**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 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 1 month of participant V9/SEV* |  |
| Initiate contact with Sexual Partner for IDI, if participant agreed and per site SOP*[Include details of invitation for sexual partner per site SOP]* |  |
| Review and update locator information |  |
| Log into REDCap and select the appropriate PTID |  |
| Administer FINAL BEHAVIORAL AND ACCEPTABILITY ASSESSMENT [FU4] CRF |  |
| Review/update UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms and social harms and benefits. If applicable, record on SOCIAL HARMS AND BENEFITS ASSESSMENT LOG CRF. |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Collect urine sample (15-60 mL) and perform:* perform pregnancy test per site SOP (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 [add site specific form] |  |
| Perform HIV Pre-test Counseling using MATRIX-003 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\*

\*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* |  |
| Review/Provide lab results |  |
| **RING REMOVAL** |  |
| Provide/review RING REMOVAL INSTRUCTIONS with participant  |  |
| Ring Removal:* Removed on 1st self-removal attempt
* Removed on 2nd self-removal attempt
* Removed by clinician

*Note: Staff should be available to answer questions (i.e., in same room behind a curtain; outside door)* |  |
| RING (SUCCESSFUL) REMOVAL TIME:  |  |
| Collect, inspect and properly dispose of used ring. If any issues on inspection, label and store ring. Contact Management Team.  |  |
| 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** |
| x | HIV |  |  | *If positive result, refer to Protocol Section 7.4* |
| x | 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.* |  |
| Complete CLINICIAN-COMPLETED OBSERVATION: REMOVAL [COR] CRF  |  |
| Assess for AEs/concerns. Document on ADVERSE EVENTS LOG as needed. Arrange additional discussion/interim visit as required |  |
| Ensure all open AEs and conmeds are reviewed and marked with appropriate end date or continuing. Make arrangements to follow up with participant regarding any ongoing AEs at this visit per protocol. Document in chart note as applicable. |  |
| Counseling per MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Counseling regarding Sexual Partner IDI component, as applicable
* Contraceptive counseling for participants of childbearing potential^
* HIV post-test counseling
* HIV/STI risk reduction counseling^
* No restrictions on sex or vaginal products
* Product Use

*^Provide referrals if needed/requested per site SOP/detail in chart notes* |  |
| Offer male condoms  |  |
| Complete HIV, STI and Urine Test Results |  |
| 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 chart note, including details of ring removal |  |
| Complete participant IDI (subset), if selected* Conducted during V9
* Scheduled for alternate day/time [sites may add details]

*IDI must be completed within 3 weeks of V9 (ideally within 1 week)** N/A

[Name of interviewer: Date completed: ] | Confirmed by: |
| If applicable, remind participant that this is the last scheduled visit and/or provide any other informational materials, referrals, and/or counseling if needed. |  |
| Complete PARTICIPANT DISPOSITION*Note: If IDI is conducted after V9, wait and complete PARTICIPANT DISPOSITION after IDI is complete.*  |  |
| Perform QC2 review, including accuracy and completeness of REDCap and paper forms  |  |

Comments: