**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. Use a new Screening Visit Checklist if a second screening attempt is needed.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity and age per site SOPs. * 18 years or older 🡪 CONTINUE.
* Under 18 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.

*NOTE: Participation in studies involving drugs, medical devices, genital or rectal products, or vaccines within 45 days of enrollment is exclusionary.*   |  |  |
|  | Determine screening attempt (Verify if a MTN-037 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 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 **Screening Date of Visit CRF** |  |  |
|  | 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.
 |  |  |
|  | Administer **Demographics CRF**  |  |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Collect baseline medical, menstrual (as applicable), medications history using the Baseline Medical History Guide and complete:* **Baseline Medical History Summary/ Log CRFs**
* **Concomitant Medications Summary/ Log CRFs**
 |  |  |
|  | Collect urine (15-60 mL) and perform tests:* **FOR FEMALES:** Qualitative hCG (pregnancy)
* NAAT for GC/CT
* Dipstick urinalysis and/or culture per site SOP***, if indicated***

*NOTE: If symptomatic and diagnosed with a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.* |  |  |
|  | **FOR FEMALES:** Confirm and document pregnancy results:* NOT pregnant ⇒ CONTINUE.
* Pregnant ⇒ STOP. NOT ELIGIBLE.

Complete **Pregnancy Test Results CRF** upon receipt of lab test results. |  |  |
|  | Using the **Protocol Counseling Worksheet,** provide and document required elements of protocol counseling at screening, namely contraceptive counseling for female participants. **FOR FEMALES:** Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD) inserted\*
* sterilization of participant or partner\*
* self-identifies as having sex with women exclusively.

[Prescribe/provide/refer for] contraception if needed; if applicable, document current contraceptive method on **Concomitant Medications Log**.*\*To occur at least 42 days prior to Enrollment.* |  |  |
|  | Provide and document HIV pre-testing and HIV/STI risk reduction counseling, including offering male/female 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
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets and differentials
	+ [X] mL [color] top [additive/no additive] tube
* Blood creatinine, AST, and ALT
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube
* Coagulation (PT/INR)
	+ [X] mL [color] top [additive/no additive] tube
 |  |  |
|  | 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. * If negative 🡪UNINFECTED 🡪 CONTINUE.
* If positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm to determine eligibility

Document HIV test results on **HIV Test Results CRF.**  |  |  |
|  | Perform full physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF.** |  |  |
|  | Collect pharyngeal sample for NAAT for GC/CT and send to lab. Collect pharyngeal sample for NAAT for GC/CT and send to lab. |  |  |
|  | Perform and document the following, including specimen collection, per the **Genital Exam Checklist.*** Rectal exam
* Male genital exam***, if indicated***
* **FOR FEMALES:** Pelvic Exam***, if indicated***
 |  |  |
|  | Determine whether participant has current RTI/STI/UTI symptoms:* No symptoms 🡪 CONTINUE.
* Symptom(s) present 🡪 evaluate per site SOPs. Treat or refer for treatment *if indicated\** 🡪 STOP. MAY BE INELIGIBLE.

Document provision of results, treatment and/or referrals in chart notes.*\* If symptomatic and is diagnosed with an RTI/STI/UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment. Treat if indicated per site SOP.* |  |  |
|  | Evaluate findings identified during genital and physical examinations and medical history review. Document in chart notes and update **Concomitant Medications Log** **CRF**, if applicable. Document ongoing conditions on the **Baseline Medical History Log** **CRF**. Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Assess participant’s current eligibility status:* ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt 🡪 PAUSE. Perform and document relevant outcomes of all clinically indicated procedures. Schedule Enrollment Visit when participant is likely to be eligible.
* NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt 🡪 STOP. Provide clinical management and referrals as needed.
 |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* This visit checklist and genital exam checklist to ensure all required procedures were completed
* **Screening Behavioral Eligibility Worksheet** ensure all items are complete and to verify participant eligibility.
* All CRFs are completed and accurate based on participant response and clinical findings
* **Baseline Medical History Log** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently.
* **Chart notes** to ensure complete and accurate.
 |  |  |
|  | Provide any other study informational materials, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit: *[add site-specific list if desired]* |  |  |
|  | Determine last possible enrollment date for this screening attempt (within 45 days) using the **Participant** **Visit Calendar Tool.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |
| Mon |  | Day |  | Year |

 Schedule next visit and advise of potential length of next visit.  |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to Enrollment, leave **Eligibility Checklist** blank and complete form along with the **Eligibility Criteria CRF** *at Enrollment Visit*.If participant will not proceed to Enrollment, complete the **Eligibility Checklist.** Complete and submit **Eligibility Criteria CRF.** 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. Review participant chart contents and EDC data: Required CRFs* Screening Date of Visit
* Demographics
* Vital Signs
* Physical Exam
* Anorectal Exam and Sigmoidoscopy
* Pelvic Exam (for females)
* Hematology
* Local Laboratory Results
* STI Test Results
* HIV Test Result
* Pregnancy Test Result
* Eligibility Criteria

*If indicated/applicable:** Baseline Medical History Summary/ Log *(if pre-existing conditions are reported)*
* Concomitant Medications Summary/ Log *(if medications are reported)*

Paper Forms:* Informed Consent Coversheet
* Informed Consent Comprehension Assessment
* PTID Name Linkage Log
* Screening and Enrollment Log Form
* Screening Behavioral Eligibility Worksheet
* Baseline Medical History Questions Form
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable*
* Eligibility Checklist, *if applicable*
* Participant Visit Calendar Tool, *if applicable*
 |  |  |