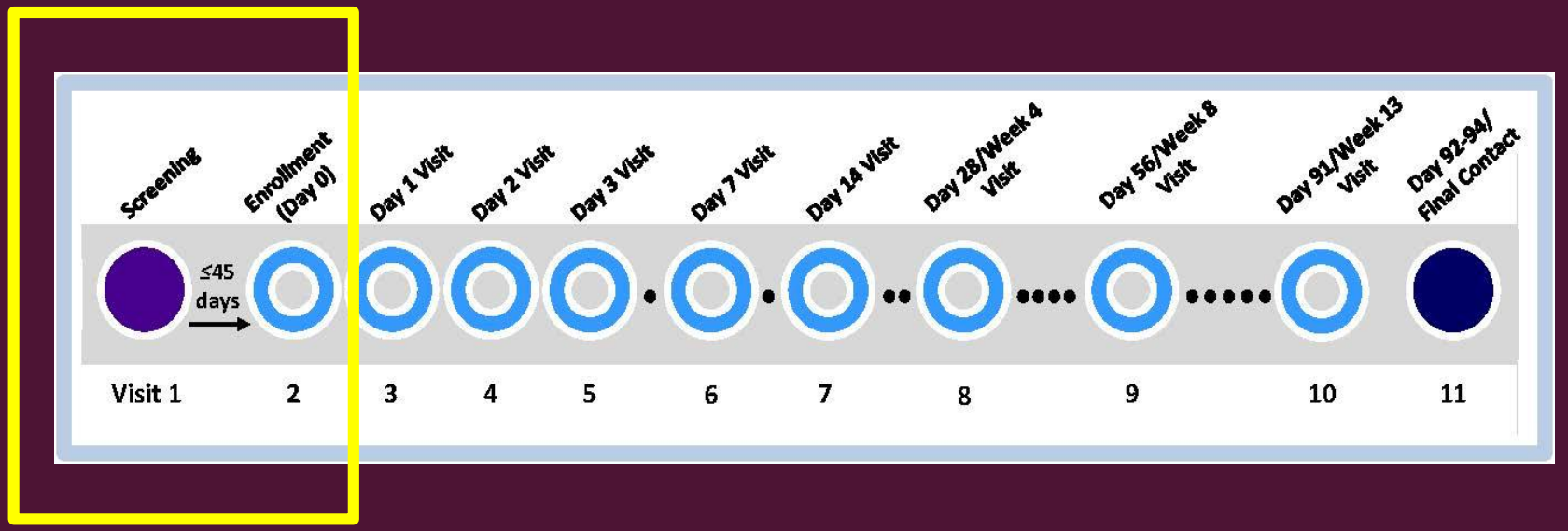
SCREENING AND ENROLLMENT CONSIDERATIONS

MTN-036/ IPM 047 STUDY-SPECIFIC TRAINING



SCREENING AND ENROLLMENT VISITS

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

45 day window

*not to coincide with participant's menses

ADMINISTRATIVE PROCEDURES

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

Informed Consent

MTN-036/ IPM 047 — Informed Consent (IC) Coversheet

COMPLETE BEFORE IC DISCUSSION

PTID/Name		IC Discussion Date (MM/DD/YY)	
ICF Version Number		Date of Approved ICF	
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-036.	
Start time (HH:MIN) 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?	☐ N/A (Participant had no questions.) ☐ 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 was provided?	☐ 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?	☐ N/A (Participant chose not to provide informed consent.) ☐ Yes ☐ No → Offer alternative form of study contact information to participant.
End time (HH:MIN) of IC process/discussion	
"No study visit procedures took place prior to obtaining informed consent"	☐ Initials of staff person obtaining consent_____
Notes/Comments:	
Study staff person completing informed consent process/discussion (and this coversheet):	
[Printed Name]	[Signature]

Complete 1st part of coversheet

Read ICF

Assess Comprehension

Complete 2nd part of Coversheet

MTN-036/ IPM 047 — Informed Consent Comprehension Assessment (TRUE/FALSE)

PTID		DATE	

No.	Question	True	False
1	If you decide to join this research study, you will be in the study for about 13 weeks.	❒	❒
2	The primary purpose of this study is to test how effective three different vaginal rings are at preventing HIV.	❒	❒
3	You will be asked to insert a vaginal ring either three times for 4-5 weeks at a time, or once for 13 weeks depending on random assignment to one of these study groups.	❒	❒
4	If you take part in the research study, you will have physical and pelvic exams, be tested for HIV and other health problems, and answer questions about your experience wearing the vaginal ring.	❒	❒
5	You will be asked to abstain from receptive vaginal sex for the duration of study participation.	❒	❒
	The study ring will prevent you from getting pregnant, so you may choose not to		

MTN-036/ IPM 047 — Informed Consent Comprehension Assessment (OPEN ENDED)

PTID		DATE		Staff Signature		Staff Date	

	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 (dapivirine) enters and exits the body; and testing safety of ring in three different doses (drug amount/duration used).		
2	**Tell me what you understand about the three different groups in the study.**	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 VRs to wear continuously for 13 weeks.		
3	**What are participants being asked to do in this study?**	Wear one of three rings for a total of 13 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. Use an effective contraceptive method for the duration		
4	**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		
		Free to make her own decision about joining the study		

Screening and Enrollment Log

MTN-036/ IPM 47 **Screening and Enrollment Log**

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.

Screening Date	Screening Attempt	PTID	Staff Initials/Date	Enrollment Date (or N/A if not enrolled)	Screen Failure Date (or N/A if enrolled)	Screening Failure/ Discontinuation Codes (or N/A if enrolled)	Staff Initials/Date

Screening Failure/Discontinuation Codes

I1	Not assigned female sex at birth	I8	Not willing to use condoms during intercourse for study duration	I15	Not willing to refrain from other studies	E5c	Injection drug use w/in 12 months	E7b	Hemoglobin Grade 1 or higher
I2	Under age 18 or older than age 45	I9	No effective contraceptive	E1	Pregnant/ plans to become pregnant	E5d	Pregnancy outcome w/in 90 days	E8	Any other condition (IoR/designee)
I3	No informed consent	I10	Not in general good health (IoR/designee)	E2	Diagnosed UTI/RTI	E5e	Gyno/genital procedure w/in 45 days	O1	Other – Declines enrollment
I4	Inadequate locator	I11	HIV infected	E3	Diagnosed with acute STI	E5f	Breastfeeding/ plans to breastfeed	O2	Other – No enrollment visit within 45-day window
I5	Not proficient in English	I12	Irregular menses	E4	Pelvic finding Grade 2 or higher	E5g	Participation in drug/device/vaginal product/vaccine trial w/in 30 days	O3	Other:
I6	Not available for all visits/not willing to comply with study	I13	Not willing to refrain from non-study vaginal products	E5a	Known study product adverse reaction	E6	Use of PrEP or PEP w/in 3 month /unwilling to not use PrEP in study	O4	Other:
I7	Not willing to follow abstinence requirements or requirements in 6.6 and 6.7	I14	Inadequate/ Unsatisfactory Pap documentation for past 3 yrs	E5b	Chronic/recurrent vaginal candidiasis	E7a	AST/ALT Grade 1 or higher		

- 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

MTN-036/ IPM 047 — Screening Behavioral Eligibility Worksheet

PTID		VISIT DATE (DD/MM/YY)		VISIT CODE		Staff Initials & Date	

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-rectal 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), sterilization (you or your partner), having sex exclusively with cis-women for 30 days prior to your Enrollment visit; or abstinence from penile-vaginal intercourse for 90 days prior to Enrollment.	Yes ☐	No ☐
7.	Do you have regular menstrual cycles with at least 21 days between menses?	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, intravaginal 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 during your study participation?	Yes ☐	No ☐

Screening Behavioral Eligibility Worksheet

MTN-036/ IPM 47 — Enrollment Behavioral Eligibility Worksheet

PTID		VISIT DATE (DD/MM/YY)		VISIT CODE		Staff Initials & Date	

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

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-rectal 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), sterilization (you or your partner), having sex exclusively with cis-women for the past 30 days; or abstinence from penile-vaginal intercourse for the past 90 days? AND Are you also willing to continue use of the same method for the duration of the study, which is expected to be 13 weeks (about 3 and a half months)?	Yes ☐	No ☐
5.	Have you refrained from inserting any non-study vaginal products or objects into the vagina including, but not limited to spermicides, female condoms, diaphragms, intravaginal rings, vaginal medications, menstrual cups, cervical caps, douches, lubricants, and sex toys (vibrators, dildos, etc.) for the 24 hours preceding this visit and duration of study participation? AND Are you willing to continue refraining from these activities for the duration of your study participation?	Yes ☐	No ☐
6.	Do you agree not to take part in any other research studies involving drugs, medical devices, vaginal products, or vaccines for the duration of your study participation AND can you confirm that you have not participated in any of these research activities in the last 60 days?	Yes ☐	No ☐
7.	Are you willing to abstain from using pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention for the during your study participation?	Yes ☐	No ☐
8.	In the past 3 months, have you used PrEP for HIV prevention or post-exposure prophylaxis (PEP) for HIV exposure?	Yes ☐	No ☐
9.	Are you pregnant or planning to become pregnant during your study participation?	Yes ☐	No ☐
10.	In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional?	Yes ☐	No ☐
11.	Have you been pregnant within the last 90 days (3 months)?	Yes ☐	No ☐
12.	Have you had a gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 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 ☐

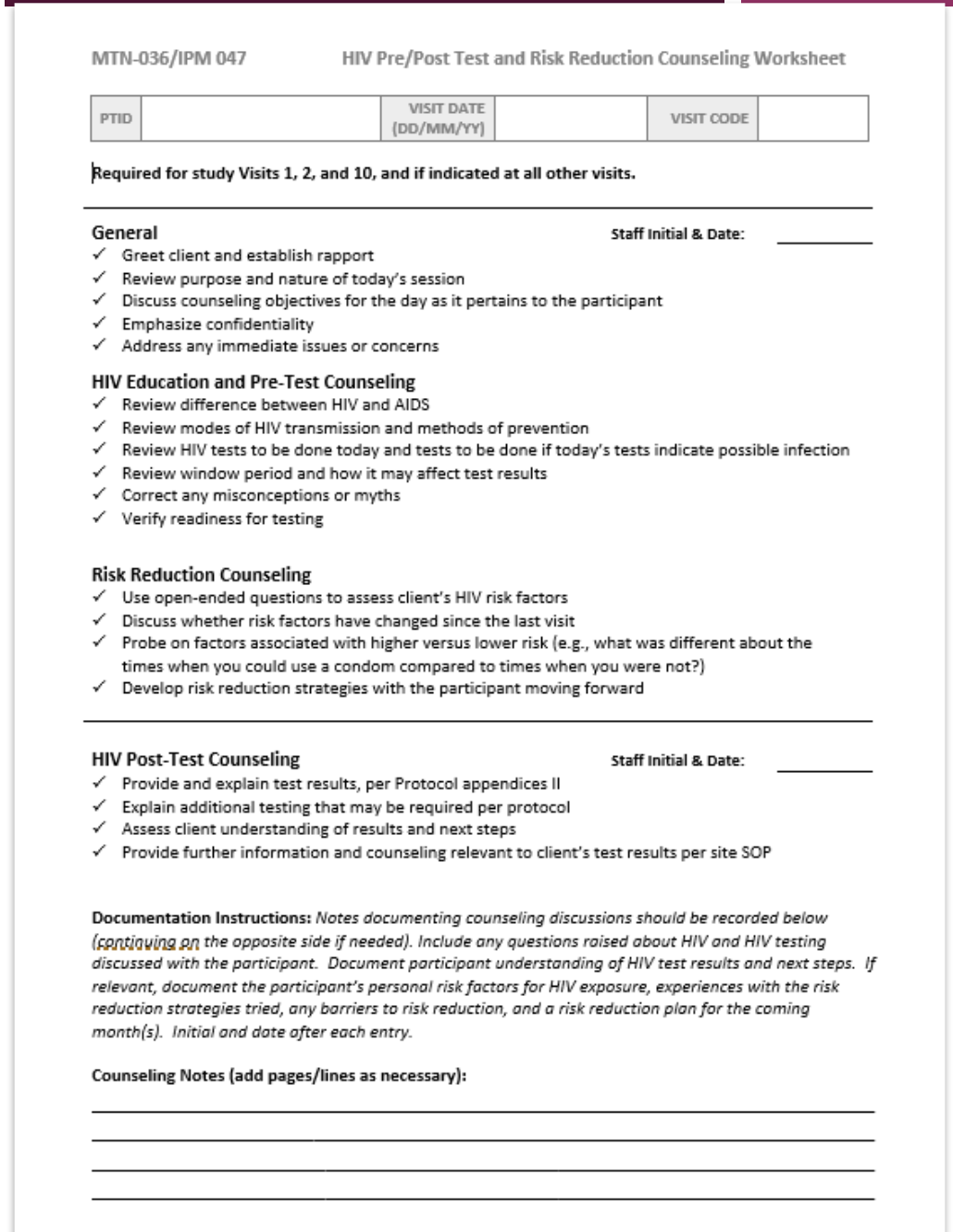
For the participant to be eligible, the responses to items 1-7 above must be "Yes" and responses to items 8-13 must be "No."

Enrollment Behavioral Eligibility Worksheet

COUNSELING AND BEHAVIORAL PROCEDURES

Screening Visit	Procedure	Enrollment Visit
Select for IDI (after study arm randomization)	Behavioral Assessment	Baseline CASI (before HIV and pregnancy testing)
HIV Pre-Test STI Risk Reduction HIV Post-Test	HIV/STI Counseling	HIV Pre-Test STI Risk Reduction HIV Post-Test
Contraceptive Component only	Protocol Adherence Counseling	Protocol Adherence, Contraceptive, and Product Use components
Offer	Male Condoms	Offer

Counseling Considerations



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 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/ IPM 047 — Protocol Counseling Worksheet

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:

_____
_____
_____

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:

_____
_____

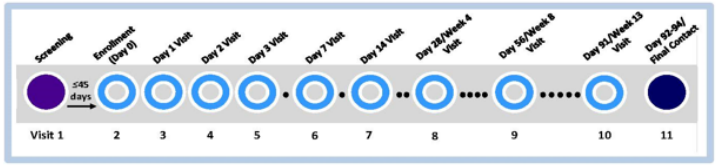
Protocol Counseling Worksheet: Protocol Adherence, Product Use, and Contraceptive Counseling

Counseling Considerations

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:**

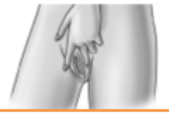
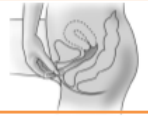
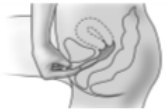
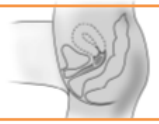
Duration of study participation beginning 24 hours before the enrollment visit

- 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
	• Taking Aspirin (greater than 81 mg)
	• Vaginal Sexual Practices

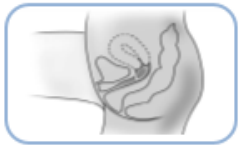
VAGINAL RING INSERTION INSTRUCTIONS

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 han around your vagin
5.  Place the tip of the then use your finge into your vagina.
6.  Push it up towards If the ring feels un inserted far enoug to push the ring up
7.  The ring should no your hands when y contact the clinic o

MTN-036/IPM 047
Version 1.0

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.

Protocol Adherence Support documents:

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

CLINICAL/ PRODUCT PROCEDURES

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

Baseline Medical History Review

MTN-036/IPM 047

Baseline Medical History Questions Form

PTID	

Staff Initials & Date			
Enrollment Visit		Screening Visit	

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.

		No	Yes → (associated body system)	Comments
1	Does the participant have any health problems?	☐	☐ → _____	
2	Has the participant ever been hospitalized for any reason other than giving birth?	☐	☐ → _____	
3	Has the participant ever had surgery, including a hysterectomy?	☐	☐ → _____	
4	In the past year, has the participant been to the emergency room?	☐	☐ → _____	
5	Has the participant had any medical or health problems in the past year?	☐	☐ → _____	

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.**

#	Body System	No	Yes	Onset Date	Outcome Date	Severity Grade	Med. Taken?	Description/Comments
1	Head, Eyes, Ears, Nose and Throat (HEENT)	☐	☐		☐ ongoing			
2	Gastrointestinal (GI)	☐	☐		☐ ongoing			
3	Lymphatic	☐	☐		☐ ongoing			
4	Cardiovascular	☐	☐		☐ ongoing			

Part IV: Menstrual History

Ask participant the following about pregnancy and menstrual history.

		Since Screening Visit	Since Enrollment Visit
1	What was the first and last day of your last menstrual period? *NOTE: For purposes of scheduling the Enrollment Visit (if otherwise eligible), discuss when the participant anticipates her next menses to start/end, as applicable. Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-6 (Days 0, 1, 2, 3, 7).*	**First day:** **Last Day:**	**First day:** **Last Day:**
2	Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern:		

Document on:

Baseline Medical History Questions sheet

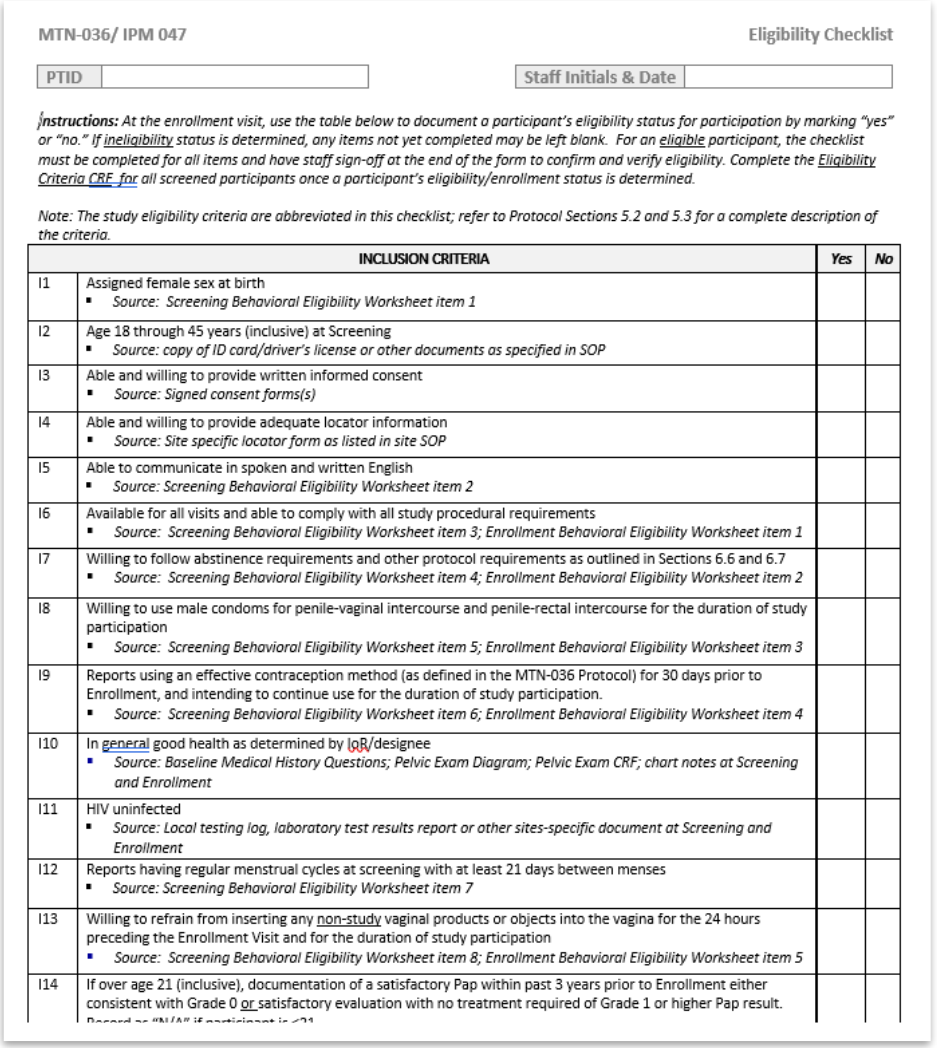
- Guide for assessing baseline medical history
- Sites can modify depending on if the document is source
- Used to record menstrual history

Chart Notes
Baseline Medical History Log
Medications Log

LABORATORY ASSESSMENTS

Screening Visit	Procedure	Enrollment Visit
HIV 1 AST/ALT CBC with differentials/ platelets Syphilis serology	**Blood**	HIV 1 Plasma for archive *CBC with differentials/ platelets** DPV levels (1, 2, & 4 hrs-post ring insertion)
Pregnancy *Dipstick UA, Urine Culture**	**Urine**	Pregnancy *Dipstick UA, Urine Culture**
NAAT for GC/CT and trichomonas *Pap Test^* *Wet prep/KOH wet mounts**	**Pelvic**	Vaginal swabs for microbiota Vaginal gram stain CVL *Wet prep/KOH wet mounts** *NAAT for GC/CT and trichomonas** CVF (1, 2, & 4 hrs-post ring insertion)
NA	**Rectal**	RF DVP levels (4 hrs-post ring insertion)

ELIGIBILITY DETERMINATION



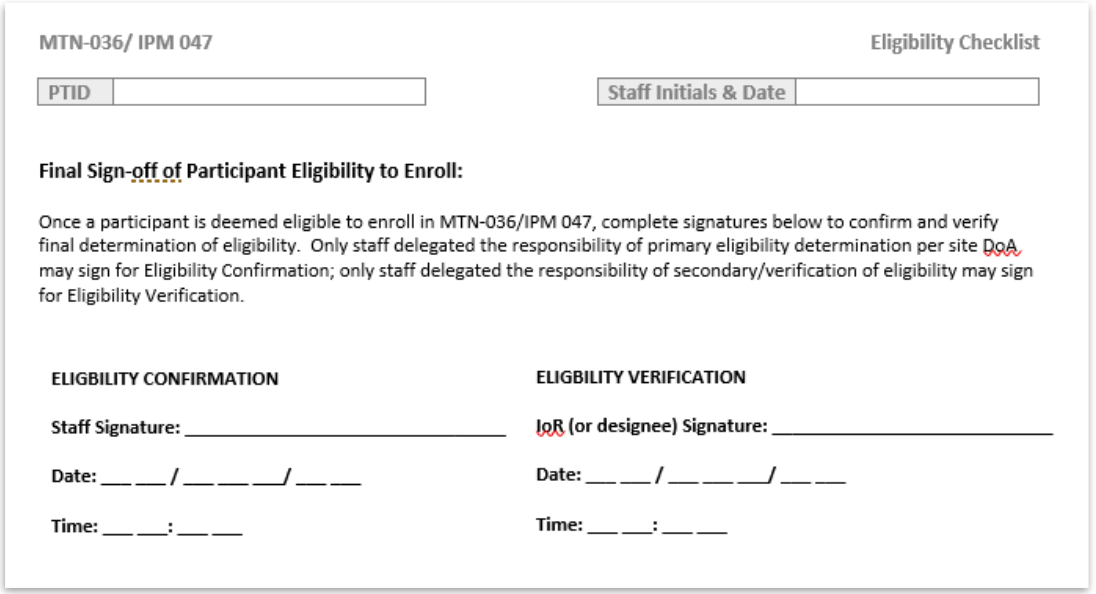
MTN-036/ IPM 047 Eligibility Checklist

PTID | Staff Initials & Date

Instructions: *At the enrollment visit, use the table below to document a participant's eligibility status for participation by marking "yes" or "no." If ineligibility status is determined, any items not yet completed may be left blank. For an eligible participant, the checklist must be completed for all items and have staff sign-off at the end of the form to confirm and verify eligibility. Complete the Eligibility Criteria CRF for all screened participants once a participant's eligibility/enrollment status is determined.*

Note: The study eligibility criteria are abbreviated in this checklist; refer to Protocol Sections 5.2 and 5.3 for a complete description of the criteria.

	INCLUSION CRITERIA	Yes	No
I1	Assigned female sex at birth ▪ *Source: Screening Behavioral Eligibility Worksheet item 1*		
I2	Age 18 through 45 years (inclusive) at Screening ▪ *Source: copy of ID card/driver's license or other documents as specified in SOP*		
I3	Able and willing to provide written informed consent ▪ *Source: Signed consent forms(s)*		
I4	Able and willing to provide adequate locator information ▪ *Source: Site specific locator form as listed in site SOP*		
I5	Able to communicate in spoken and written English ▪ *Source: Screening Behavioral Eligibility Worksheet item 2*		
I6	Available for all visits and able to comply with all study procedural requirements ▪ *Source: Screening Behavioral Eligibility Worksheet item 3; Enrollment Behavioral Eligibility Worksheet item 1*		
I7	Willing to follow abstinence requirements and other protocol requirements as outlined in Sections 6.6 and 6.7 ▪ *Source: Screening Behavioral Eligibility Worksheet item 4; Enrollment Behavioral Eligibility Worksheet item 2*		
I8	Willing to use male condoms for penile-vaginal intercourse and penile-rectal intercourse for the duration of study participation ▪ *Source: Screening Behavioral Eligibility Worksheet item 5; Enrollment Behavioral Eligibility Worksheet item 3*		
I9	Reports using an effective contraception method (as defined in the MTN-036 Protocol) for 30 days prior to Enrollment, and intending to continue use for the duration of study participation. ▪ *Source: Screening Behavioral Eligibility Worksheet item 6; Enrollment Behavioral Eligibility Worksheet item 4*		
I10	In general good health as determined by IoR/designee ▪ *Source: Baseline Medical History Questions; Pelvic Exam Diagram; Pelvic Exam CRF; chart notes at Screening and Enrollment*		
I11	HIV uninfected ▪ *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment*		
I12	Reports having regular menstrual cycles at screening with at least 21 days between menses ▪ *Source: Screening Behavioral Eligibility Worksheet item 7*		
I13	Willing to refrain from inserting any non-study vaginal products or objects into the vagina for the 24 hours preceding the Enrollment Visit and for the duration of study participation ▪ *Source: Screening Behavioral Eligibility Worksheet item 8; Enrollment Behavioral Eligibility Worksheet item 5*		
I14	If over age 21 (inclusive), documentation of a satisfactory Pap within past 3 years prior to Enrollment either consistent with Grade 0 or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result.		



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Final Sign-off of Participant Eligibility to Enroll:

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

ELIGBILITY CONFIRMATION

Staff Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___

ELIGBILITY VERIFICATION

IoR (or designee) Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___

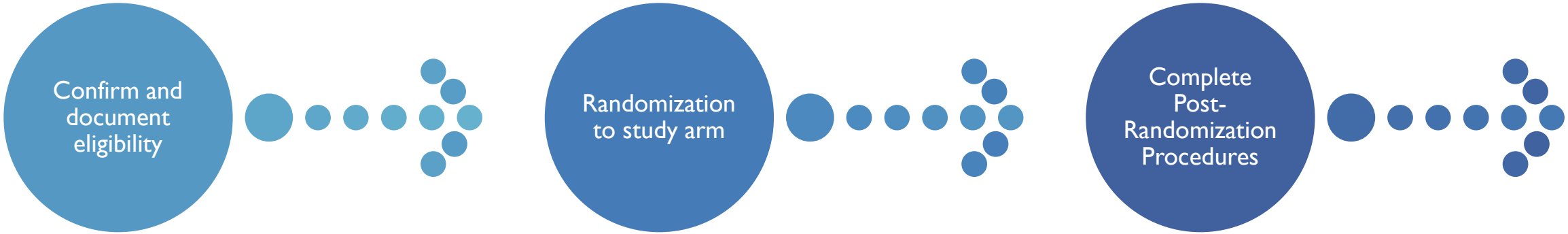
Eligibility Criteria Checklist

- 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 ineligibly 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



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?