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. |  |  |
|  | *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.***   * 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 * HIV-1/2   + [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, Hematology, Chemistry Panel, 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. Document test results on HIV Test Results CRF.   * If negative 🡪 UNINFECTED 🡪 CONTINUE. * If positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm. |  |  |
|  | 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. |  |  |
|  | 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 48-hrs after participant received study product; +/- 4-hour allowable window for Group 1.* |  |  |
|  | 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 * 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.  *Note: Coordinate visit time to align with collecting rectal and vaginal (if applicable) PK and PD samples about 72 hours 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 * Specimen Collection and Storage * Follow-up Visit Y/N / Summary   *If indicated/applicable CRFs*   * Adverse Events Summary/Log * Medical History Summary/Log * Concomitant Medications Summary/Log * Hematology * Chemistry Panel * HIV Testing * 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, if applicable * Pelvic Exam Diagrams, *if applicable* * LDMS Specimen Tracking Sheet * Genital Exam Checklist |  |  |