Overview of Screening Visit Procedures
Inclusion Criteria

- Male/transgender female ≥ age of 18
- Able/willing to provide IC
- Adequate locator info
- HIV uninfected
- Available for study visits and willing to comply with study requirements
- History of consensual RAI at least once in the past 3 months

- Agrees not to engage in receptive/insertive sexual activity with another study participant
- Willing to use study condoms for penetrative intercourse
- Agrees not to participate in other research
Inclusion Criteria for Subset

- PPTs must agree to abstain from:
  - Inserting anything into the rectum, including abstaining from RAI for 72 hours after the collection of biopsies
  - Taking NSAIDs, aspirin and/or other drugs that are associated with increased likelihood of bleeding following mucosal biopsy collection for 72 hours prior to and following the collection of biopsies.
Exclusion Criteria

- Active anorectal or RTI requiring treatment
- Symptomatic UTI
- History of inflammatory bowel disease
- Known allergy to:
  - methylparaben
  - propylparaben
  - Any of the study products
- PEP in past 12 weeks or anticipates use during study
- Symptoms of acute HIV seroconversion at Screening or Enrollment
- Positive for Hep B or C
- Lab abnormalities
- Subset: Coagulation (PT/INR)
Exclusion Criteria

- Use of meds and/or products 12 weeks prior to screening, and/or anticipated use or unwillingness to abstain from use throughout study participation:
  - a. Any investigational products
  - b. Systemic immunomodulatory medications
  - c. Use of Heparin, including Lovenox®
  - d. Warfarin
  - e. Plavix® (clopidogrel bisulfate)
  - f. Rectally-administered medications or products, containing N-9 or corticosteroids

- IoR Discretion
Study Informed Consents

**Main Study Consent**
- Screening
- Enrollment
- Specimen Storage

**In Depth Interview**
- Subset
- 40 total
- 2-5 per site

**Biopsy**
- Subset
- 15 per site*

* Pittsburgh and Bangkok sites only

Optional
Informed Consent Tools

- Comprehension Assessment
- IC Coversheet
- IC Booklet
- Sample Pill Bottle and Tablet
- Sample Gel Applicator
Comprehension Checklist

- Administered after IC discussion but before PPT signs the ICF
- Assists staff in assessing PPT comprehension and ensures PPT understanding prior to providing consent for study participation
IC Coversheet

- Captures all required elements of IC documentation
- Use of a coversheet strongly recommended

![Sample Informed Consent Coversheet for MTN-017](image)

- **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:
- Participant choice of language for the IC process and written ICF:
  - Is the participant comfortable/fluent in other language(s) that are used at this CRS for MTN-017?
    - Yes (List)
    - No
  - Is the participant of legal age to provide independent informed consent for research?
    - Yes
    - No  STOP. Participant is not eligible for MTN-017.
- Can the participant read?
  - Yes
  - No  STOP. Participant is not eligible for MTN-017
- 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 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.
Eligibility Determination

- All eligibility criteria are **initially assessed** at the Screening visit.

- All eligibility criteria are **confirmed** on the day of Enrollment/Initiate Period 1 visit.

- 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 are enrolled in the study.
### Eligibility Checklist

- **Documents**
  - participant eligibility
- **Provides further operational guidance**
  - on the timing of assessment
- **Recommended**
  - Source doc for each item is listed in italics for ease of reference

#### ELIGIBILITY CRITERIA

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Screening Visit</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Male or transgender female ≥ age of 18 at Screening</td>
<td>Yes</td>
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<tr>
<td>Source: copy of identification card or other documents as specified in the site SOP</td>
<td>No</td>
<td>not required</td>
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<tr>
<td>2. Able and willing to provide written informed consent</td>
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<tr>
<td>Source: signed/marked consent form(s)</td>
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<td>3. HIV-1 uninfected</td>
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<tr>
<td>Source: Site HIV rapid testing logs/Lab results report</td>
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<tr>
<td>4. Able and willing to provide adequate locator information</td>
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<tr>
<td>Source: locator forms as listed in SOP</td>
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<tr>
<td>5. Available to return for all study visits and willing to comply with study participation requirements</td>
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<tr>
<td>Source: item 8 in Screening Behavioral Eligibility CRF</td>
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<td>6. In general good health</td>
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<tr>
<td>Source: Baseline Medical History Questions, Abbreviated Physical Exam CRF, Pre-existing Conditions CRF, Anorectal Exam CRF</td>
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<tr>
<td>7. History of consensual RAI at least once in the past 3 months</td>
<td></td>
<td>not required</td>
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<tr>
<td>Source: item 7 in Screening Behavioral Eligibility CRF</td>
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<tr>
<td>8. Agrees not to engage in receptive or insertive sexual activity with another study participant for the duration of study participation.</td>
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<tr>
<td>Source: item 10 in Screening Behavioral Eligibility CRF and item 1 in Enrollment Behavioral Eligibility CRF</td>
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<tr>
<td>9. Willing to use study-provided condoms for the duration of the study for penetrative intercourse</td>
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<tr>
<td>Source: item 6 in Screening Behavioral Eligibility CRF and item 2 in Enrollment Behavioral Eligibility CRF</td>
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<tr>
<td>10. Willing to not take part in other research studies involving drugs, medical devices, vaccines or genital products for the duration of study participation (including the time between Screening and Enrollment).</td>
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<tr>
<td>Source: item 9 in Screening Behavioral Eligibility CRF and item 3 in Enrollment Behavioral Eligibility CRF</td>
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<tr>
<td>11. Agree to abstain from:</td>
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<tr>
<td>Source: items 11a-11b in Screening Behavioral Eligibility CRF and Concomitant Medications Log CRF</td>
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<tr>
<td>a) inserting anything into the rectum, including the avoidance of RAI for 72 hours after the collection of biopsies</td>
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<tr>
<td>b) taking any medication with increased likelihood of bleeding for 72 hours prior to and following collection of biopsies</td>
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</table>
Screening Visit

**Administrative/Regulatory:**
- Informed Consent
- PTID
- Locator Information
- Eligibility Assessment
- Demographic Information
- Disclose test results
- Schedule Next Visit/Contact
- Reimbursement

**Laboratory:**

**Blood:**
- HIV serology
- Syphilis Serology (RPR)
- Hepatitis B Surface Antigen
- Hepatitis B Surface Antibody
- Hepatitis C Antibody
- CBC with platelets/diff.
- Serum Chemistries (ALT, AST, Creatinine, **Creatinine Clearance**)
- HSV 1/2 antibody

**Urine:**
- Dipstick UA
- NAAT for GC/CT

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

**Clinical:**
- Medical History
- Concomitant Meds
- Physical Exam
- Rectal Exam
- STI/RTI treatment*

**Counseling:**
- HIV pre- and post-test
- HIV/STI risk reduction
- Rectal biopsy/fluid procedural counseling

**Study Product/Supplies:**
- Male condoms

* If clinically indicated
# Screening Visit Checklist

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Staff Initials</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Verify identity and age.</td>
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<tr>
<td>- ≥ 18 years of age at screening  ==&gt; CONTINUE.</td>
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<tr>
<td>- &lt; 18 years of age at screening  ==&gt; STOP, NOT ELIGIBLE.</td>
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<tr>
<td>2. Check for co-enrollment in other studies or prior screening/enrollment into MTN-017:</td>
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<tr>
<td>- NOT currently enrolled in another study, including MTN-017  ==&gt; CONTINUE.</td>
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<tr>
<td>- Currently enrolled in another study  ==&gt; STOP, NOT ELIGIBLE.</td>
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<tr>
<td>3. Determine screening attempt (Verify if MTN-017 PTID has previously been assigned)</td>
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<tr>
<td>- First attempt  ==&gt; Document recruitment source, CONTINUE.</td>
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<tr>
<td>- *Second attempt  ==&gt; CONTINUE.</td>
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<tr>
<td>* Consult the SSP Section 5 for all exceptions to rescreening requirements.</td>
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<tr>
<td>4. Obtain written informed consent for screening and enrollment, specimen storage and future testing, and IDPI. [Bangkok and Pittsburgh sites only: Obtain Informed consent for Extra Samples Group]</td>
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</tr>
<tr>
<td>- Willing and able to provide written informed consent for screening and enrollment  ==&gt; CONTINUE.</td>
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</tr>
<tr>
<td>- NOT willing and able to provide written informed consent for screening and enrollment  ==&gt; STOP, NOT ELIGIBLE.</td>
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</tr>
</tbody>
</table>
If needed, screening visit procedures can be completed over multiple visits.
Reasons for Second Screening Attempt

- One second screening attempt will be allowed only in the following cases:
  - The PPT but did not complete all screening visit procedures within 30 days of providing IC
  - A PPT is diagnosed at screening with non-anorectal GC/CT
  - The PPT screened out due to symptoms suggestive of acute HIV seroconversion
  - PPTs with exclusionary lab result – at the discretion of the IoR/designee following resolution of condition – in consultation with PSRT
  - PPTs that screen out due to IoR/designee discretion - in consultation with PSRT
Documentation for Screen Failures

- Completed ICF
- Reason(s) for ineligibility, with date of determination, as per the completed Eligibility Checklist
- 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)
- All source documentation complete up until the time that ineligibility was determined
- Chart notes complete up until the time ineligibility was determined
- Indication of what visit procedures were conducted (on visit checklists)
- Completed Eligibility Criteria CRF, updated with screen failure reason(s) and faxed to SCHARP
Thank you!