| **MTN-033 Screening Visit Checklist** |
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| **Procedures** | **Staff Initials** |
|  | Confirm identity, per site SOP. Assess age eligibility and proceed accordingly. * ≥ 18 years old🡪 CONTINUE.
* < 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 after the Screening Visit and while taking part in MTN-033 unless approved by the PSRT is exclusionary.* |  |
|  | Determine screening attempt (Verify if MTN-033 PTID has previously been assigned)* First attempt 🡪 CONTINUE.
* Second attempt 🡪 CONTINUE.
 |  |
|  | Explain, conduct, and document the informed consent process. Complete **Informed Consent Coversheet** and **Informed Consent 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.
 |  |
|  | Generate PTID (if not done during a previous screening attempt). Complete **Screening and Enrollment Log** and **PTID Name Linkage Log**. |  |
|  | Complete **Screening Date of Visit CRF**. |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Document behavioral eligibility on **Screening Behavioral Eligibility Worksheet**:* Eligible 🡪 CONTINUE.
* Not Eligible but likely to meet eligibility criteria within this screening attempt 🡪 PAUSE 🡪 Schedule Enrollment Visit when eligibility is likely.
* Not Eligible and Not likely to meet eligibility criteria within this screening attempt 🡪 STOP.
 |  |
|  | Obtain locator information, determine adequacy per site SOPs and document on site specific document:* Adequate locator information 🡪 CONTINUE.
* Inadequate locator information 🡪 PAUSE and re-assess.
* Adequate information NOT likely to be available 🡪 STOP. NOT ELIGIBLE.
 |  |
|  | Complete **Demographics CRF**. |  |
|  | Collect baseline medical and medications history using the **Baseline Medical History Questions Guide** and complete:* **Baseline Medical History Summary/Log CRFs**
* **Concomitant Medications Summary/Log CRFs**
 |  |
|  | Perform full physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF**.  |  |
|  | Administer pharyngeal swab for GC/CT. Complete **STI Test Results CRF** upon receipt of lab results. |  |
|  | Collect urine (15-60 mL) for required testing: * NAAT GC/CT
* Dipstick urinalysis and/or culture, per site SOP, if indicated

Document results on site-specific form and **STI Test Results CRF**. |  |
|  | Administer 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 blood for required testing:* CBC with differential and platelets \_\_\_ mL [tube type]
* AST, ALT \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* Syphilis serology\_\_\_ mL [tube type]
* HIV 1/2 serology \_\_\_ mL [tube type]
* HBsAg\_\_\_ mL [tube type]
* HCV serology\_\_\_ mL [tube type]
* Coagulation (PT/INR) \_\_\_ mL [tube type]

When results are available, document on **Local Laboratory Results CRF**, **Hematology CRF, STI Test Results CRF** and **HIV Test Results CRF**, as applicable. Document any Grade 1 or higher lab results on the **Baseline Medical History Log 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 if needed/requested per site SOPs. * If HIV negative 🡪 UNINFECTED 🡪 CONTINUE.
* If HIV positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm to determine eligibility.
 |  |
|  | Perform and document genital and rectal examinations using the **Genital Exam Checklist** and complete the **Genital Exam CRF** and **Anorectal Exam CRF**. Add relevant findings to **Baseline Medical History Log CRF**. |  |
|  | 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 diagnosed with an UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.*  |  |
|  | Evaluate findings identified during genital, rectal and physical examinations and medical history review. Document relevant conditions on the **Baseline Medical History Log CRF and** update **Concomitant Medications Log CRF**, if applicable. Provide and explain all available findings and results. Refer for other findings, as indicated. |  |
|  | Assess participant’s current eligibility status, per **Eligibility Checklist**:* 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.
 |  |
|  | Provide and document protocol adherence messaging using **Protocol Counseling Worksheet**.  |  |
|  | Perform QC1 review while participant is still present. Review the following:* This **Screening Visit Checklist** and **Genital Exam Checklist**, to ensure that all required procedures have been completed.
* **Screening Behavioral Eligibility Worksheet**, **Eligibility Checklist** and **Demographics CRF** to ensure that all items are complete and to verify participant eligibility.
* **Anorectal Exam CRF**, **Genital Exam CRF**, **Vital Signs CRF** and/or **Physical Exam CRF** to ensure all findings are clearly documented.
* **Baseline Medical History Log CRF,** and **Concomitant Medications Log CRF** to ensure all conditions and medications are captured consistently.
* **Chart notes** to ensure completeness and accuracy.
 |  |
|  | Provide contact information and instructions for contacting the site for additional information and/or counseling, if needed, before the next visit. |  |
|  | Provide reimbursement. |  |
|  | Determine last possible enrollment date for this screening attempt (30 days), using the **Visit Calendar Tool**. DD MON YY  |  |
|  | Schedule next visit taking into consideration the length of time required to receive lab results. Advise participant of potential length of next visit.  |  |
|  | If participant will proceed to Enrollment, leave **Eligibility Checklist** blank and complete form at Enrollment Visit along with **Inclusion/Exclusion Criteria CRF**.If participant will not proceed to Enrollment, complete the **Eligibility Checklist.** Complete and submit **Inclusion/Exclusion Criteria CRF.** Other CRFs that were completed during the failed screening attempt may remain in the study database, and will not undergo QC review. |  |
| **POST-VISIT PROCEDURES** |
|  | Ensure that data is entered into Medidata Rave and perform QC2 review, ensuring all data entered is accurate and complete.Required CRFs* Anorectal Exam
* Demographics
* Genital Exam
* Hematology
* HIV Test Results
* Inclusion/Exclusion Criteria
* Local Laboratory Results
* Physical Exam
* Screening Date of Visit
* STI Test Results
* Vital Signs
* Baseline Medical History Summary
* Concomitant Medications Summary

Log CRFs (if applicable)* Baseline Medical History Log (*if pre-existing conditions are reported)*
* Concomitant Medications Log *(if medications are reported)*
* Protocol Deviations Summary/Log

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

**Additional Notes/Comments/Referrals:**