MTN-026
Screening Procedures

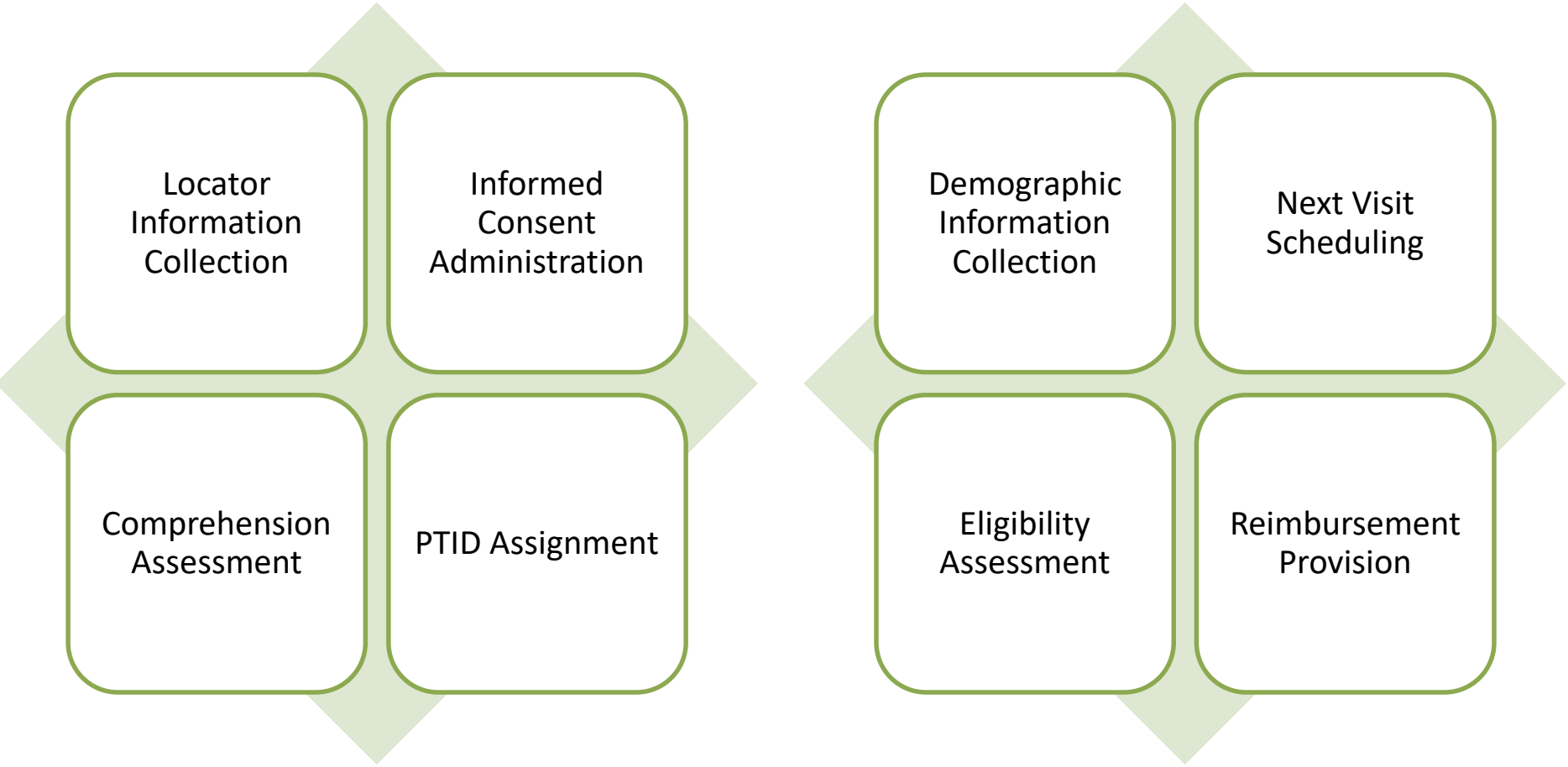
SSP Manual References

- Protocol Section 7.2 and Table 7 (Screening Visit)
- Section 4: Informed Consent
- Section 5: Study Procedures
- Section 9: Laboratory Considerations
- Section 10: Counseling Considerations

Screening Considerations

- Conducted to determine participant eligibility
- Administration of Informed Consent must be done before any other procedure
- May only be re-screened a maximum of one time if
  - All screening and enrollment procedures are not completed within 45 days of providing informed consent or if screened out due to IoR/designee discretion (Consultation with the PSRT is required)
- Screening process will be discontinued when ineligibility is determined

Administrative Procedures



Counseling Procedures

- HIV Pre-and Post Test
- HIV/STI Risk Reduction
- Protocol Adherence
- Contraceptive Counseling ♀

Clinical Evaluations

- Physical Exam (comprehensive)
- Pelvic Exam ♀
- Rectal Exam
- Medical History Review
- Menstrual History Review ♀
- Medication History Review
- Referrals/Rx for UTIs/RTIs/STIs

Laboratory Evaluations

Blood

- CBC with diff./platelets
- Chemistries (ALT/AST/Creatinine)
- Syphilis Serology
- HIV-1/2 Testing
- HSV 1/2 Serology
- Hepatitis B Surface Antigen
- Hepatitis C Antibody
- Coagulation (PT/INR)

Urine

- hCG (pregnancy)
- NAAT for GC/CT
- *Dipstick UA**
- *Urine Culture**

Rectal

- HSV 1/2 detection*
- NAAT for GC/CT

Vaginal

- NAAT for GC/CT
- *Pap Test**

SCREENING VISIT TOOLS

Informed Consent Coversheet

[Sample] Informed Consent Coversheet for MTN-026

Name or PTID:	
Name of study staff person completing informed consent process/discussion (and this coversheet):	
Date of informed consent process/discussion:	
Start time of informed consent process/discussion:	
Is the participant comfortable/fluent in other language(s) that are used at this CRS for MTN-026?	☐ Yes: (List) _____ ☐ No
Participant choice of language for the IC process and written ICF:	
Is the participant of legal age to provide independent informed consent for research?	☐ Yes ☐ No ⇒ STOP. Participant is not eligible for MTN-026.
Can the participant read?	☐ Yes ☐ No ⇒ STOP. Participant is not eligible for MTN-026.
Version number/date of informed consent form used during informed consent process/discussion:	
Were all participant questions answered?	☐ Yes ☐ No ⇒ Explain in Notes/Comments. ☐ NA (participant had no questions)
Did the participant comprehend all information required to make an informed decision?	☐ Yes ☐ No ⇒ Explain in Notes/Comments.
Was the participant given adequate time and	

IC Comprehension Assessment

Name or PTID:		Date:	
Question	**Answers**	**✓**	**Comments**
Please describe your understanding of the purpose of this study.	Assess if a gel containing a drug called dapivirine is safe when used rectally		
	To understand how the drug in the gel enters and exits the body		
Please tell me about the different groups of participants in the study.	Participants will be randomly assigned to use one of two different gels, which may or may not contain the study drug		
	Neither participants nor study staff will know which gel participants are assigned to		
What are you being asked to do in this study?	Insert a gel ir		
	some visits w		
	Have rectal,		
	Provide samp		
	cervical tissu		
	If you are a fe		
	and agree to		
	Abstain from		
	vaginal) and		
	certain times		
What are some possible risks of being in the study?	Pain or disco		
	exams or blo		
	mention at le		
	Gel may caus		
	and discomfo		

No.	Question	True	False
1	**If I decide to join this research study, I will be in the study for about 40 days (6 weeks)**	☐	☐
2	The study will show whether the rectal gel will protect me from getting HIV	☐	☐
3	If the study staff determines that I have any medical problems, they will treat me or refer me to available sources of medical care for those problems	☐	☐
4	**The purpose of this study is to assess if a gel containing an experimental drug called dapivirine is safe**	☐	☐
5	If I do not agree to specimen storage for future testing, I cannot be in this research study	☐	☐
6	I may contact the study staff at any time if I have any questions or problems	☐	☐
7	**During clinic visits, I will receive a gel in the rectum 8 times over the course of the study**	☐	☐
8	**If I decide not to join this research study, I can still come to the clinic for routine services**	☐	☐
	If I take part in the research study, I will have physical and rectal exams and testing for HIV and		

Visit Checklist

Screening Visit Checklist			
Procedures:		**Staff Initials**	**Comments:**
1.	Confirm identity and age per site SOPs. ❒ Yes ==> CONTINUE. ❒ No ==> STOP. NOT ELIGIBLE. Note: [If female and on menses, reschedule screening visit within the window.]		
2.	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ⇒ CONTINUE. ❒ Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY. CONSULT PSRT as needed.		
3.	Determine screening attempt (Verify if MTN-026/IPM 038 PTID has previously been assigned) ❒ First attempt ==>CONTINUE. ❒ Second attempt ==> CONTINUE.		
4.	Explain, conduct, and document the informed consent process for potential participant. Review and provide information booklet to participant. Complete **Informed Consent Coversheet** and **Comprehension Assessment**, per site SOP: ❒ Willing and able to provide written informed consent ⇒ CONTINUE. ❒ NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE.		
5.	Assign a PTID (if not done during a previous screening attempt). Complete **Screening and Enrollment Log** and **PTID Name Linkage Log**.		

ELIGIBILITY ASSESSMENT

Eligibility Determination

- All eligibility criteria are initially assessed at Screening.
- All eligibility criteria are confirmed on the day of Enrollment.
- It is the responsibility of the site Investigator of Record (IoR) and other designated staff to ensure that only participants who meet the study eligibility criteria be enrolled in the study.

Screening Behavioral Eligibility Worksheet

Recommended source document for assessing eligibility criteria which are based on self-report

MTN-026 Screening Behavioral Eligibility Worksheet
(Page 1 of 2)

PTID: ___ ___ ___-___ ___ ___ ___ ___-___ VISIT CODE: 1. 0

VISIT DATE: __ __ __ __ __ __ __

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

All Participants			
1	If you were to join this research study, are you able and willing to return for all study visits and comply with study participation requirements?	Yes ☐	No ☐
2	If you were to join this research study, are you willing to not take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation?	Yes ☐	No ☐
3	**Have you had consensual receptive anal intercourse at least one in the past year?**	Yes ☐	No ☐
4	If you were to join this research study, would you be willing to be sexually abstinent for 72 hours prior to each study visit, during the study product use periods and for 72 hours after biopsy collection?	Yes ☐	No ☐
5	If you were to join this research study, would you be willing to abstain from inserting any non-study products into the rectum for 72 hours prior to each study visit, for 72 hours after biopsy collection, and during the study product use periods?	Yes ☐	No ☐

Screening and Enrollment Log

No.	Screening Date DD-MMM-YY	Screening Attempt (1 or 2)	PTID	Date Enrollment window closes DD-MMM-YY	Staff Initials / Date DD-MMM-YY	Enrollment Date (not enrolled: NA) DD-MMM-YY	Screen Failure Date (enrolled: NA) DD-MMM-YY	Screening Failure Codes (enrolled: NA) DD-MMM-YY	Staff Initials / Date DD-MMM-YY

List ALL reasons the participant fails screening, especially if there is more than one reason. Codes on the lower part of the log will help abbreviate documentation.

Screen Failure Codes

I1	Not 18-45 (inclusive)	I10	Unwilling to abstain from use of non-study products in rectum (72 hrs)	E1iii	WBC grade 2 or higher	E4	PEP within 6 months	E12	Diagnosed RTI/STI/UTI at Enrollment
I2	Not able to provide IC			E1iv	Serum creatinine >1.3x site lab ULN	E5	PrEP within 6 months or anticipated use	E13	Any other condition (IoR/designee)
I3	HIV positive	I11	Females: Unsatisfactory Pap, ≥21 years of age	E1v	INR >1.5x site lab ULN	E6	Systemic Immunomodulatory Meds within 6 months or anticipated use		
I4	Inadequate locator info.	I12	Females: Unwilling to be abstinent (72hrs/7days)	E1vi	AST or ALT grade 1 or higher			E14	Females: Pregnant or Breastfeeding
I5	Noncompliance w/ study requirements	I13	Females: Unwilling to abstain from use of non-study products in vagina (72hrs/7days)	E1vii	Hepatitis C positive	E7	Unprotected sex with known HIV+ partner within 6 months	E15	Females: Last pregnancy within 90 days
I6	Not in good general health			E1viii	Hepatitis B Surface Antigen positive	E8	IV drug use within 12 months	E16	Females: Had hysterectomy
I7	No history of RAI within past year	I14	Females: No contraception	E1ix	History of inflammatory bowel disease	E9	Participation in a study within 45 days	E17	Females: Pelvic finding grade 1 or higher
I8	May participate in other studies	E1i	Hemoglobin grade 1 or higher	E2	Anticipated/use of prohibited medication	E10	Treated for anogenital STI within 3 months		
I9	Unwilling to be abstinent (72hrs)	E1ii	Platelet count grade 1 or higher	E3	Known allergy to study product	E11	Diagnosed RTI/STI/UTI at Screening		

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)

Trivia

Name at least 3 “visual aids” that may be used during the informed consent discussion?

- Calendar with study visit schedule
- Sample gel applicator
- Gel Use Instructions
- Blood collection tubes
- Study Information Booklet

All screening procedures must take place within how many days before Enrollment?

1. 15
2. 30
3. 45
4. 56

Schedule Next Visit Considerations

Negotiate visit date with participant keeping in mind:

- 45-day screening and enrollment period
- Time required to receive lab test results
- Current genital symptoms / time to resolution following treatment

How long are participants required to abstain from receptive sexual activity?

a) 5 days prior to enrollment and throughout study participation

b) 24 hours prior to each study visit and during study product use periods

c) 72 hours prior to each study visit, during the study product use period and 72 hours after biopsy collection

What is the timeframe in which a participant cannot participate in any other research study prior to Enrollment?

1. 90 days
2. 60 days
3. 45 days

Name 2 products that are prohibited?

- Hormone replacement therapy
- Anticoagulants

Questions? Comments?