| **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:**