| **Screening Visit (Visit 1.0) Checklist** |
| --- |
| **Procedure** | **Staff Initials** | **Comments:** |
| 1. 1
 | Confirm identity and age. |  |  |
|  | Check for co-enrollment * NOT currently enrolled in another study ==CONTINUE.
* Currently enrolled in another study ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Determine screening attempt (Verify if PTID has previously been assigned). Only a total of two screening attempts are allowed. |  |  |
|  | Explain, conduct, and document informed consent process:* Willing and able to provide written informed consent ==> CONTINUE.
* NOT willing and able to provide written informed consent ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Assign PTID (if not done during a previous screening attempt). Complete PTID Name Linkage Log and Screening and Enrollment Log. |  |  |
|  | Obtain locator information using site-specific form and determine adequacy:* Adequate locator information ==> CONTINUE.
* Inadequate locator information ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Assess participant behavioral eligibility using the Screening Behavioral Eligibility Worksheet* ELIGIBLE thus far ==> 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
 |  |  |
|  | Explain procedures to be performed at today’s visit. |  |  |
|  | Administer Demographics CRF |  |  |
|  | Provide and document counseling:* HIV pre-test counseling
* HIV/STI risk reduction and male condom counseling (provide male condoms if needed)
 |  |  |
|  | Collect (15-60 mL) urine for the following testing. Complete [*add site-specific laboratory testing source document]* upon receipt of lab test results:* hCG (pregnancy testing)
* Dipstick urinalysis and/or culture per site SOP (if indicated)
 |  |  |
|  | Review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant ==> STOP. NOT ELIGIBLE.
 |  |  |
|  | Collect baseline medical, menstrual, medications history: complete Screening Menstrual History, Baseline Medical History Questions Sheet, Pre-existing Conditions CRF, and Concomitant Medications Log CRF.  |  |  |
|  | Collect blood for : * CBC with platelets

**Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.*** Serum Chemistries
* HIV serology
* Syphilis
* FSH

Review HIV test results:* HIV negative ==> CONTINUE.
* HIV positive ==> STOP. NOT ELIGIBLE.

Transcribe results onto Safety Laboratory Results CRF, HIV Results CRF once available. |  |  |
|  | Perform physical exam. Complete Physical Exam CRF. |  |  |
|  | Perform and document pelvic exam per Pelvic Exam Checklist. |  |  |
|  | 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. |  |  |
|  | 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.
 |  |  |
|  | Perform QC1 review while participant is still present:* Review Pelvic Exam Diagrams, Pelvic Exam, and 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
 |  |  |
|  | 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]*  |  |  |
|  | Determine last possible enrollment date (45 days): \_ \_ /\_ \_ \_/ \_ \_ (DD/MMM/YY)Schedule next visit and advise her of potential length of next visit.  |  |  |
|  | Provide reimbursement |  |  |
|  | If participant will not proceed to Enrollment, complete ‘Screening Visit’ column of Eligibility Checklist and complete and fax Eligibility Criteria CRF.If participant will proceed to Enrollment, move Eligibility Checklist and Eligibility Criteria CRF to Enrollment Visit form packet and complete at Enrollment Visit.  |  |  |
|  | Assemble all completed CRFs for the Screening Visit. Do not fax until participant has enrolled into the study:* Demographics
* Pelvic Exam
* Physical Exam
* Safety Laboratory Results
* HIV Results
* STI Test Results
* Pre-existing Conditions
* Concomitant Medications Log
* Pelvic Exam Diagrams (non-DataFax)
 |  |  |
|  | Once all applicable laboratory results are available, update all applicable forms and CRFs based on lab results. |  |  |