| **Screening Visit Checklist** | | |
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| **Procedures:** | | **Staff Initials** |
|  | Confirm identity and age per site SOPs.   * Yes ==> CONTINUE. * No ==> STOP. NOT ELIGIBLE.   Note: [If female and on menses, reschedule screening visit within the window.] |  |
|  | Check for co-enrollment in other studies:   * NOT enrolled in another study ⇒ CONTINUE. * Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY. CONSULT PSRT as needed. |  |
|  | Determine screening attempt (Verify if MTN-026 PTID has previously been assigned)   * First attempt ==>CONTINUE. * Second attempt ==> CONTINUE. |  |
|  | Explain, conduct, and document the informed consent process for potential participant. Review and provide information booklet to participant. Complete **Informed Consent Coversheet** and **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**. |  |
|  | 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 participant is likely to be eligible. * Not Eligible and Not likely to meet eligibility criteria within this screening attempt ==> STOP |  |
|  | Obtain locator information and determine adequacy per site SOPs:   * Adequate locator information ⇒ CONTINUE. * Inadequate locator information ⇒ PAUSE and re-assess. * Adequate information NOT likely to be available ==> STOP. NOT ELIGIBLE. |  |
|  | Administer **Demographics CRF**. |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. Document on the **Baseline Medical History Questions Sheet**, **Baseline Medical History Summary/Log CRFs, Screening Menstrual History CRF** and **Concomitant Medications Summary/Log CRF** as needed. |  |
|  | Females participants: determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs. [Prescribe/provide/refer for] contraception if indicated per site SOP; Document contraceptive counseling using Contraceptive Counseling Worksheet. |  |
|  | Perform and document full physical examination on the **Physical Exam CRF**. Add relevant findings to **Baseline Medical History Log CRF.** |  |
|  | Obtain vitals and document on **Vital Signs CRF**. |  |
|  | Collect (15-60 mL) urine for the following testing. Complete **STI Tests CRF** and **Pregnancy Test CRF** (if female) upon receipt of lab test results:   * NAAT GC/CT * Qualitative hCG (if female) * Dipstick urinalysis (if indicated) * Urine culture (if indicated)   NOTE: If participant is symptomatic and is diagnosed with a UTI, treatment must be completed and all symptoms must resolve before participant is eligible for enrollment. |  |
|  | Female participants: Perform pregnancy test:   * NOT pregnant ⇒ CONTINUE. * Pregnant ⇒ STOP. NOT ELIGIBLE. |  |
|  | Provide and document HIV/STI risk reduction counseling and testing using 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 serology \_\_\_ mL [tube type] * HSV 1/2 serology\_\_\_ mL [tube type] * HBsAg\_\_\_ mL [tube type] * HCV serology\_\_\_ mL [tube type] * Coagulation (INR/PT) \_\_\_ mL [tube type]   Review lab results when available and enter applicable results on the **Hematology CRF, Local Laboratory Results CRF, HIV Test Results CRF** and **STI Tests CRF**. Add any grade 1 or higher labs to **Baseline Medical History Log CRF.** |  |
|  | Provide test results and post-test counseling using HIV Pre/Post Test and Risk Reduction Counseling Worksheet; provide/document referrals if needed/requested. |  |
|  | Perform and document genital examination on the Genital Exam Checklist, **Anorectal Exam CRF, Pelvic Exam CRF** and **Pelvic Exam Diagrams** (as applicable). Add relevant findings to **Baseline Medical History Log CRF**. |  |
|  | Evaluate any abnormal findings. Explain test results and exam findings. If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document provision of results, treatments and referrals in chart notes.   * Symptom(s) present ⇒ evaluate per site SOPs. If treatment is required ⇒ STOP. MAY BE INELIGIBLE. * No symptoms ⇒ CONTINUE. |  |
|  | Provide and explain all available findings and results. |  |
|  | 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 ==> 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 this visit checklist and genital exam checklist to ensure all required procedures were completed. * Review [add site-specific pelvic exam, vital signs, and physical exam source documents, or Anorectal Exam CRF, Pelvic Exam Diagrams, Pelvic Exam CRF, Vital Signs CRF and/or Physical Exam CRF if source] to ensure all findings are clearly documented. * Review Screening Menstrual History CRF, Baseline Medical History Questions, Baseline Medical History Log CRF, and Concomitant Medications Log CRF to ensure all conditions and medications are captured consistently.   Briefly review Demographics CRF, Screening Behavioral Eligibility Worksheet, and chart notes to ensure completeness and accuracy. |  |
|  | Provide contact information and instructions to contact the site for additional information and/or counseling if needed before the next visit. |  |
|  | Provide reimbursement. |  |
|  | Schedule Enrollment Visit and determine last possible enrollment date for this screening attempt using visit calendar tool (+45 days):    DD MON YY |  |
|  | Schedule next visit taking into consideration the length of time required to receive lab results and participant’s menses (if female), as applicable. Advise participant of potential length of next visit. |  |
|  | If participant will not proceed to Enrollment, complete Eligibility Checklist and Eligibility Criteria CRF, selecting the applicable inclusion and/or exclusion criteria that contributed to the participant’s study ineligibility as applicable. For failed screening attempts, the only CRFs that require completion is the Eligibility Criteria CRF. Other CRFs that were completed during the failed screening attempt may remain in the study database.  If participant will proceed to Enrollment, complete the Eligibility Checklist and Eligibility Criteria CRF at the Enrollment Visit.  For successful screening attempts, ensure that data is entered into the study database (and perform QC2 review, if applicable) for the following required CRFs:   * Participant Date of Visit * Eligibility Criteria, if applicable * Demographics * Concomitant Medications Summary * Concomitant Medications Log (if medications are reported) * Screening Menstrual History (female participants only) * Baseline Medical History Summary * Baseline Medical History Log (if baseline conditions are reported) * Pelvic Exam (female participants only) * Pelvic Exam Diagrams (female participants only)Vital Signs * Physical Exam * Anorectal Exam * Local Laboratory Results * Hematology * STI Tests * Pregnancy Test (female participants only) * HIV Test Results |  |

**Additional Notes/Comments/Referrals:**