**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 and PTID. |  |
|  | 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. |  |
|  | Log into Medidata Rave and select the appropriate PTID. Begin visit by opening the applicable visit folder. |  |
|  | Complete the **Follow-up Visit Y/N** and **Follow-up Visit Summary** **eCRFs.** |  |
|  | Collect mid-stream catch urine (15-60 mL) and perform tests:   * **FOR INDIVIDUALS WHO CAN GET PREGNANT:** Qualitative hCG (pregnancy) * NOT pregnant 🡪 CONTINUE. * Pregnant 🡪 STOP. * ***if indicated***: NAAT for GC/CT/TV * ***if indicated***: Dipstick urinalysis and/or culture per site SOP.   For individuals who can get pregnant, document pregnancy test results on local testing log and the Pregnancy Test Results eCRF. If pregnant→ Refer to SSP and site-specific SOPs Document GC/CT/TV test results on the **STI Test Results eCRF,** *if applicable*. |  |
|  | Review/update medical 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**. |  |
|  | Administer Behavioral Assessment and document on the **CASI Tracking eCRF**. |  |
|  | If chosen to be part of the subset, conduct brief in-depth interview (IDI) and document on the **Behavioral Assessments Summary eCRF** |  |
|  | 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**. |  |
|  | Collect the following amounts of blood and send to lab for testing:   * HIV-1/2 (rapid test required)   + [X] mL [color] top [additive/no additive] tube   ***If indicated:***   * Syphilis serology   + [X] mL [color] top [additive/no additive] tub   Document syphilis results on the **Syphilis Serology eCRF**, if applicable |  |
|  | 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.** Provide referrals for appropriate follow up care/treatment. |  |
|  | 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 a targeted physical exam and complete the Vital Signs eCRF and Physical Exam eCRF* |  |
|  | *If clinically indicated, collect pharyngeal sample for NAAT for GC/CT and complete 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.* |  |
|  | *If clinically indicated, for individuals with a natural vagina or neo-vagina, perform pelvic examination and/or collect vaginal swab per Pelvic Exam Checklist. Document results on STI Test Results eCRF and exam findings on the Pelvic Exam Diagrams Form and Pelvic Exam eCRF.* |  |
|  | *If clinically indicated, perform anorectal exam per Anorectal Exam Checklist and document findings on the Anorectal Exam eCRF* |  |
|  | *If indicated, evaluate findings identified during anorectal (if applicable, genital and pelvic) and physical examinations 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, treat 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 Study Product Request Slip, indicating “Product Use Period Complete.” Deliver the top (white) copy along with the [site-specific form] to the pharmacy. Retain yellow copy of prescription in participant’s binder. |  |
|  | Complete the **Study Termination eCRF**. |  |
|  | If any unused study product remains in the participant’s possession, document in chart notes all efforts to retrieve, up to five working days post-study termination. |  |
|  | Perform QC1 with participant still present, review the following for completion and clear documentation:   * Visit and Anorectal Exam checklists (if applicable, pelvic and genital exam checklists) to ensure all required procedures were completed. * **Adverse Event Summary/Log** and **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 eCRFs for completeness and accuracy, based on participant responses and clinical findings. |  |
|  | Provide any other study informational materials, male condoms (as needed), site contact information, and instructions to contact the site for additional information and/or counseling if needed: *[add site-specific list if desired]* |  |
|  | Provide reimbursement. |  |

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| --- | --- | --- |
|  | Perform QC2. Review participant chart contents and EDC data:  Required CRFs,   * Follow-up Visit Y/N/Summary * Pregnancy Test Results (for individuals who can get pregnant) * Behavioral Assessments Summary * CASI Tracking * Study Termination   *Paper Forms:*   * Pelvic Exam Diagrams, *if applicable* * HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet   *if indicated/applicable*   * Vital Signs * Adverse Events Summary/Log * Medical History Summary/Log (if newly reported baseline conditions) * Concomitant Medications Summary/Log * HIV Test Results * Physical Exam * Genital Exam * Pelvic Exam * Syphilis Serology * STI Test Results * Anorectal Exam * Protocol Deviation Log * Product Hold Log * Social Impact Y/N * Social Impact Log * Additional Study Procedures |  |
| Comments: | | |
|  | | |