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.

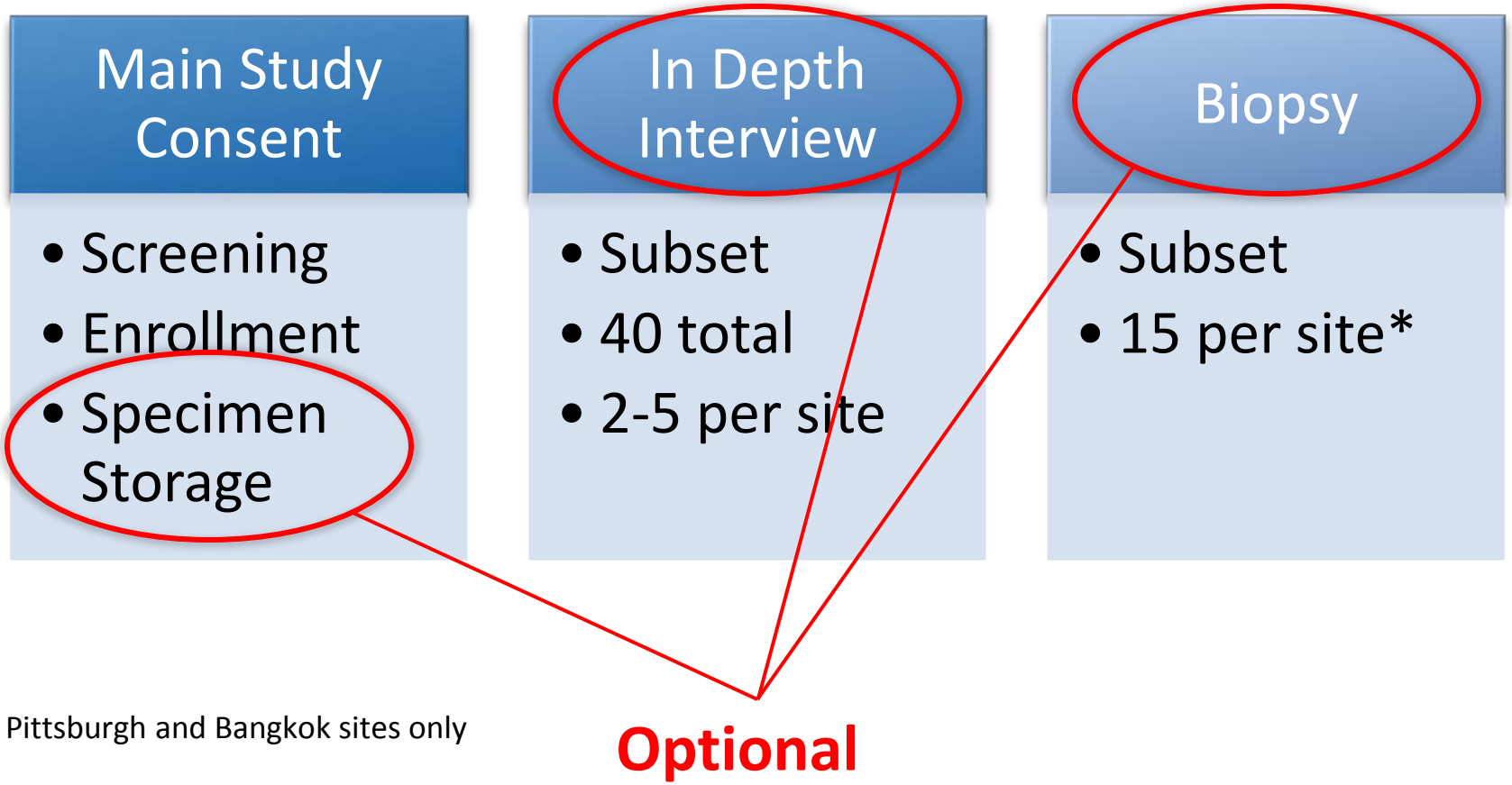
Exclusion Criteria

- 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



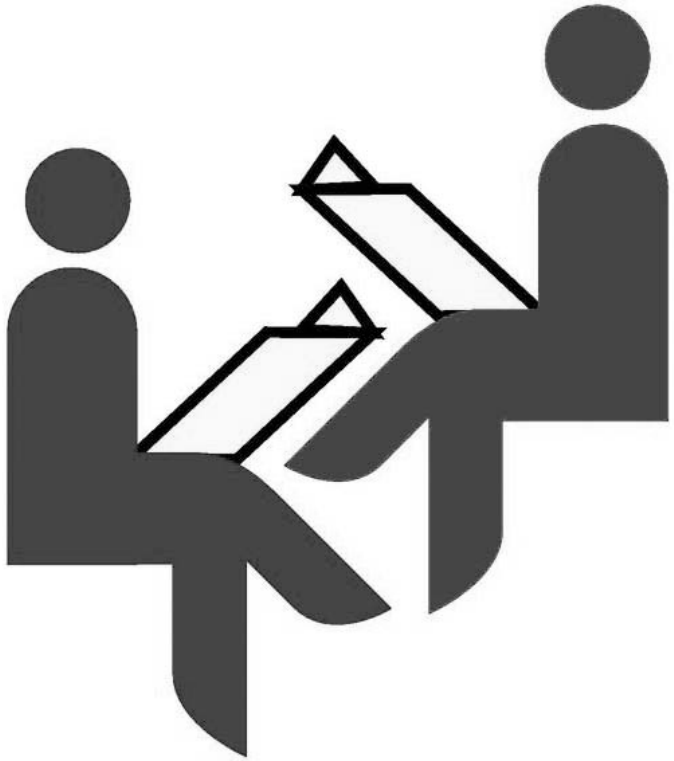
* Pittsburgh and Bangkok sites only

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

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

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

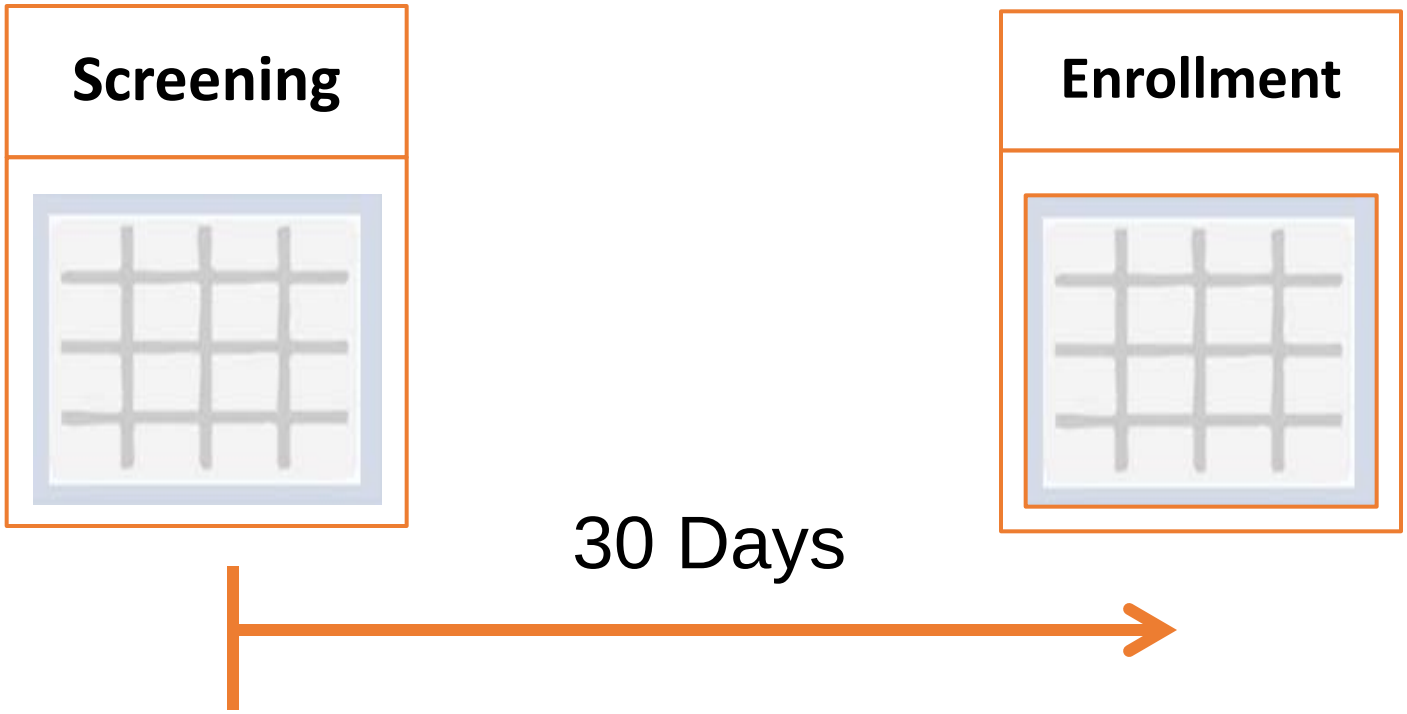
Screening Visit Checklist

PTID: __ __ __- __ __ __ __ __- __ Page 1 of 3 Visit Code: 1.0
Date: _____ Visit Type: Screening

Instructions: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, add a note on the checklist documenting who completed the procedure initial, date this entry, e.g., "done by {staff initials}" or "done by nurse." If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

Screening Visit Checklist			
Procedures		**Staff Initials**	**Comments:**
1.	**Verify identity and age.** ❒ ≥ 18 years of age at screening ==> CONTINUE. ❒ < 18 years of age at screening ==>STOP. NOT ELIGIBLE.		
2.	**Check for co-enrollment in other studies or prior screening/enrollment into MTN-017:** ❒ NOT currently enrolled in another study, including MTN-017 ==> CONTINUE. ❒ Currently enrolled in another study ==> STOP. NOT ELIGIBLE.		
3.	**Determine screening attempt (Verify if MTN-017 PTID has previously been assigned)** ❒ First attempt ==> Document recruitment source, CONTINUE. ❒ *Second attempt ==> CONTINUE. ** Consult the SSP Section 5 for all exceptions to rescreening requirements.*		
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]** ❒ Willing and able to provide written informed consent for screening and enrollment ==> CONTINUE. ❒ NOT willing and able to provide written informed consent for screening and enrollment ==> STOP. NOT ELIGIBLE.		

Screening Window



→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!