**Checklist Instructions:** Enter your 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 this entry. If any procedure is not conducted on the visit date recorded above, ensure the date the procedure was conducted is included.

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

GREEN TEXT = MATRIX-003 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| Confirm participant identity, per site SOP and PTID |  |
| Confirm visit is within window period, *per SSP* |  |
| Location of visit   * Study clinic * Off-site visit: document continued understanding of Consent for Off-site Visit and agreement in a chart note | [site may delete row if off-site visits NA] |
| Explain procedures to be performed at today’s visit |  |
| Confirm willingness to continue |  |
| Log into REDCap and select the appropriate PTID |  |
| Review and update locator information |  |
| Administer FOLLOW-UP BEHAVIORAL AND ACCEPTABILITY ASSESSMENT [FU3] CRF |  |
| Review/update UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms and social harms. If applicable, record social harms on SOCIAL HARMS AND BENEFITS ASSESSMENT LOG CRF. |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| IF INDICATED, collect urine sample (15-60 mL) and perform:   * perform pregnancy test per site SOP, *only if indicated and/or per local SOC* * 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] |  |
| If HIV test is indicated and/or per local standard of care*,* perform HIV Pre-test Counseling using MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET  Document reason for performing in chart note |  |
| [Sites with CLIA certification: If HIV test is indicated or per local standard of care, have pt collect sample and perform HIV Saliva test] [Document result on site specific form]  \*Document reason for performing in chart note |  |
| IF INDICATED, 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\*   \*as indicated or per local standard of care; document reason for performing in chart note |  |
| Perform symptom directed physical exam, if indicated or per local standard of care. Record on PRN SYMPTOM-DIRECTED PHYSICAL EXAM  Review exam findings with participant.  *Note: document reason for performing PE in chart note* |  |
| Perform external genital exam and pelvic exam with speculum  Collect genital samples in the following order:   * Vaginal pH * Vaginal Gram stain x 2 * Vaginal swab(s) for microbiota x 2 POLY * GC/CT/TV NAAT test\* * NSS/KOH wet mount for candidiasis and/or BV\* * Vaginal swab(s) for microbiota x 2 CALG   \*as indicated or per local standard of care; document reason for performing in chart note  Record on PELVIC EXAM. Review exam findings with participant |  |
| Complete SPECIMEN STORAGE |  |
| Review/provide test results and findings to participant   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Required** | **Test result** | **Provided by** | **Date** | **Note** | |  | HIV |  |  | *If positive result, refer to Protocol Section 7.4* | |  | Pregnancy |  |  | |  | GC/CT/TV |  |  | *If positive result, see below & refer to protocol* | |  | 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.* |  |
| Assess for AEs.  Document on ADVERSE EVENT LOG if applicable |  |
| Provide counseling per MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET:   * Protocol counseling * HIV post-test counseling, *only if test indicated* * HIV/STI risk reduction counseling ^ \* * Contraceptive counseling for participants of childbearing potential^   *^Provide referrals if needed/requested per site SOP/detail in chart notes*  *\*if indicated and/or per local standard of care* |  |
| Offer male condoms |  |
| Complete HIV, STI and Urine Test Results, if applicable |  |
| Complete HEMATOLOGY AND CHEMISTRY RESULTS, if applicable |  |
| Complete VISIT SUMMARY |  |
| 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 |  |
| Document visit in a detailed narrative chart note. |  |
| Schedule next visit/contact  Refer to MATRIX-003 PARTICIPANT VISIT CALENDAR TOOL to confirm next visit window  *[NOTE:  If off-site visit is anticipated, site must ensure participant consented to off-site visits in advance of visit; include details in chart note]* |  |
| As applicable, provide study informational materials, site contact information, and instructions to contact the site for information and/or counseling if needed before the next visit. |  |
| Perform QC2 review, including accuracy and completeness of REDCap and paper forms |  |

Comments: