**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” 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. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity and PTID |  |  |
|  | Check for co-enrollment * NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding on-going product use and safety considerations.
 |  |  |
|  | Explain procedures to be performed at today’s visit.Assigned time-point for post-dose anorectal/pelvic specimen collection for PK:0.5-1 hour 1.5-3 hours 3.5-5 hours 24 hours\*\*if assigned this time-point, PK specimens will be collected at 24-hr Post Dose visit instead. |  |  |
|  | Review/update locator information. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Log into Medidata Rave database, and select the appropriate PTID. Begin visit by opening the applicable Visit folder. |  |  |
|  | Collect urine (15-60 mL) and perform tests/send to lab:* **FOR FEMALES:** Qualitative hCG (pregnancy)
* NAAT for GC/CT, ***if indicated***
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***
 |  |  |
|  | **FOR FEMALES:** Confirm pregnancy results:* NOT pregnant ⇒ CONTINUE.
* Pregnant ⇒ STOP. Advise SSP and site-specific SOPs for next actions.

Complete **Pregnancy Test Results CRF** upon receipt of lab test results. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* Creatinine
* [X] mL [color] top [additive/no additive] tube
* PK testing prior to study gel administration (for MTN LC)
* [X] mL [color] top [additive/no additive] tube

***If indicated****:** CBC with platelets and differentials
* [X] mL [color] top [additive/no additive] tube
* Syphilis serology
* [X] mL [color] top [additive/no additive] tube

Document on the **Specimen Storage CRF** and **LDMS Tracking Sheet.** |  |  |
|  | Review participant’s baseline medical history and current medications, to verify and/or update all information recorded at previous visit. Assess/document any adverse events. Document all updates as needed on:* **Relevant source documents**
* **Concomitant Medications Log CRF**
* **AE Summary/ Log CRFs**

*Note: For Visit 5 and 7, a participant with a current AE Grade 2 or higher judged to be related to study product may not receive the next study gel dose; PSRT consultation is required.* |  |  |
|  | ***If indicated,*** perform a targeted physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF** |  |  |
|  | ***If indicated,*** collect pharyngeal sample for NAAT for GC/CT and send to lab.  |  |  |
|  | Perform and document the following per the **Genital Exam Checklist.*** Rectal exam\*
* Male genital exam***, if indicated***
* **FOR FEMALES:** Pelvic Exam***, if indicated***

*\*The anoscopy should occur at the time of the assigned post-dose rectal swab collection when the anoscope is inserted, unless there is indication to do an anoscopy prior to gel administration.* |  |  |
|  | Complete a **MTN-037 Study Gel** **Prescription** for the study gel dose to be administered at the respective visit: Visit 3 (4ml), Visit 5 (16ml), Visit 7 (32 ml).* Deliver the top (white) copy along with the [site-specific form] to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.
 |  |  |
|  | Conduct protocol counseling with participant and document on **Protocol Counseling Worksheet**. Offer Study Adherence Guide hand-out. |  |  |
|  | Administer dose of study gel to participant via pre-filled syringe. Document visit number, date, time, and dosage of dose application on **Dose Administration CRF** |  |  |
|  | Administer the Follow-Up WSI assessment and document on the **Behavioral Assessment CRF** and **WSI Tracking CRF**. *Note WSI can occur any time after dosing.* |  |  |
|  | Collect blood for PK testing at time-points following study gel administration (For MTN LC)* + 1 hrs: [X] mL [color] top [additive/no additive] tube
	+ 2 hrs: [X] mL [color] top [additive/no additive] tube
	+ 3 hrs: [X] mL [color] top [additive/no additive] tube
	+ 4 hrs: [X] mL [color] top [additive/no additive] tube
	+ 5-6 hrs: [X] mL [color] top [additive/no additive] tube

*Note: 24 hrs post-dose blood collection to be done at 24 hr post-dose visits (V 4, 6, & 8)*Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Tracking Sheet.** |  |  |
|  | Collect post-dosing rectal and Pelvic (if female) specimens per the **Genital Exam Checklist.** |  |  |
|  | Evaluate findings and assess for AEs identified during genital, rectal and physical examinations (if done) and medical history review. Document in chart notes and update/complete **Concomitant Medications Log** **CRFs** and **AE Log** **CRFs**, as applicable. |  |  |
|  | Provide and explain all available findings and results. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), ***if indicated***). |  |  |
|  | Complete the **Follow-up Visit Y/N** and **Follow-up Visit Summary** **CRFs.** |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* Visit checklist to ensure all required procedures were completed
* Follow-Up WSI is completed and recorded in **Behavioral Assessment and WSI Tracking CRFs**
* **LDMS Tracking Sheet** and **Specimen Storage CRFs** and complete and entries are consistent.
* **AE Logs CRFs** and **Concomitant Medications Log CRF** to ensure all medications and AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | Confirm/schedule 24hr post-dose visit (V 4, 6, 8)*Note: Coordinate visit time to align with collecting PK and PD samples about 24-hrs after study gel dose administration.* |  |  |
|  | Provide any other study informational materials, male condoms (as needed), site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit: *[add site-specific list if desired]* |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Behavioral Summary
* WSI Tracking
* Pregnancy Test Results (for females)
* Anorectal Exam and Sigmoidoscopy
* Local Laboratory Results
* Specimen Storage
* Anorectal Specimen Storage
* Pelvic Specimen Storage (for females)
* Follow-up Visit Y/N / Summary
* Dose Administration

*If indicated/applicable CRFs** Adverse Events Summary/ Log
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log
* Hematology
* Vital Signs
* Physical Exam
* STI Test Results
* Pelvic Exam (for females)

Paper Forms:* MTN-037 Study Gel Prescription
* Protocol Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable (for females)*
* LDMS Specimen Tracking Sheet
 |  |  |