Instructions: Complete staff initials next to procedures completed. Do not initial for other staff members. 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. |  |  |
|  | 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 and perform test/send to lab for pregnancy (as applicable). Complete Pregnancy Test Results CRF upon receipt of lab test results. |  |  |
|  | Prepare participant for rectal enema (rectal lavage) and instruct participant to self-administer the enema by gently inserting the tip into the rectum and slowly dispelling the fluid, hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the toilet **(minimum of 45 minutes prior to dosing)** |  |  |
|  | *If indicated*, collect urine and perform tests/send to lab for NAAT for GC/CT (if pelvic GC/CT cannot be performed) and/or Dipstick urinalysis/culture per site SOP. Complete STI Test Results CRFs upon receipt of lab test results. |  |  |
|  | *If indicated*, 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 the following amounts of blood and send to lab for testing: and document results on the Chemistry Panel, Hematology and/or STI Test Results CRFs when available. * HIV-1/2
* [4] mL [red] top [no additive] tube
* CBC with platelets and differentials

***Sites to confirm and update tube type and aliquots per local requirements.**** [4] mL [lavender] top [EDTA] tube
* Creatinine, AST, ALT
* [4] mL [green] top [Na Hep] tube
* Syphilis serology
* [4] mL [red] top [no additive] tube
 |  |  |
|  | *If indicated,* 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.  |  |  |
|  | Review participant’s 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. Document results on the STI Test Results CRF when available.  |  |  |
|  | Perform and document visual and digital rectal exam only per the Genital Exam Checklist. |  |  |
|  | Complete Study Prescription. Deliver the top (white) copy along with the [site-specific form] to the pharmacy. Retain yellow copy of prescription in participant’s binder.  |  |  |
|  | Review product administration procedures with participant using Rectal Insert Guide. **Administer study product**. Document dosing on Dose Administration CRF. |  |  |
|  | Collect blood for PK testing at time-points following product administration:* + 1 hr: 10 mL lavender top EDTA tube
	+ 2 hr: 10 mL lavender top EDTA tube
	+ 4 hr: 10 mL lavender top EDTA tube
	+ 6 hr: 10 mL lavender top EDTA tube

Document stored specimen collection on the Specimen Collection and Storage CRF and LDMS Tracking Sheet. |  |  |
|  | Collect post-dose rectal and vaginal specimens per the applicable Genital Exam Checklist.* Rectal exam
* Pelvic exam*, as applicable* *and if indicated*
* Male genital exam*, as applicable and if indicated*
 |  |  |
|  | Evaluate findings and assess for AEs identified during genital 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*). |  |  |
|  | Conduct and document protocol counseling on Protocol Counseling Worksheet.  |  |  |
|  | Complete the Follow-up Visit Yes/No and Follow-up Visit Summary CRFs. |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* This visit checklist to ensure all required procedures were completed.
* LDMS Tracking Sheet and Specimen Collection and Storage CRF to ensure complete and consistent entries.
* AE Summary/Log CRFs and Concomitant Medications Log CRF to ensure all medications and AEs are captured consistently and updated.
* Chart notes to ensure completeness and accuracy
 |  |  |
|  | Confirm/schedule 24hr post-dose visit (visits 4 and 8)*Note: Coordinate visit time to align with collecting rectal and vaginal (if applicable) PK and PD samples about 24-hrs after study product administration for Group 2.* |  |  |
|  | Provide any other study informational materials, site contact information, and instructions to contact the site for additional information, condoms 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
* Chemistry Panel
* Specimen Collection and Storage
* Follow-up Visit Y/N / Summary
* Dose Administration

*If indicated/applicable CRFs** Pregnancy Test Results
* Pelvic Exam
* Adverse Event Summary/Log
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log
* Hematology
* Vital Signs
* Physical Exam
* STI Test Results
* HIV Test Results

Paper Forms:* Study Prescription
* Protocol Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable*
* LDMS Specimen Tracking Sheet
* Genital Exam Checklist
 |  |  |