**Instructions:** Complete staff initials next to procedures completed for both female and male participants. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, enter, 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.

| **GROUPS 1 and 2 Screening Procedures** | **Female ppt** | **Male ppt** |
| --- | --- | --- |
| 1 | Confirm identity and age per site SOP  |  |  |
| 2 | Check for co-enrollment * NOT currently enrolled in another study ==> CONTINUE.
* Currently enrolled in another study ==> STOP. ASSESS ELIGIBILITY.
 |  |  |
| 3 | Provide brief overview of study procedures and if applicable, request participant to choose study group:* Group 1
* Group 2
* NA, couple screened to complete matched paired visits:

Group:\_\_\_\_\_\_ Matched Pair Visits: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 4 | Explain, conduct, and document applicable screening and enrollment informed consent process:* Conduct IC Comprehension Assessment
	+ Willing and able to provide written informed consent ==> CONTINUE.
	+ NOT willing and able to provide written informed consent ==> STOP. NOT ELIGIBLE.
 |  |  |
| 5 | Determine screening attempt number * First attempt
* Second attempt ==> maximum of two attempts per group is allowed
 |  |  |
| 6 | Assign PTID (if not done during a previous screening attempt for same Group) |  |  |
| 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.
 |  |  |
| 8 | Administer Demographic CRF  |  |  |
| 9 | Document behavioral eligibility on MTN-011 Eligibility Checklist |  |  |
| 10 | Collect urine (15-60 mL) and send to lab for:* Urine hCG (FEMALE ONLY)
* NAAT for GC/CT
* Urine Culture (if indicated)
 |  |  |
| 11 | Provide and document counseling:* HIV pre-test counseling
* Full HIV/STI risk reduction counseling
 |  |  |
| 12 | Collect 5 mL blood and perform and document HIV testing.  |  |  |
| 13 | Prepare remaining blood for required testing:

|  |  |  |
| --- | --- | --- |
| M | F |  |
|  | ❒ | 5 mL lavender top (EDTA) tube for CBC with platelets (FEMALE ONLY) |
| ❒ | ❒ | 5 mL EDTA, plain, or serum separator tube for syphilis serology |
| ❒ | ❒ | 5 mL EDTA, plain, or serum separator tube for HBsAg |

 |  |  |
| 14 | Collect baseline medical and medications history: document on relevant source documents and case report forms, per site SOPs  |  |  |
| 15 | Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling (FEMALE ONLY).  |  | NA |
| 16 | Perform physical exam– complete Physical Exam CRF for female participants and Physical Exam – Male form (non-DataFax) for male participants. |  |  |
| 17 | Perform and document pelvic exam per Pelvic Exam Checklist (FEMALE ONLY). |  | NA |
| 18 | Perform and document genital exam (MALE ONLY):General inspection via naked eye and if necessary, hand=held magnifying glass of the following:* Internal and external foreskin (if present)
* Entire penile surface
* Shaft
* Glans
* Urethral meatus
* Scrotum
* Inguinal lymph nodes (right and left)
 | NA |  |
| 19 | Instruct male participant to collect semen sample (MALE ONLY) | NA |  |
| 20 | If STI/RTI/UTI is diagnosed, provide treatment.  |  |  |
| 21 | Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
| 22 | 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 ==> 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.
 |  |  |
| 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 (30 days): \_ \_ /\_ \_ \_/ \_ \_ (DD/MMM/YY)Schedule next visit to occur 2-12 days after final day of menses |  |  |
| 25 | Provide Reimbursement |  |  |
| 26  | Assemble all completed CRFs for the Screening Visit. Do not fax until participant has enrolled into the study:* Demographics (for female and male participants)
* Physical Exam
* Pelvic Exam
* Laboratory Results
* STI Test Results
* Pharmacokinetics
* Family Planning
* Pre-existing Conditions
* Concomitant Medications Log (for female and male participants)
* Pelvic Exam Diagrams (non-DataFax)
* Screening Menstrual History (non-DataFax)
* Genital Exam – Male (non-DataFax)
* Physical Exam – Male (non-DataFax)
* LDMS Specimen Tracking Sheet (non-DataFax)
 |  |  |