**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 testDocument 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 EXAMReview 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 noteRecord 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: