**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) in the comments section or chart notes; initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in comments section. Use a new Screening Visit Checklist if a second screening attempt is needed.

| **Procedure** | | **Staff Initials** |
| --- | --- | --- |
|  | Confirm identity and, age per site SOP.   * 18-35 years (inclusive) 🡪 CONTINUE. * Under 18 **or** over 35 years old 🡪 STOP. NOT ELIGIBLE. |  |
|  | 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 PSRT if needed.   *NOTE: Participation in studies involving drugs, medical devices, genital products, or vaccines within 30 days of enrollment is exclusionary. Participation in any research study involving rectal products* ***ever*** *is exclusionary.* |  |
|  | Determine screening attempt (verify if an MTN-035 PTID has previously been assigned)   * First attempt 🡪Document recruitment source. CONTINUE * Re-screen attempt 🡪 CONTINUE.   *Note: Only one re-screen permitted per participant.* |  |
|  | Explain, conduct, and document the informed consent process. Complete **Informed Consent Coversheet** and **IC****Comprehension Assessment**, per site SOP:   * Willing and able to provide written informed consent 🡪 CONTINUE. * NOT willing and able to provide written informed consent 🡪 STOP. NOT ELIGIBLE. |  |
|  | Log into Medidata Rave and generate PTID (if not done during a previous screening attempt). Open the Screening Visit folder to begin CRF data entry. Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**. |  |
|  | Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**. |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Obtain and record locator information and determine adequacy:   * Adequate locator information 🡪 CONTINUE. * Inadequate locator information 🡪 PAUSE and re-assess:   + Adequate information likely to be available prior to enrollment 🡪 CONTINUE.   + Adequate information NOT likely to be available 🡪 STOP. NOT ELIGIBLE. |  |
|  | Complete **Screening Date of Visit eCRF**. |  |
|  | Administer **Demographics eCRF**. |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet**   * ELIGIBLE thus far 🡪 CONTINUE. * NOT ELIGIBLE 🡪 STOP. |  |
|  | Collect mid-stream catch urine (15-60 mL) and perform tests:   * NAAT for GC/CT/TV * **FOR INDIVIDUALS WHO CAN GET PREGNANT:** Qualitative hCG (pregnancy) * NOT pregnant 🡪 CONTINUE. * Pregnant 🡪 STOP. NOT ELIGIBLE. * ***(If indicated):***  Dipstick urinalysis and/or culture, per site SOP   *NOTE: If symptomatic and diagnosed with a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.*  Document GC/CT/TV 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**. |  |
|  | **FOR INDIVIDUALS WHO CAN GET PREGNANT:** Review study contraception requirements and provide contraceptive counseling, per protocol. Determine current contraceptive method. Effective study methods, per protocol, include:   * hormonal methods (≥30 days prior to Enrollment) * intrauterine device (IUD) (≥30 days prior to Enrollment) * sterilization of participant or partner * Receptive vaginal-penile intercourse (RVI) abstinence (≥90days prior to Enrollment)   [Prescribe/provide/refer for] contraception if needed. Document contraceptive method on **Concomitant Medications Log eCRF** orin **chart notes (RVI abstinence or sterilization)** or *[add site-specific form if desired]***.** |  |
|  | Collect baseline medical and medications history using the Baseline Medical History Guide. Document on the **Medical History Summary/Log eCRFs** and **Concomitant Medications Summary/Log eCRFs**. |  |
|  | 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.   * 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 🡪Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→STOP →INELIGIBLE * NEGATIVE OR INDETERMINATE→CONSULT LC   *The following applies to sites running two rapid tests:*   * If both tests negative → UNINFECTED → CONTINUE. * If both tests positive OR discordant → Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→STOP →INELIGIBLE * NEGATIVE OR INDETERMINATE→CONSULT LC   Document results on **HIV Test Results eCRF.** |  |
|  | 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. |  |
|  | Perform full physical exam and complete the **Vital Signs eCRF** and **Physical Exam eCRF.** |  |
|  | Collect pharyngeal swab 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.* |  |
|  | Collect two (2) vaginal swabs for NAAT for GC/CT/TV. Document results on the **STI Test Results** eCRF.  *If clinically indicated, perform pelvic examination and collect vaginal swab (as part of the exam) per Pelvic Exam Checklist. Document findings on the Pelvic Exam Diagrams Form and Pelvic Exam eCRF.* |  |
|  | Perform anorectal exam and collect rectal swabs for GC/CT/HSV per Anorectal Exam Checklist. Document findings on the Anorectal Exam eCRF and sample collection on the **STI Test Results eCRF**. |  |
|  | Evaluate findings identified during rectal and physical examinations (if indicated, pelvic and genital exams) and medical history review. Determine whether participant has current RTI/STI/UTI symptoms:   * No symptoms 🡪 CONTINUE. * Symptom(s) present 🡪 evaluate per site SOPs. 🡪 STOP. MAY BE INELIGIBLE.   *If symptomatic and diagnosed with an RTI/STI/UTI, t*reat or refer for clinically indicated treatment*, per site SOP. The participant must complete treatment and all symptoms must resolve to be eligible for enrollment.* |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |
|  | Document referrals in chart notes and update **Concomitant Medications Log** **eCRF**, if treatment provided or prescribed. Document relevant ongoing conditions on the **Medical History Log** **eCRF**. |  |
|  | Assess participant’s current eligibility status:   * ELIGIBLE thus far 🡪 CONTINUE. * NOT ELIGIBLE but likely to meet eligibility criteria during this screening attempt 🡪 PAUSE. Schedule Enrollment Visit when participant is likely to be eligible. * NOT ELIGIBLE and NOT likely to meet eligibility criteria during this screening attempt 🡪 STOP. Provide clinical management and referrals as needed. |  |
|  | 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. * **Screening Behavioral Eligibility Worksheet** to ensure all items are complete and to verify participant eligibility. * **Demographics CRF, Vital Signs CRF, and Physical Exam CRF, Anorectal Exam, (**clinically indicated CRFs/forms: Genital Exam, Pelvic Exam Diagrams, Pelvic Exam CRF**)** * **Medical History Log** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently. * All CRFs for completeness and accuracy, based on participant responses and clinical findings. * **Chart notes** to ensure completeness and accuracy. |  |
|  | Provide protocol adherence counseling, including review of prohibited practices and medications. Document on **Protocol Counseling Worksheet**. |  |
|  | Provide any other study informational materials (e.g. factsheet), site contact information, and instructions to contact the site for additional information and/or counseling, [add site specific list if desired], before the next visit. |  |
|  | Determine last possible enrollment date for this screening attempt (within 45 days) using the **Participant** **Visit Calendar Tool.**   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  | | Day | |  | Month | | |  | Year | | | |     Schedule next visit and advise of potential length of next visit. |  |
|  | Provide reimbursement per site SOPs. |  |
|  | If participant **will proceed** to Enrollment, leave the Eligibility Checklist **blank** and complete form along with the **Inclusion/Exclusion Criteria eCRF** *at the Enrollment Visit*.  If participant **will not proceed** to Enrollment, complete and submit the **Inclusion/Exclusion Criteria eCRF.** Other CRFs that were completed during the failed screening attempt may remain in the study database and will not undergo QC review. |  |
|  | Perform QC2. Review participant chart contents, paper forms and EDC data:  **Case Report Forms:**   * Screening Date of Visit * Demographics * Vital Signs * Physical Exam * Anorectal Exam * STI Test Results * HIV Test Results * Syphilis Serology * Pregnancy Test Result (*for individuals who can get pregnant*) * Medical History Summary/Log * Concomitant Medications Summary/Log * Inclusion/Exclusion Criteria, *if applicable* * Genital Exam, *if applicable* * Pelvic Exam, *if applicable*   **Paper Forms:**   * Informed Consent Coversheet * Informed Consent Comprehension Assessment * PTID Name Linkage Log * Screening and Enrollment Log * Screening Behavioral Eligibility Worksheet * HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet * Protocol Counseling Worksheet * Participant Visit Calendar Tool, *if applicable* * Genital Exam Checklist, *if applicable* * Pelvic Exam Diagrams, *if applicable* * Pelvic Exam Checklist, *if applicable* |  |
| **Comments:** | | |