**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.

NOTE: If Early Termination Visit, conduct the procedures as necessary. Enter “NA” for any procedures that are not applicable. Schedule a telephone/follow-up visit as required to continue to follow any applicable condition (i.e. ongoing AE, pregnancy) per protocol.

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/rows as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| Confirm participant identity and PTID, *per site SOP* |  |
| Ensure visit is within window, *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 participant is still willing to participate. |  |
| Review and verify consent choice for IDI and Permission to Contact Sexual Partner  *Note: If participant changes original choice, include in chart note and follow local guidelines regarding re-consent. Update* ICF SUMMARY*.* |  |
| Confirm permission to contact sexual partner for IDI (subset).  *Note: Sexual partner IDI must be completed within one month of participant V9.* |  |
| Review and update locator information |  |
| Initiate contact with Sexual Partner for IDI, per site SOP   * Participant given business card/research contact information to provide to sexual partner * [Include details of invitation for sexual partner per site SOP] |  |
| Log into REDCap and select the appropriate PTID |  |
| Administer FINAL BEHAVIORAL AND ACCEPTABILITY CRF [FU4] |  |
| Review/update UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms and social harms & benefits assessment. |  |
| Complete SOCIAL HARMS AND BENEFITS ASSESSMENT LOG as applicable |  |
| Assess for adverse events. Document on ADVERSE EVENT LOG as applicable |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Collect urine sample (15-60 mL) and perform:   * 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 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 lab result 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 |  |
| Perform targeted physical exam, if indicated or per local standard of care. Record on PRN TARGETED 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.   * Remove any residual film prior to sample collection * Collect genital samples in the following order: * Vaginal pH * Vaginal Gram stain x 2 * Vaginal swab(s) for microbiota x 2 * GC/CT/TV NAAT test * NSS/KOH wet mount for candidiasis and/or BV\*   \*as indicated or per local standard of care; document reason for performing in chart note  Record on PELVIC EXAMINATION. Review exam findings with participant. |  |
| Complete SPECIMEN STORAGE |  |
| Counseling per MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET:   * Protocol counseling, abbreviated as applicable * Contraceptive counseling for participants of childbearing potential^ * HIV post-test counseling and HIV/STI risk reduction counseling^ * No restrictions on sex or vaginal products   *^Provide referrals if needed/ requested per site SOP/detail in chart notes* |  |
| Offer male condoms |  |
| Review/provide test results and findings to participant.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Required** | **Test result** | **Provided by** | **Date** | **Note** | | x | HIV |  |  | *If positive test, refer to Protocol Section 7.4* | | x | Pregnancy |  |  | | x | GC/CT/TV |  |  | *If abnormal test result, see below &/or refer to protocol* | | x | Hematology & Chemistry |  |  | |  | 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.* |  |
| Complete HIV, STI and Urine Test Results |  |
| Complete HEMATOLOGY AND CHEMISTRY RESULTS |  |
| 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 |  |
| Complete participant IDI (subset), if selected   * Conducted during V9 * Scheduled for alternate day/time (at/after V9 but before V10) * Provide reimbursement   [Name of interviewer: Date completed: ] |  |
| Schedule next visit/contact.  Note: Target for V10 is 7 days following this visit. If using MATRIX-002 Participant Visit Calendar Tool, enter today’s actual visit date to calculate window period for V10.  *[NOTE: If off-site visit is anticipated, site must ensure participant consented to off-site visits in advance of visit and include details in chart note]* |  |
| Remind participant that this is the last scheduled in-person visit. Provide any other informational materials, referrals, and/or counseling if needed. |  |
| Perform QC2 review, including accuracy and completeness REDCap and paper forms |  |

Comments: