**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 to 24-hr post-dose anorectal/pelvic specimen collection for PK?   * YES ⇒ collect at this visit * NO, specimens were collected at Dosing Visit |  |  |
|  | 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. |  |  |
|  | **AT Visit 8 ONLY**: Administer the In-Depth Interview (IDI) and document on the **Behavioral Summary CRF.** |  |  |
|  | **AT Visit 8 ONLY**: Provide and document HIV pre-testing and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |  |
|  | ***If indicated,*** collect urine and perform tests/send to lab for NAAT for GC/CT and/or Dipstick urinalysis/culture per site SOP. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * Creatinine, AST and ALT * [X] mL [color] top [additive/no additive] tube * CBC with platelets and differentials * [X] mL [color] top [additive/no additive] tube * PK testing for 24-hr post dose time-point\* (For MTN LC) * [X] mL [color] top [additive/no additive] tube * **(AT Visit 8 ONLY)** HIV-1/2 * [X] mL [color] top [additive/no additive] tube   ***If indicated****:*   * Syphilis serology * [X] mL [color] top [additive/no additive] tube   Document on the **Specimen Storage CRF, HIV Test Results, STI Test Results** and **LDMS Tracking Sheet as appropriate.**  *\*Time collection as close as possible to 24-hrs after participant received study gel dose; +/- 4 hr window permitted.* |  |  |
|  | 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** |  |  |
|  | ***If indicted,*** 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, including post-dosing specimen collection,\* per the **Genital Exam Checklist.**   * Rectal exam * Male genital exam***, if indicated*** * **FOR FEMALES:** Pelvic Exam***, if indicated***   *\*Time collection as close as possible to 24-hrs after participant received study gel dose; +/- 4 hr window permitted.* |  |  |
|  | **AT Visit 8 ONLY**: Provide HIV test results in the context of post-test counseling and document on **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.** Provide referrals if needed/requested per site SOPs.   * If negative 🡪 UNINFECTED 🡪 CONTINUE. * If positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm.   Document test results on **HIV Test Results CRF.** |  |  |
|  | 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 to participant. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), ***if indicated***). |  |  |
|  | Conduct protocol counseling with participant and document on **Protocol Counseling Worksheet**. Offer Study Adherence Guide hand-out. |  |  |
|  | **Early Termination ONLY:** Complete the **Product Discontinuation** *(if terminating before Visit 7)* and **Study Discontinuation CRF** and complete permission to contact or [site specific log]. As indicated per protocol, arrange future contact for follow-up on ongoing AEs. |  |  |
|  | 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 and genital exam checklist to ensure all required procedures were completed * IDI is completed and recorded on the **Behavioral Summary CRF** (Visit 8) * **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 next visit.\*  *Note: Take note of participant’s assigned 48-hr post dose visit (V 4a, 6a, 8a) and, when necessary, coordinate visit time to align with collecting PK and PD samples about 48-hrs after study gel dose administration.*  \*Only if indicated for an Early Termination. |  |  |
|  | Provide any other study informational materials, 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 (Visit 8 ONLY for IDI) * Anorectal Exam and Sigmoidoscopy * Hematology * Local Laboratory Results * HIV Testing (Visit 8 ONLY) * Specimen Storage * Anorectal Specimen Storage * Pelvic Specimen Storage (for females) * Follow-up Visit Y/N / Summary   *If indicated/applicable CRFs*   * Adverse Events Summary/ Log * Baseline Medical History Summary/ Log * Concomitant Medications Summary/ Log * STI Test Results * Vital Signs * Physical Exam * Pregnancy Test Results (for females) * Pelvic Exam (for females) * Product Discontinuation (for early termination) * Study Discontinuation (for early termination)   Paper Forms:   * Protocol Counseling Worksheet * HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet (Visit 8 ONLY) * Pelvic Exam Diagrams, *if applicable (for females)* * LDMS Specimen Tracking Sheet |  |  |