**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.
 |  |
| 1.
 | 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:** |