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. |  |  |
|  | Administer the Follow up CASI assessment and document on the Behavioral Assessment CRF and CASI Tracking CRF. |  |  |
|  | *If indicated*, collect urine and perform tests/send to lab for pregnancy (as applicable), NAAT for GC/CT (if pelvic GC/CT cannot be performed) and/or Dipstick urinalysis/culture per site SOP. Complete Pregnancy Test Results and 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. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* Plasma for PK
* 10 mL lavender top EDTA tube

*If indicated:****Sites to confirm and update tube type and aliquots per local requirements.**** HIV-1/2
* [4] mL [red] top [no additive] tube
* CBC with platelets and differentials
	+ [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

Document on the Specimen Collection and Storage CRF and LDMS Tracking Sheet. If applicable, complete HIV Test Results, Chemistry Panel, Hematology, STI Test Results CRFs.   |  |  |
|  | *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 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. Document results on STI Test Results CRF. |  |  |
|  | Perform and document the following, including post-dosing specimen collection, per the Genital Exam Checklist.* Rectal exam
* Pelvic exam*, as applicable and indicated*
* Male genital exam*, as applicable and if indicated*

*Time collection as close as possible to 24-hrs after participant received study product; +/- 2-hour allowable window for Group 2.*  |  |  |
|  | 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 and document protocol counseling on Protocol Counseling Worksheet.  |  |  |
|  | Visit 8 only: Complete Product Discontinuation CRF to document end of study product use.  |  |  |
|  | 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 and genital exam checklist to ensure all required procedures were completed.
* LDMS Tracking Sheet and Specimen Collection and Storage CRFs to ensure entries are complete and consistent.
* AE Summary/Log 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: Coordinate visit time to align with collecting rectal and vaginal (if applicable) PK and PD samples about 48-hrs after study product administration for Group 1.* |  |  |
|  | 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* Behavioral Assessment
* CASI Tracking
* Anorectal Exam
* Specimen Collection and Storage
* Follow-up Visit Yes/No and Summary
* Product Discontinuation (Visit 8 only)

*If indicated/applicable CRFs** Adverse Events Summary/Log
* Medical History Summary/Log
* Concomitant Medications Summary/Log
* HIV Testing
* Hematology
* Chemistry Panel
* STI Test Results
* Vital Signs
* Physical Exam
* Pregnancy Test Results
* Pelvic Exam
* Study Discontinuation (for early termination)

Paper Forms:* Protocol Counseling Worksheet
* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable (for females)*
* LDMS Specimen Tracking Sheet
 |  |  |