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. |  |  |
|  | **Visit 10 Only**: Administer the In-Depth Interview (IDI) and document on the Behavioral Assessment CRF.* NA at Visit 6
 |  |  |
|  | *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. |  |  |
|  | Visit 10 and if clinically indicated at Visit 6: Provide and document HIV pre-testing and HIV/STI risk reduction counseling using the HIV Pre/Post Test and Risk Reduction Counseling Worksheet.* NA at Visit 6
 |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* Plasma for PK
* 10 mL lavender top EDTA tube

**Visit 10**, in addition to blood for PK testing, collect blood and send to lab for testing: * HIV-1/2
* [4] mL [red] top [no additive] tube

***Sites to confirm and update tube type and aliquots per local requirements.**** CBC with platelets and differentials
* [4] mL [lavender] top [EDTA] tube
* Creatinine, AST, ALT
* [4] mL [green] top [Na Hep] tube

 *If indicated:** Syphilis serology
* [4] mL [red] top [no additive] tube

Document on the Specimen Collection and Storage CRF and LDMS Tracking Sheet. **Visit 10**: Complete Hematology, Chemistry Panel CRF. If indicated: Complete STI Test Results CRF. |  |  |
|  | Visit 10 and if clinically indicated at Visit 6*,* 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 STI Test Results CRF. |  |  |
|  | **Visit 6**: Complete Home Saline Enema Kit Request Slip to obtain enema kit for administration prior to dosing visit. Deliver the top (white) copy to the pharmacy. Retain yellow copy of prescription in participant’s binder. Review content of kit and use instructions with participant and address any questions or concerns.* NA at Visit 10
 |  |  |
|  | 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*, if indicated*

*Time collection as close as possible to 72-hrs after participant received study product; +/- 6-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.  |  |  |
|  | 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:* Visit checklist and genital exam checklist to ensure all required procedures were completed.
* IDI is completed and documented on the Behavioral Summary CRF (Visit 10)
* LDMS Tracking Sheet and Specimen Collection and Storage CRFs to ensure entries are complete and 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/contact. |  |  |
|  | 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
* Specimen Collection and Storage
* Behavioral Assessment (Visit 10)
* Follow-up Visit Yes/No and Summary
* Hematology (Visit 10)
* HIV Testing (Visit 10)
* Chemistry Panel (Visit 10)

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

Paper Forms:* Protocol Counseling Worksheet
* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet (Visit 10)
* Pelvic Exam Diagrams, *if applicable*
* LDMS Specimen Tracking Sheet
* Home Saline Enema Kit Request Slip
 |  |  |