**Checklist Instructions:** Enter your own initials next to the procedure(s) you completed. Do not initial for other staff members. 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 the entry. If any procedure is not conducted on the visit date recorded above, ensure the date the procedure was conducted is included. Use a new Screening Visit Checklist with a second screening attempt, if applicable.

RED TEXT = REDCap Instrument (direct data entry unless otherwise specified in site Source Document SOP)

GREEN TEXT = MATRIX-002 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| [Review and file screening script, *if applicable*] |  |
| Confirm participant identity, *per site SOP* |  |
| Determine screening attempt*NOTE: only one re-screen is permitted per participant.*  |  |
| Review and obtain written informed consent for Screening and Enrollment in one of the study languages and *per site SOP*, including:* Informed Consent Comprehension Assessment using MATRIX-002 ICCA (T/F)
* IC documentation using MATRIX-002 INFORMED CONSENT COVERSHEET

*Note: IC document includes consent for HIV testing in addition to:* * *Consent for long term storage and future testing of specimens and related health information*
* *Consent to participate in an In-depth Interview*
* *Permission to contact sexual partner*
* *[Consent for off-site visits]*
 |  |
| Second researcher: check IC and ICCA accuracy & completeness while the participant is present |  |
| Assign PTID by completing MATRIX-002 PTID ASSIGNMENT Log  |  |
| Select matching PTID in REDCap. Complete ESTABLISH PTID |  |
| Administer DEMOGRAPHICS [DEM], includes background information |  |
| Review and assess inclusion/exclusion criteria by completing MATRIX-002 ELIGIBILITY CHECKLIST |  |
| Explain procedures to be performed at today’s visit |  |
| Collect medical history using BASELINE MEDICAL HISTORY REVIEW GUIDE, including assessment of RTI/STI/UTI symptoms |  |
| Complete BASELINE MEDICAL AND MENSTRUAL HISTORY |  |
| Collect concomitant meds by completing the CONCOMITANT MEDICATION LOG*Note: Be sure to include hormonal contraceptive method and copper IUD, if applicable* |  |
| Collect urine sample (15-60 mL) and perform: * pregnancy test (required)
* dipstick urinalysis per site SOP, *only if indicated and/or per local SOC*
* urine culture per site SOP, *only if indicated and/or per local SOC*

Document result(s) on [add site specific form] |  |
| Perform HIV Pre-test Counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| [Sites with CLIA certification: Have participant collect sample and perform HIV Saliva test Document result on site specific form] |  |
| Collect Blood [site may add collection order/tubes/volumes per site’s standards]:* HIV [*not required if HIV saliva test done*]
* CBC
* Serum creatinine
* AST/ALT
* Syphilis serology
 |  |
| Perform full\* SCREENING PHYSICAL EXAM AND VITAL SIGNS (height, weight and BP)Discuss exam findings with participant *\*Per protocol full PE = general appearance, cardiac, respiratory, and abdominal exam* |  |
| Perform PELVIC EXAMINATION (including EXTERNAL GENITAL AND BIMANUAL EXAM) Collect genital samples with speculum in place *in this order*:* GC/CT/TV NAAT test
* NSS/KOH wet mount for candidiasis and/or BV, *as indicated and/or per local SOC*
* Pap test, *if indicated\**

*\**required if unable to provide normal Pap result (Grade 0) within 3 years prior to enrollment Discuss exam findings with participant |   |
| Conduct counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Contraceptive counseling for participants of childbearing potential^
* HIV post-test counseling and HIV/STI risk reduction counseling^
* “Pelvic rest” in Month 1 (after first film is inserted) counseling

*^Provide referrals if needed/requested per site SOP and detail in chart notes* |  |
| Review/provide test results and findings to participant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Required** | **Test result** | **Provided by** | **Date** | **Note** |
| x | HIV |  |  | *If positive test, participant is ineligible* |
| x | Pregnancy |  |  |
| x | GC/CT/TV |  |  |
| x | Syphilis  |  |  |
| x | Hematology & Chemistry |  |  | *Refer to Eligibility Criteria for eligibility parameters* |
|  | Pap smear |  |  |
|  | Other: |  |  |
|  | Other: |  |  |

*NOTE: Treat or prescribe treatment for RTI/UTI/STI if indicated and per local standard of care. Provide referrals if needed. Detail in chart notes.*  |  |
| If participant is diagnosed with symptomatic BV, symptomatic yeast or UTI, offer treatment consistent with WHO recommendations |  |
| Collect adequate locator information, *per site SOP* |  |
| Complete ICF SUMMARY |  |
| Complete HIV, STI and Urine Test Results |  |
| Complete HEMALOGY AND CHEMISTRY RESULTS |  |
| Complete PRE-EXISTING CONDITION LOG*Note: Reminder to include relevant items from medical history, physical exam, pelvic exam, laboratory findings, etc.*  |  |
| Provide reimbursement [sites may add details] |  |
| Assess participant’s current eligibility status:* Eligible thus far, may schedule tentative enrollment
* Not eligible, but likely to become eligible in this screening attempt. Schedule enrollment when participant is likely to be eligible
* NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt. Provide and document referrals as needed. Complete PARTICIPANT DISPOSITION
 |  |
| Schedule next visit (V2 enrollment) Determine last possible enrollment date for this screening attempt using the MATRIX-002 Participant Visit Calendar Tool [last possible enrollment date = \_\_\_\_\_\_\_\_\_\_\_\_\_\_]*NOTE: Enrollment must be scheduled:** *within 45 days of screening*
* *when participant is not expecting menses-like bleeding*
* *when participant is symptom-free, if diagnosed with symptomatic BV, Yeast, UTI at screening*
* *> 7 days after completion of systemic or intravaginal antibiotics, if applicable*
 |  |
| Document visit in a detailed chart note  |  |
| Provide any other study informational materials, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit |  |
| Perform QC1 review while participant is still present, including:* Visit checklist to ensure all relevant procedures were completed during the visit
 |  |
| Perform QC2 review, including REDCap and paper forms* Ensure findings identified during genital, pelvic and/or physical examinations and medical history review are consistent with Concomitant Medications Log and PRE-EXISTING CONDITIONS LOG. Cross reference items from logs for consistency (i.e., con med indication is included as a pre-existing condition)
* Review chart notes to ensure completeness and accuracy
 |  |

REMINDER: Multiple visits may be conducted within the 45-day screening window to complete all required screening procedures including any re-testing, as necessary.

Comments: