**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 and 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.Use a new Genital Exam Checklist for each study visit in which either a rectal, male genital, and/or pelvic exam is performed. Samples must be collected in the order listed on the checklist.

* Rectal exams are required for all participants at all study visits except for the final contact visit (V9), which is to be performed if indicated.
* Pelvic exams for females and male genital exams are only performed if indicated at study visits. Note that sample collection may be required, even if other elements of the exam are not indicated.

| **Procedure** | **Required at Visit(s)** | **Staff Initials** |
| --- | --- | --- |
|  | Prepare for exam: * Exam equipment, documentation, and specimen collection supplies; label as needed.
* Explain exam procedures to participant and answer any questions.
* Position and drape participant comfortably.
 | Required:* Screening (V1) thru V8a

If indicated:* Final Contact (V9)
 |  |
|  | Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.  | Required:* Screening (V1) thru V8a

If indicated:* Final Contact (V9)
 |  |
|  | Perform naked eye examination and evaluate for abnormalities of the external genitalia per applicable exam performed:* Rectal (ALL participants): perineum and perianal area
* Pelvic (females only): epithelial lining of the introitus
* Male Genital: entire penile surface (glans, urethral meatus, internal/external foreskin (if present), shaft; scrotum. (Use hand-held magnifying glass)
 | Required:* Screening (V1) thru V8a

If indicated:* Final Contact (V9)
 |  |
|  | **FOR PELVIC EXAM (female participants)**Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the vagina and cervix, if applicable.  | Only if indicated at ALL visits |  |
|  | **FOR FEMALES:** Collect vaginal fluid for **GC/CT/TV NAAT test** at local lab.* 2 swabs from lateral vaginal wall.

*Note: Depending on testing platform, Trichomonas and GC/CT testing may be performed using the same swab.*  | Required: * Screening (V1)

If indicated:* Enrollment (V2) thru V8a
 |  |
|  | **FOR FEMALES:** Collect vaginal fluid for **PK analysis** at MTN LC. * 1 swab from posterior fornix.

*Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24 hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post dose visit.* | As applicable per collection time-point assignment:* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | **FOR PELVIC EXAM (female participants)**Remove speculum and perform bimanual exam | Only if indicated at ALL visits |  |
|  | Collect anal fluid for **HPV testing** at MTN LC. * 1 swab inserted min. of 6 mm in anus; rotate while withdrawing over 10-15 seconds.
 | Required: * Enrollment (V2)
* 24 Hr Post-Dosing (V4, 6, 8)
 |  |
|  | Collect swab for anorectal **HSV 1/2 testing** at local lab.* 1 swab per site SOP
 | Only if indicated at ALL visits |  |
|  | Perform digital rectal examination and evaluate for abnormalities. * Lubricate gloved index finger with study-specified lubricant
* Gently and slowly insert finger (palmar surface down) into the anus.
* Sweep finger circumferentially around the entire anal/distal rectal surface.
 | Required: For Rectal Exam* Screening (V1) thru V8a

If indicated:* Final Contact (V9)
 |  |
|  | Prepare and insert anoscope for rectal fluid collection. Perform anoscopy. | Required: For Rectal Exam* Screening (V1) thru V8a

If indicated:Final Contact (V9) |  |
|  | Collect rectal fluid for **GC/CT NAAT test** at local lab.* 1 swab inserted through the anoscope to proximal rectal lumen.

Document storage/results on [site-specific source document, e.g.], **STI Tests CRF**. | Required: * Screening (V1)

If indicated:* Enrollment (V2) thru V8a
 |  |
|  | Collect rectal fluid for **PK testing** at MTN LC.* 1 sponge from proximal rectal lumen holding in place for 2 minutes.

*Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24-hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post-dose visit.* | Required: as applicable per collection time-point assignment* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | Collect rectal sponge for **PD and biomarker** **analysis** at MTN LC. * 1 sponge inserted through the anoscope to proximal rectal lumen; remove after 2 minutes.

*Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24-hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post-dose visit*Remove anoscope after sample collection.  | Required: * Enrollment (V2)

As applicable per collection time-point assignment - Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)- 48-hr Post-dosing (V4a, 6a, 8a) |  |
|  | Prepare for rectal enema (rectal lavage)* Apply a small amount of study-specified lubricant to the tip of the pre-packaged enema bottle.

*Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24 hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post dose visit.* | Required: * Enrollment (V2)

As applicable per collection time-point assignment* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | Collect rectal enema effluent for **PD analysis** at MTN LC.\* * Administer the enema by gently inserting the tip into the rectum and slowly dispel the fluid.
* Instruct participant to hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the collection ‘hat’ placed under the toilet seat designated for this purpose.

*\*To be done prior to biopsy collection.**Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24 hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post dose visit.* | Required: * Enrollment (V2)

As applicable per collection time-point assignment* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | Prepare and insert sigmoidoscope for rectal tissue (biopsy) collection*Note: Collect per ppt’s randomly assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24 hrs post-dose [V4, 6, 8]). Collect for all participants at assigned 48-hrs post dose visit.* | Required:* Enrollment

As applicable per collection time-point assignment* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | Collect rectal tissue for **PK, PD, and biomarker analysis**.* Biopsy ~3x5mm of rectal tissue at ~15 cm from anal verge for each of the following:
* Three (3) for PK for MTN LC *\*Not collected at Enrollment (V2)*
* Three (3) for PD for Local lab
* One (1) for histology for MTN LC
* Two (2) for archive for MTN LC

Remove sigmoidoscope after sample collection. *Note: Collect per participant’s assigned time-points (either 0.5-1hr, 1.5-3hrs, 3.5-5 hrs [V3 ,5, 7] or 24 hrs post-dose [V4, 6, 8]), and at assigned 48-hrs post dose visit.* | Required:* Enrollment (V2)\*

As applicable per collection time-point assignment* Dosing (V3, 5, 7) or 24-hr Post-dosing (V4, 6, 8)
* 48-hr Post-dosing (V4a, 6a, 8a)
 |  |
|  | Document all findings on **Anorectal Exam and Sigmoidoscopy CRF,** **Pelvic Exam Diagram** and **Pelvic Exam CRF** *(for females),* and **STI Test Results CRF**, as applicable.Document storage of all specimens collected on the following, as applicable:* **Anorectal Specimen Storage Enrollment CRF** *(Enrollment visit only)*
* **Anorectal Specimen Storage CRF**
* **Pelvic Specimen Storage CRF**
* **LDMS Specimen Tracking Sheet**
 | All visits |  |

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| **Comments:** |
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