**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.

| **Screening Visit Checklist** | | | |
| --- | --- | --- | --- |
| **Procedure** | | **Staff Initials** | **Comments:** |
| 1. 1 | Confirm identity, age, and prescreening ID per site SOP  *Note: if participant presents for screening and does not have a prescreening ID already assigned, complete this process* |  |  |
| 1. 2 | Check for co-enrollment   * NOT currently or recently enrolled in another study ==> CONTINUE. Enter in co-enrollment database. * Currently or recently enrolled in another study ==> STOP. Assess eligibility to continue.   *NOTE: Participation in studies involving drugs, medical devices, vaginal products, or vaccines within 60 days of enrollment is exclusionary.* |  |  |
| 1. 3 | Explain, conduct, and document screening informed consent process:   * Willing and able to provide written informed consent ==> CONTINUE. * NOT willing and able to provide written informed consent ==> STOP. NOT ELIGIBLE. |  |  |
| 1. 4 | Determine screening attempt number (check if MTN-025 Screening ICF has been previously signed): \_\_\_\_\_\_\_\_\_\_\_ (write in) |  |  |
| 1. 5 | Assign PTID (if not done during a previous screening attempt or as part of HOPE decliner enrollment) by completing a row on the PTID name-linkage log |  |  |
| 1. 6 | Enter PTID onto Screening and Enrollment Log |  |  |
| 1. 7 | Obtain 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. |  |  |
| 1. 7 | Administer Demographics CRF and Screening Behavioral Eligibility Worksheet   * ELIGIBLE thus far ==> CONTINUE. * NOT ELIGIBLE ==> STOP. |  |  |
| 1. 8 | Provide and document HIV pre-test counseling |  |  |
| 1. 9 | Perform and document two Finger Stick HIV tests. *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* |  |  |
| 1. 11 | Collect first catch urine (15-60 mL) and send to lab for:   * Urine hCG (pregnancy) * NAAT for GC/CT * Urine culture if indicated (per standard of care) |  |  |
|  | Collect blood and send to lab for required testing:   * X x X mL lavender top (EDTA) tube, for CBC with platelets, HIV test (*if not doing fingerstick)* * X x X mL red top (no additive) tube, for chemistries and syphilis serology |  |  |
| 1. 12 | Collect baseline medical, menstrual, medications history: complete Baseline Medical History Questions, Baseline Medical History Log CRF, and Concomitant Medications Log CRF. |  |  |
|  | Perform physical exam with measurement of height and weight: complete Vital Signs CRF, Physical Exam CRF and Baseline Medical History Log CRF (as needed) |  |  |
|  | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
|  | Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling. |  |  |
|  | Review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant ==> STOP. NOT ELIGIBLE. |  |  |
|  | Prescribe contraceptives if indicated. |  |  |
| 1. 13 | If STI/RTI/UTI is diagnosed, provide treatment. Participant must complete treatment and be free of symptoms prior to enrollment. |  |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 1. 14 | Provide HIV test results in the context of post-test counseling. Provide referrals if needed/requested.   * If both tests negative ==> UNINFECTED ==> ELIGIBLE ==> CONTINUE. * If both tests positive ==> INFECTED ==> STOP. NOT ELIGIBLE. * If one test positive and one test negative ==> DISCORDANT ==> STOP. NOT ELIGIBLE. ==> Submit HIV Query form to inform LC, collect *blood and perform a Geenius confirmatory test and plasma viral load (HIV RNA PCR).* |  |  |
|  | Provide and document HIV risk reduction counseling, including offering condoms. |  |  |
| 1. 15 | 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. |  |  |
| 1. 16 | Perform QC1 review while participant is still present:   * Review interviewer-administered Screening Behavioral Eligibility Worksheet to ensure all items are complete * Review Pelvic Exam Diagrams, Pelvic Exam CRF, Vital Signs CRF, and Physical Exam CRF to ensure all findings are clearly documented. * Review Baseline Medical History Questions, Baseline Medical History Log, Concomitant Medications Log to ensure all conditions and medications are captured consistently * Briefly review chart notes to ensure complete and accurate |  |  |
| 1. 17 | Provide study informational material (e.g. factsheets), 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]* |  |  |
| 1. 18 | Determine last possible enrollment date for this screening attempt (56 days):  \_ \_ /\_ \_ \_/ \_ \_ (DD/MMM/YY)  Schedule next visit and advise her of potential length of next visit. |  |  |
| 1. 19 | Provide Reimbursement |  |  |
| 1. 20 | If participant will not proceed to Enrollment, complete Eligibility Checklist. Complete and submit Eligibility Criteria CRF.  If participant will proceed to Enrollment, complete and submit Eligibility Criteria CRF at the Enrollment Visit. |  |  |
|  | Assemble all completed CRFs for the Screening Visit. Do not submit until participant has enrolled into the study:   * Demographics * Pelvic Exam * Vital Signs * Physical Exam * Laboratory Results * STI Test Results * Baseline Medical History Log * Concomitant Medications Log * Pelvic Exam Diagrams * Screening Visit LDMS Specimen Tracking Sheet, if using * Screening Behavioral Eligibility Worksheet |  |  |
| 1. 21 | Once all applicable laboratory results are available, add any Grade 1 or higher values to Baseline Medical History Log (unless captured under a diagnosis) and reassess eligibility as needed. |  |  |
| 1. 22 | Enter PTID into Participant Tracking Database (or site-specific tracking system/log) |  |  |