**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 & WORKSHEETDocument 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 EXAMReview exam findings with participant.*Note: document reason for performing PE in chart note* |  |
| Perform external genital exam and pelvic exam with speculumCollect 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 noteRecord 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: