draws (must mention at least one).
   - Embarrassment and anxiety about discussions and tests

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### Screening and Enrollment Log

**MTN-036/ IPM 47**

If you are creating a new entry, complete the first three columns and initial and date in the fourth column. When enrollment or screen fail status is determined, complete the remaining columns and initial and date in the last column. Include all codes for screen failure/discontinuation that apply.

<table>
<thead>
<tr>
<th>Screening Date</th>
<th>Screening Attempt</th>
<th>PTID</th>
<th>Staff Initials/Date</th>
<th>Enrollment Date (or N/A if not enrolled)</th>
<th>Screen Failure Date (or N/A if enrolled)</th>
<th>Screening Failure/Discontinuation Codes (or N/A if enrolled)</th>
<th>Staff Initials/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Screening Failure/Discontinuation Codes**

- **11**: Not assigned female sex at birth
- **12**: Under age 18 or older than age 45
- **13**: No informed consent
- **14**: Inadequate locator
- **15**: Not proficient in English
- **16**: Not available for all visits/willing to comply with study
- **17**: Not willing to follow enrollment requirements or requirements in 6.6 and 6.7

- **18**: Not willing to use condoms during irrespective of study duration
- **19**: No effective contraceptive
- **20**: Not in general good health (full diagnosis)
- **21**: HIV infected
- **22**: Irregular menses
- **23**: Not willing to refrain from non-study vaginal products
- **24**: Inadequate/Unsatisfactory Pap documentation for past 3 yrs

- **E5**: Injection drug use within 12 months
- **E5a**: Ingestion of strong appetite suppressants within 7 days
- **E5b**: Ingestion of strong appetite suppressants within 30 days
- **E6**: Use of PEP or PEP within 3 months
- **E7**: AST/ALT Grade 1 or higher

- **E8**: Any other condition specified

- **19a**: Pregnancy outcome within 90 days
- **19b**: Prenatal visit within 45 days
- **19c**: Participation in drug/device/product trial within 30 days
- **19d**: Use of PEP or PEP within 3 months
- **19e**: AST/ALT Grade 1 or higher

- **19f**: Any other condition specified

**Notes**

- Only complete if ppt provides IC
- Completed immediately after IC completion
- One entry for each screening attempt
- Fill out all codes that apply
Screening and Enrollment Behavioral Eligibility Worksheet

MTN-036/ IPM 047
Screening Behavioral Eligibility Worksheet

<table>
<thead>
<tr>
<th>PTID</th>
<th>Visit Date (DD/MM/YY)</th>
<th>Visit Code</th>
<th>Staff Initials &amp; Date</th>
</tr>
</thead>
</table>

To confirm eligibility for the study, ask the participant the following questions and mark her responses accordingly.

1. Were you assigned female sex at birth?  Yes ☐  No ☐
2. Are you able to speak, read and write proficiently in English?  Yes ☐  No ☐
3. Are you available for all visits and willing and able to comply with all study procedural requirements?  Yes ☐  No ☐
4. Are you willing to comply with the abstinence and other protocol requirements as explained to you during the informed consent process?  Yes ☐  No ☐
5. Are you willing to use male condoms for penile-vaginal intercourse and penile-vaginal intercourse for the duration of study participation?  Yes ☐  No ☐
6. If you were to join this research study, would you be willing to use an effective form of contraception for 30 days prior to enrollment and for the duration of the study (about 13 weeks)? Effective methods include hormonal methods (except contraceptive ring, intrauterine device (IUD), barrier methods (condoms, diaphragms, cervical caps, douche, lubricants, and sex toys [vibrators, dildos, etc.]) for the 24 hours preceding your first visit and duration of study participation?  Yes ☐  No ☐
7. Do you have regular menstrual cycles with at least 21 days between menstruations?  Yes ☐  No ☐
8. Are you willing to refrain from inserting any non-study vaginal products or objects into your vagina including, but not limited to, spermicides, female condoms, diaphragms, intrauterine rings, vaginal medications, menstrual cups, cervical caps, douches, lubricants, and sex toys (vibrators, dildos, etc.) for the 24 hours preceding your Enrollment Visit and for the duration of study participation?  Yes ☐  No ☐
9. Do you agree not to take part in any other research studies involving drugs, medical devices, vaginal products, or vaccines after this Screening visit and for the duration of your study participation?  Yes ☐  No ☐
10. Are you willing to abstain from using pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention for the duration of your study participation?  Yes ☐  No ☐

MTN-040 / IPM 47
Enrollment Behavioral Eligibility Worksheet

1. Are you available for all visits and willing and able to comply with all study procedural requirements?  Yes ☐  No ☐
2. Are you willing to comply with the abstinence and other protocol requirements?  Yes ☐  No ☐
3. Are you willing to use male condoms for penile-vaginal intercourse and penile-vaginal intercourse for the duration of study participation?  Yes ☐  No ☐
4. Have you used one of the following contraceptive methods for the past 30 days: hormonal methods (except contraceptive ring, intrauterine device (IUD), barrier methods (condoms, diaphragms, cervical caps, douche, lubricants, and sex toys [vibrators, dildos, etc.]) for the 24 hours preceding this visit and duration of study participation?  Yes ☐  No ☐
5. Are you willing to continue using the same method for the duration of the study, which is expected to be 13 weeks (about 3 and a half months)?  Yes ☐  No ☐
6. Have you refrained from inserting any non-study vaginal products or objects into your vagina including, but not limited to, spermicides, female condoms, diaphragms, intrauterine rings, vaginal medications, menstrual cups, cervical caps, douches, lubricants, and sex toys (vibrators, dildos, etc.) for the 24 hours preceding your study visit and duration of study participation?  Yes ☐  No ☐
7. Are you willing to continue refraining from these activities for the duration of your study participation?  Yes ☐  No ☐
8. Do you agree not to take part in any other research studies involving drugs, medical devices, vaginal products, or vaccines after this Screening visit and for the duration of your study participation?  Yes ☐  No ☐
9. Are you willing to abstain from using pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention for the duration of your study participation?  Yes ☐  No ☐
10. In the past 3 months, have you used PrEP for HIV prevention or post-exposure prophylaxis (PEP) for HIV exposure?  Yes ☐  No ☐
11. Have you been pregnant within the last 90 days (3 months)?  Yes ☐  No ☐
12. Have you had a gynecologic or gynecologic procedure (i.e., tubal ligation, dilation and curettage, paring) in the last 45 days (1.5 months)?  Yes ☐  No ☐
13. Are you breastfeeding or planning to begin breastfeeding during your study participation?  Yes ☐  No ☐

For the participant to be eligible, the responses to items 1-7 above must be "Yes" and responses to items 8-13 must be "No."
<table>
<thead>
<tr>
<th>Screening Visit</th>
<th>Procedure</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select for IDI (after study arm randomization)</td>
<td>Behavioral Assessment</td>
<td>Baseline CASI (before HIV and pregnancy testing)</td>
</tr>
<tr>
<td>HIV Pre-Test</td>
<td>HIV/STI Counseling</td>
<td>HIV Pre-Test</td>
</tr>
<tr>
<td>STI Risk Reduction</td>
<td></td>
<td>STI Risk Reduction</td>
</tr>
<tr>
<td>HIV Post-Test</td>
<td></td>
<td>HIV Post-Test</td>
</tr>
<tr>
<td>Contraceptive Component only</td>
<td>Protocol Adherence Counseling</td>
<td>Protocol Adherence, Contraceptive, and Product Use components</td>
</tr>
<tr>
<td>Offer</td>
<td>Male Condoms</td>
<td>Offer</td>
</tr>
</tbody>
</table>
HIV Pre- and Post-Test and STI Risk Reduction Counseling

- Prior to HIV testing: provide HIV pre-test and STI risk reduction Counseling
- Refer to SSP Table 11-1 for HIV Test interpretation guidance
- If test results not ready at visit, ensure to provide HIV post-test counseling and document upon provision of test results
- Document on Worksheet or in chart notes

Counseling Considerations

MTN-036/PA0 067 HIV Pre/Post Test and Risk Reduction Counseling Worksheet

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

General
✓ Great 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
✓ 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 (pregnancy or the opposite side (if needed). Include any questions asked about HIV and STI testing and 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):
Protocol Counseling Worksheet: Protocol Adherence, Product Use, and Contraceptive Counseling

**Counseling Considerations**

**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:

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**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/issue/questions/concerns discussed at this visit?
- [ ] No
- [ ] Yes. Describe discussion, indicated counseling provided, and note issues to follow-up at next visit:

---
Counseling Considerations

MTQ-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 (e.g., 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
  - Using any vaginal products, including:
    - Antacids
    - Lubricants
    - Contraceptive VRA
  - Taking specific medications, such as:
    - Anti-coagulants or blood thinners (such as heparin, warfarin, Flexeril®; [classified as nonsteroidal])
    - Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)

  **72 hours before each clinic visit**
  - Engaging in receptive vaginal sexual practices, including:
    - Penile-vaginal intercourse
    - Receptive oral intercourse
  - Taking aspirin (greater than 81 mg)
  - Vaginal Pessaries

**MTQ-036 Study Adherence Guidelines**

**VR Use 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 support your vagina.
5. Place the tip of the ring up to your cervix and insert it into your vagina.
6. Push it toward the uterine wall. If the ring feels uncomfortable, remove it and replace it correctly.
7. The ring should not be removed except by a healthcare provider.

**MTQ-036 Study Adherence Guidelines**

**Protocol Adherence Support documents:**

- **Study Adherence Guidelines**
- **VR Use Instructions**

**VAGINAL RING INSERTION INSTRUCTIONS**

**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 reinset the ring as soon as possible. If you cannot reinset it right away, place the ring in the bag provided to you. Before you reinset, 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 reinset 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 study participation or at specific time points before and after clinic visits. See the Study Adherence Guidelines handbook 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.
## CLINICAL/PRODUCT PROCEDURES

<table>
<thead>
<tr>
<th>Screening Visit</th>
<th>Procedure</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect baseline medical/ menstrual/ Medications Hx</td>
<td>Medical History Review</td>
<td>Review/update baseline medical/ menstrual/ Medications Hx</td>
</tr>
<tr>
<td><strong>Full</strong></td>
<td>Physical Exam</td>
<td>Targeted</td>
</tr>
<tr>
<td><strong>Full exam</strong></td>
<td>Pelvic Exam</td>
<td>Full Exam</td>
</tr>
<tr>
<td>Lab and exam findings for initial eligibility</td>
<td>Review findings</td>
<td>Lab and exam findings for eligibility confirmation</td>
</tr>
<tr>
<td>If indicated</td>
<td>Referrals/Rx for UTIs/RTIs/STIs</td>
<td>If indicated</td>
</tr>
<tr>
<td>Per site SOP (at visit or when available)</td>
<td>Provision of Available Results</td>
<td>Per site SOP (at visit or when available)</td>
</tr>
<tr>
<td><strong>N/A</strong></td>
<td>Study Product</td>
<td>Initial VR provision, digital placement check</td>
</tr>
</tbody>
</table>
Baseline Medical History Questions sheet

- Guide for assessing baseline medical history
- Sites can modify depending on if the document is source
- Used to record menstrual history

Chart Notes
Baseline Medical History Log
Medications Log

Part I: General Medical History
Ask participant the following questions. If response is YES, indicate the associated body system number from Part II where the description can be found and describe in Part II. If response is NO, the remainder of this form should still be completed.

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
<th>Associated Body System</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Part II: Body System Medical History
Ask if the participant ever experienced any significant medical problems involving the following organ/systems. If response is YES, include onset and outcome dates (if not resolved at baseline, mark "ongoing"), severity grade, medications taken, and any comments relevant to the diagnosis/description, and document on the Medical History Log CRF.

<table>
<thead>
<tr>
<th>#</th>
<th>Body System</th>
<th>Yes</th>
<th>Initial Date</th>
<th>Outcome Date</th>
<th>Severity Grade</th>
<th>Med. Taken?</th>
<th>Description/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Head, Eye, Ear, Nose and Throat (HEENT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Gastrointestinal (GI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Lymphatic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Cardiovascular</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Part IV: Menstrual History
Ask participant the following about pregnancy and menstrual history.

- What was the first and last day of your last menstrual period?
  - Since Screening Visit: First day:
  - Since Enrollment Visit: First day:

- NOTE: For purposes of scheduling the Enrollment Visit (if otherwise eligible), discuss when the participant anticipates her next menstrual period, if applicable. Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-4 (Days 6, 13, 19, 27). Last Day:
  - Since Screening Visit: Last Day:
  - Since Enrollment Visit: Last Day:

- Provide additional details as needed to describe the participant’s baseline menstrual bleeding pattern:
  - Since Screening Visit:
  - Since Enrollment Visit:
## LABORATORY ASSESSMENTS

<table>
<thead>
<tr>
<th>Screening Visit</th>
<th>Procedure</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1</td>
<td>Blood</td>
<td>HIV 1 Plasma for archive</td>
</tr>
<tr>
<td>HIV 1 Plasma for archive</td>
<td>CBC with differentials/ platelets*</td>
<td>DPV levels (1, 2, &amp; 4 hrs-post ring insertion)</td>
</tr>
<tr>
<td>AST/ALT</td>
<td>Blood</td>
<td></td>
</tr>
<tr>
<td>CBC with differentials/ platelets*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis serology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Urine</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Dipstick UA, Urine Culture*</td>
<td></td>
<td>Dipstick UA, Urine Culture*</td>
</tr>
<tr>
<td>NAAT for GC/CT and trichomonas</td>
<td>Pelvic</td>
<td>Vaginal swabs for microbiota</td>
</tr>
<tr>
<td>Pap Test^</td>
<td>Pelvic</td>
<td>Vaginal gram stain</td>
</tr>
<tr>
<td>Wet prep/KOH wet mounts*</td>
<td></td>
<td>CVL</td>
</tr>
<tr>
<td>Wet prep/KOH wet mounts*</td>
<td></td>
<td>* NAAT for GC/CT and trichomonas*</td>
</tr>
<tr>
<td>CVF (1, 2, &amp; 4 hrs-post ring insertion)</td>
<td>Rectal</td>
<td>RF DVP levels (4 hrs-post ring insertion)</td>
</tr>
<tr>
<td>NA</td>
<td>Rectal</td>
<td></td>
</tr>
</tbody>
</table>
Final Sign-off of Participant Eligibility to Enroll:

Once a participant is deemed eligible to enroll in MTN-036/PIP 047, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site may sign for Eligibility Confirmation; only staff delegated the responsibility of secondary/verification of eligibility may sign for Eligibility Verification.

<table>
<thead>
<tr>
<th>ELIGIBILITY CONFIRMATION</th>
<th>ELIGIBILITY VERIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Signature:</td>
<td>(In) (designee) Signature:</td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Time:</td>
<td></td>
</tr>
</tbody>
</table>

Eligibility Criteria Checklist

- Guide for inclusion/exclusion criteria and source documentation
- Required before enrollment for eligible participants (2 sign-off signatures)
- At any point the participant is deemed ineligible at Screening or Enrollment, no need to continue completing
REQUIRED DOCUMENTATION FOR SCREEN FAILURES

- Completed ICF
- All source documentation complete up until the time that ineligibility was determined indicating what procedures were or were not completed and/or screen failure reasons and date of ineligibility determination noted.
- Visit Checklist
- Eligibility Checklist
- Chart notes
- Completed Screening and Enrollment Log
- Completed Eligibility Criteria CRF with screen failure reason(s) noted
- Necessary referrals on file (as appropriate) and documentation that any clinically significant abnormalities (labs, etc.) were communicated to the participant (even if referral is not necessary)
PARTICIPANT ENROLLMENT

Confirm and document eligibility

Randomization to study arm

Complete Post-Randomization Procedures

Post-Randomization Procedures

- IDI randomization/selection
- VR Request/Retrieval from pharmacy
- Ring insertion and placement check
- Specimen collection for DVP level testing (Blood, CVF, rectal fluid)
- Schedule visit for next day (generate visit calendar)
- Provide reimbursement, study staff contact information, etc.
- Update Screening and Enrollment Log
QUESTIONS? COMMENTS?