**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 “N/D” for “not done” or “N/A” 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 | Confirm identity and age and whether she is on her menses currently. *[If on menses, reschedule screening visit.]* |  |  |
| 2 | Check for co-enrollment or prior enrollment into ASPIRE   * NOT currently enrolled in another study, including ASPIRE ==> CONTINUE. Enter in co-enrollment database. * Currently enrolled in another study ==> STOP. NOT ELIGIBLE. |  |  |
| 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. |  |  |
| 4 | Determine screening attempt number (check if MTN-020 PTID has previously been assigned):   * First attempt ==> Document recruitment source *[specify site-specific procedures]*, CONTINUE * Second attempt ==> CONTINUE (Note: max of two attempts allowed) |  |  |
| 5 | Assign PTID (if not done during a previous screening attempt) and enter PTID onto Screening and Enrollment Log |  |  |
| 6 | 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. |  |  |
| 7 | Administer Demographics and Screening Behavioral Eligibility CRFs   * ELIGIBLE thus far ==> CONTINUE. * NOT ELIGIBLE ==> STOP. |  |  |
| 8 | Provide and document counseling:   * HIV pre-test counseling * HIV/STI risk reduction counseling * Provide Condoms |  |  |
| 9 | Perform and document two Finger Stick HIV tests. *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]* |  |  |
| 10 | 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. ==> Contact NL for follow-up |  |  |
| 11 | Collect first catch urine (15-60 mL) and send to lab for:   * Urine hCG (pregnancy) * NAAT for GC/CT |  |  |
| 12 | Collect baseline medical, menstrual, medications history: complete Screening Menstrual History, Baseline Medical History Questions, Pre-existing Conditions, and Concomitant Medications Log CRFs. |  |  |
| 13 | Collect blood and send to lab for required testing:   * X x X mL lavender top (EDTA) tube, for [*CBC*] * X x X mL red top (no additive) tube, for [*chemistries, syphilis*] |  |  |
| 14 | Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling. |  |  |
| 15 | Prescribe contraceptives if indicated. |  |  |
| 16 | Review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant ==> STOP. NOT ELIGIBLE. |  |  |
| 17 | Perform physical exam with measurement of height and weight – complete Screening Visit Physical Exam CRF. |  |  |
| 18 | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
| 19 | If STI/RTI/UTI is diagnosed, provide treatment. Participant must complete treatment and be free of symptoms prior to enrollment. |  |  |
| 20 | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 21 | 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. |  |  |
| 22 | Perform QC1 review while participant is still present:   * Review interviewer-administered Screening Behavioral Eligibility CRF to ensure all items are complete * Review Pelvic Exam Diagrams, Screening Pelvic Exam, and Screening Visit Physical Exam CRF to ensure all findings are clearly documented. * Review Baseline Medical History Questions, Screening Menstrual History, Pre-existing Conditions, Con Meds Log to ensure all conditions and medications are captured consistently * Briefly review chart notes to ensure complete and accurate so far |  |  |
| 23 | Provide study informational material, 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]* |  |  |
| 24 | Determine last possible enrollment date for this screening attempt (28 days):  \_ \_ /\_ \_ \_/ \_ \_ (DD/MMM/YY)  Schedule next visit and advise her of potential length of next visit. [Try to avoid scheduling enrollment during her menses.] |  |  |
| 25 | Provide Reimbursement |  |  |
| 26 | If participant will not proceed to Enrollment, complete Eligibility Checklist and complete and fax Eligibility Criteria CRF.  If participant will proceed to Enrollment, move Eligibility Criteria CRF to Enrollment Visit form packet and complete at Enrollment Visit. |  |  |
| 27 | Assemble all completed CRFs for the Screening Visit. Do not fax until participant has enrolled into the study:   * Demographics * Screening Pelvic Exam * Screening Visit Physical Exam * Screening Menstrual History * Screening Laboratory Results * Screening STI Test Results * Pre-existing Conditions * Concomitant Medications Log * Screening Specimen Storage * Pelvic Exam Diagrams (non-DataFax) * Screening Visit LDMS Specimen Tracking Sheet, if using (non-DataFax) * Screening Behavioral Eligibility (non-DataFax) |  |  |
| 28 | Once all applicable laboratory results are available, add any Grade 1 or higher values to Pre-existing Conditions (unless captured under a diagnosis) |  |  |
| 29 | Enter PTID onto Participant Tracking Database (or site-specific tracking system/log) |  |  |