**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. |  |  |
|  | Administer the Follow-Up WSI assessment and document on the **Behavioral Assessment CRF** and **WSI Tracking CRF**. |  |  |
|  | 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** |  |  |
|  |  |  |  |
|  | 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 |  |  |