Overview of Enrollment/Initiate Period 1 Visit Procedures

What should occur between the Screening and Enrollment visits?

- Review lab results
  - Chemistries (AST/ALT and Creatinine)
  - CBC with differential and platelets
  - Syphilis RPR
  - HSV 1/2 antibody
  - HBsAg
  - HBsAb

  Results will indicate if Hep B Vaccine should be offered at Enrollment
  - Hepatitis C antibody
  - Rectal GC/CT

What should occur between the Screening and Enrollment visits?

- Confirm/update Screening column on MTN-017 Eligibility Checklist

ELIGIBILITY CRITERIA		Screening Visit			Enrollment Visit		
Exclusion Criteria		Yes	No	Staff Initials and Date	Yes	No	Staff Initials and Date
±[a]1	Participant-reported symptoms, and/or clinical or laboratory diagnosis of active anorectal or reproductive tract infection requiring treatment per current WHO guidelines or symptomatic urinary tract infection (UTI) *Source: Baseline Medical History Questions, Pre-existing Conditions CRF, Anorectal Exam CRF, Lab results report*	☐	☐		(☐)	(☐)	
2	History of inflammatory bowel disease *Source: item 4 in Screening Behavioral Eligibity CRF, Baseline Medical History Questions, Pre-existing Conditions CRF*	☐	☐		*not required*		
3a	Positive for hepatitis B surface antigen *Source: Lab results report*	☐	☐		*not required*		
3b	Positive for hepatitis C antibody *Source: Lab results report*	☐	☐		*not required*		
3c	Hemoglobin < 10.0 g/dL *Source: Lab results report*	☐	☐		*not required*		
3d	Platelet count less than 100,000/mm3v *Source: Lab results report*	☐	☐		*not required*		
3e	White blood cell count < 2,000 cells/mm3 or > 15,000 cells/mm3 *Source: Lab results report*	☐	☐		*not required*		
3f	Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula [(140-Age) * Mass (in kg)] \ [72 * Serum creatinine (in mg/dL)] *Source: Creatinine Clearance calculation worksheet*	☐	☐		*not required*		
3g	Serum creatinine > 1.3 x the site laboratory upper limit of normal (ULN) *Source: Lab results report*	☐	☐		*not required*		

What administrative procedures should occur before the participant is randomized?

- Confirm participant is within 30-day screening window
- Review/update locator information
- Provide test results from Screening
- Review informed consent and participants' willingness to continue

What behavioral procedures should occur before the participant is randomized?

- Enrollment Behavioral Eligibility (non-DataFax) Case Report Form
- Self Administered CASI Baseline Behavioral Questionnaire

What clinical procedures should occur before the participant is randomized?

- Review/update baseline medical/medication history
- Review/update concomitant medications
- Physical exam
- Rectal exam
- Document Pre-existing conditions
- Provide available test results
- Treatment or referral (if indicated)

What counseling procedures should occur before the participant is randomized?

- HIV pre- & post-test
- HIV/STI risk reduction
- Provision of condoms

What laboratory procedures should occur before the participant is randomized?

- HIV-1 serology
- Plasma archive

Note: Sites not conducting HIV rapids via finger stick, can collect plasma archive and HIV samples as part of a single blood draw in order to reduce participant burden.

What other procedure should occur before the participant is randomized?

- Conduct final determination of eligibility status
  - Review/complete Enrollment Visit column on Eligibility checklist

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	☐	☐		*not required*		
2. Able and willing to provide written informed consent	☐	☐		*not required*		
3. HIV-1 uninfected	☐	☐		☐	☐	
4. Able and willing to provide adequate locator information	☐	☐		☐	☐	
5. Available to return for all study visits and willing to comply with study participation requirements	☐	☐		☐	☐	
6. In general good health	☐	☐		☐	☐	
7. History of consensual RAI at least once in the past 3 months	☐	☐		*not required*		

Is study approved lubricant provided at all study visits?

1. No
2. Yes

- When is study lubricant required to be provided?

What procedures should occur after the participant is randomized?

- Provide relevant product use instructions and lubricant, if indicated
- Observe participant first dose/simulation of first does
  - Daily tablet - the first dose should be directly observed by study staff.
  - Daily rectal gel - first insertion or simulation of first insertion should be performed in a private space
  - RAI rectal gel - simulation of first insertion should be done in a private space
- Provide protocol adherence counseling

What other counseling procedure should occur after the participant is randomized?

- Provide participant-centered product adherence counseling

Note: Should not be the same staff person who provided product use instruction and protocol adherence counseling

What procedures should occur after the participant is randomized?

- Provide relevant SMS training and SMS diary instructions
- Generate and provide follow-up visit schedule
- Provide reimbursement
- Remind participant of follow-up phone calls:
  - 48-72 hours from date of expected product initiation
  - 2 weeks from date of expected product initiation

Questions?