**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. Use a new Screening Visit Checklist if a second screening attempt is needed.

| **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. |  |  |
|  | 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. |  |  |
|  | ***If indicated,*** collect urine and perform tests/send to lab for NAAT for GC/CT and/or Dipstick urinalysis and/or culture per site SOP |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* PK testing for 48-hr post dose time-point (for MTN LC)
* [X] mL [color] top [additive/no additive] tube

***If indicated****:** 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
* Syphilis serology
* [X] mL [color] top [additive/no additive] tube

Document on the **Specimen Storage CRF, Local Laboratories CRF, Hematology CRF, STI Tests CRF,** and **LDMS Tracking Sheet as applicable**.*Note: Time collection as close as possible to 48-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 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, 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 48-hrs after participant received study gel dose; +/- 4 hr window permitted.* |  |  |
|  | 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. |  |  |
|  | 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
* **LDMS Tracking Sheet** and **Specimen Storage CRFs** and complete and entries are consistent.
* **AE Log** and **Concomitant Medications Log CRFs** to ensure all medications and AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | Confirm/schedule next visit. |  |  |
|  | 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* Anorectal Exam and Sigmoidoscopy
* 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
* Hematology
* Local Laboratory Results
* STI Test Results
* Vital Signs
* Physical Exam
* Pregnancy Test Results
* Pelvic Exam (for females)

Paper Forms:* Protocol Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable (for females)*
* LDMS Specimen Tracking Sheet
 |  |  |