**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 = OpenClinica Instrument (direct data entry unless otherwise specified in site Source Document SOP)

GREEN TEXT = MATRIX-001 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-001 ICCA (T/F) * IC documentation using MATRIX-001 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*   + *Consent to participate in rectal fluid sample collections*   + *[Consent for off-site visits]* |  |
| Second researcher: check IC and ICCA accuracy & completeness while the participant is present |  |
| Collect adequate locator information, *per site SOP* |  |
| Administer DEMOGRAPHICS [DEM], includes background information |  |
| Complete ICF SUMMARY |  |
| Assign PTID by completing MATRIX-001 PTID SCREENING AND ENROLLMENT LOG |  |
| Select matching PTID in OpenClinica. |  |
| Collect medical history using BASELINE MEDICAL AND MENSTRUAL 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, if applicable* |  |
| Review and assess inclusion/exclusion criteria by completing MATRIX-001 ELIGIBILITY CHECKLIST and ELIGIBILITY FORM |  |
| Explain procedures to be performed at today’s visit |  |
| Perform full physical\* VITAL SIGNS AND PHYSICAL EXAM (height, weight, BP)  *\*Per protocol full PE = general appearance, cardiac, respiratory, and abdominal exam* |  |
| Collect urine sample (15-60 mL) and perform:   * pregnancy test (required) * urine dipstick/ urinalysis (required) * 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-001 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*] |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| * CBC * Serum creatinine * AST/ALT * HBsAg * Syphilis serology * HSV-2 |  |
| Perform PELVIC EXAM (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 |  |
| Conduct counseling using MATRIX-001 PROTOCOL COUNSELING GUIDE & WORKSHEET:   * Protocol counseling * Contraceptive counseling for participants of childbearing potential^ * HIV post-test counseling and HIV/STI risk reduction counseling^   *^Provide referrals if needed/requested per site SOP and detail in chart notes* |  |
| Review/provide test results and findings to participant |  |
| If participant is diagnosed with symptomatic BV, symptomatic yeast or UTI, offer treatment consistent with WHO recommendations |  |
| Complete POC TEST RESULTS |  |
| Complete LAB RESULTS |  |
| Complete PRE-EXISTING CONDITION LOG  *Note: Reminder to include relevant items from medical history, physical exam, pelvic exam, laboratory findings, etc.* |  |
| 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 FINAL DISPOSITION FORM |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| Schedule next visit (V2 enrollment)  Determine last possible enrollment date for this screening attempt using the MATRIX-001 PARTICIPANT VISIT CALENDAR TOOL [last possible enrollment date = ] *NOTE: Enrollment must be scheduled:*   * *within 8 weeks 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 |  |
| Provide reimbursement [sites may add details] |  |
| 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 OpenClinica 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 MEDICAL 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 8 week screening window to complete all required screening procedures including any re-testing, as necessary.

Comments: