**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.

| **Procedure** | | **Staff Initials** |
| --- | --- | --- |
|  | Confirm identity, age, and PTID |  |
|  | Check for co-enrollment   * NOT currently or recently enrolled in another study 🡪 CONTINUE. * Currently or recently enrolled in another study 🡪 STOP. Assess eligibility to continue. 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(s), if not already provided. Treat and/or refer for care as required. |  |
|  | Collect unused study product and return to the site pharmacy. |  |
|  | Log into Medidata Rave and select the appropriate PTID. Begin visit by opening the applicable Visit folder. |  |
|  | Complete the **Follow-up Visit YN** and **Follow up Visit Summary eCRFs.** |  |
|  | Collect mid-stream catch urine (15-60 mL) and perform tests:   * NAAT for GC/CT/TV *(****required at Visit 7****; if indicated at Visits 3 and 5)* * ***If indicated***: Qualitative hCG (pregnancy) * ***If indicated***: Dipstick urinalysis and/or culture per site SOP   Document GC/CT/TV test results on the **STI Test Results eCRF**. For individuals who can get pregnant, document pregnancy test results on local testing log and the **Pregnancy Test Results eCRF**, when *applicable*.   * If pregnant**→** STOP. Refer to SSP and site-specific SOPs. |  |
|  | Review/update baseline medical and medications history to verify and/or update all information previously recorded. Document all updates as needed on the **Adverse Event Summary/Log eCRFs** and **Concomitant Medications Summary/Log eCRFs**.  *Note: A participant with a current unresolved pelvic, genital or anorectal AE Grade 3 or higher* ***AND*** *any other AE that in the opinion of the investigator is judged to be related to study product and would preclude the participant from continuing to the next product use period may not proceed to the next scheduled regimen, without prior PSRT consultation.* |  |
|  | Administer Behavioral Assessment and document on the **CASI Tracking eCRF**. |  |
|  | Conduct brief in-depth interview (IDI) and document on the **Behavioral Assessments Summary eCRF**. |  |
|  | **At Visit 7** (*if indicated at Visits 3 and 5)***,** provide and document HIV pre-test and HIV/STI risk reduction counseling, including offering male condoms, using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |
|  | **At Visit 7** (*if indicated at Visits 3 and 5)***,** collect the following amounts of blood and send to lab for testing:   * HIV 1/2 * [X] mL [color] top [additive/no additive] tube * Syphilis serology * [X] mL [color] top [additive/no additive] tube   Document syphilis results on the **Syphilis Serology eCRF**. |  |
|  | Perform and document HIV test (s) per site SOPs and in accordance with HIV Testing Algorithm.  *The following applies to sites running one EIA:*   * If negative 🡪 UNINFECTED 🡪 CONTINUE. * If positive or indeterminate 🡪HOLD PRODUCT→ Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC   *The following applies to sites running two rapid tests:*   * If both tests negative → UNINFECTED → CONTINUE. * If both tests positive → HOLD PRODUCT→ Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC * If one test positive and one test negative → DISCORDANT → HOLD PRODUCT→ Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC   Document results on **HIV Test Results eCRF.** If a HOLD or DISCONTINUATION is initiated, complete **Study Product Request Slip** and the **Product Hold Log** or **Discontinuation of Study Product CRF**. |  |
|  | 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 for care and treatment, if applicable, per site SOPs. |  |
|  | *If clinically indicated, perform targeted physical exam and complete the Vital Signs eCRF and Physical Exam eCRF.* |  |
|  | **At Visit 7** (*if indicated at Visits 3 and 5)****,***collect pharyngeal sample for NAAT for GC/CT. Document results on the **STI Test Results eCRF**. |  |
|  | *If clinically indicated, for individuals with a natural phallus or neo-phallus, perform genital examination per Genital Exam Checklist and document findings on the Genital Exam eCRF.* |  |
|  | **At Visit 7:** *For individuals with a natural vagina or neo-vagina, collect two (2) vaginal swabs for NAAT for GC/CT/TV. Document results on the* ***STI Test Results*** *eCRF.*  ***At other visits or if clinically indicated****, perform pelvic examination and collect vaginal swab per Pelvic Exam Checklist. Document findings on the Pelvic Exam Diagrams Form and Pelvic Exam eCRF.* |  |
|  | Perform anorectal exam per Anorectal Exam Checklist and document findings on the **Anorectal Exam eCRF**. |  |
|  | Evaluate findings identified during anorectal examination (if applicable, genital, pelvic and physical exams) and medical history review. Determine whether participant has current RTI/STI/UTI symptoms:   * No symptoms 🡪 CONTINUE. * Symptom(s) present 🡪 evaluate per site SOPs.   *If symptomatic and diagnosed with an RTI/STI/UTI, t*reat or refer for treatment *if indicated, per site SOP.* |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |
|  | Document referral in chart notes and update **Concomitant Medications Log eCRF**, if treatment provided or prescribed. Document relevant conditions on the **Adverse Event Log** **eCRF**. |  |
|  | Complete **Discontinuation of Study Product eCRF**. |  |
|  | Perform QC1 with participant still present. Review the following for completion and clear documentation:   * Visit and Anorectal Exam checklists to ensure all required procedures were completed. * **AE Summary/Log eCRFs** and **Concomitant Medications Log eCRF** to ensure all medications and AEs are captured consistently and updated. * **Chart notes** to ensure completeness and accuracy based on participant responses and clinical findings. * All CRFs for completeness and accuracy, based on participant responses and clinical findings. |  |
|  | Schedule next visit and provide any other study informational materials, site contact information, and instructions to contact the site for additional information, study product and/or counseling if needed before the next visit: *[add site-specific list if desired]* |  |
|  | Provide reimbursement. |  |
|  | Perform QC2. Review participant chart contents, paper forms and EDC data:  **eCRFs**   * Anorectal Exam * Behavioral Assessments Summary * CASI Tracking * Follow-up Visit Y/N and Summary * STI Test Results **(required at Visit 7)** * Syphilis Serology **(required at Visit 7)** * HIV Test Results **(required at Visit 7)**   **Paper Forms:**   * HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet **(required at Visit 7)** * Protocol Counseling Worksheet * Pelvic Exam Diagrams, *if applicable*   ***If indicated/applicable:***   * Vital Signs * Adverse Events Summary/Log * Medical History Summary/Log (if newly reported baseline conditions) * Concomitant Medications Summary/Log * Physical Exam * Pregnancy Test Results * Genital Exam * Pelvic Exam * Protocol Deviation Log * Product Hold Log * Social Impact Y/N * Social Impact Log * Study Termination * Discontinuation of Study Product * Participant Replacement Assessment * Additional Study Procedures |  |
| **Comments:** | | |
|  | | |