**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) |  |  |