**Checklist Instructions:** Complete your own initials next to the procedure(s) 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. Use the first column to mark which procedures were performed at this INTERIM VISIT.

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

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

| **X** | **PROCEDURE** | **Initials** |
| --- | --- | --- |
|  | Confirm participant identity and PTID, *per site SOP* |  |
|  | Explain procedures to be performed at today’s visit and confirm willingness to continue |  |
|  | Complete UPDATED MEDICAL AND MENSTRUAL HISTORY |  |
|  | Review/update concomitant meds using CONCOMITANT MEDICATION LOG |  |
|  | Collect urine sample (15-60 mL) for:   * perform pregnancy test\* * dipstick urinalysis per site SOP\* * urine culture per site SOP\*   \*as indicated or per local standard of care; document reason for performing in chart note  Document result on site specific form |  |
|  | HIV Pre-test Counseling per MATRIX-003 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\* * Syphilis serology\*   \*as indicated or per local standard of care; document reason for performing in chart note |  |
|  | Perform targeted 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 PELVIC EXAMINATION (includes EXTERNAL GENITAL)  Collect genital samples, as applicable with speculum in place *in this order*:   * Vaginal pH\* * Vaginal Gram stain x 2\* * Vaginal swabs 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\* * Pap test\*   \*as indicated or per local standard of care; document reason for performing in chart note  Discuss exam findings with participant |  |
|  | Perform bimanual exam if indicated |  |
|  | Complete SPECIMEN STORAGE |  |
|  | Review/update locator information, *per site SOP* |  |
|  | **RING INSERTION** – complete the following as applicable for this INTERIM visit. If ring insertion is not applicable, staff may strikethrough, initial and mark this section as N/A.  If a ring insertion is required and the participant needs new ring (i.e. original IVR unable to be re-inserted due to contamination), obtain new IVR from pharmacy, otherwise mark appropriate rows as N/A | |
|  | Original IVR status\*:   * Participant did NOT bring original IVR to this visit * Participant brought original IVR to this visit   + Original IVR is appropriate for re-insertion   + Original IVR is not appropriate for re-insertion (i.e. contaminated)   \*Include details in narrative chart note |  |
|  | Provide/review RING USE INSTRUCTIONS with participant |  |
|  | If a new ring is needed, confirm randomization (ring) sequence from V2 |  |
|  | If a new ring is needed, complete MATRIX-003 PRESCRIPTION for assigned ring |  |
|  | If a new ring is needed, obtain ring from pharmacy |  |
|  | IVR Insertion. Provide assigned ring to participant or have participant use original ring if appropriate.   * IVR inserted on 1st self-insertion attempt * IVR inserted on 2nd self-insertion attempt * IVR inserted by clinician |  |
|  | Perform digital exam to check IVR placement.  *Note: The participant should be asked to walk around the room to assess comfort. If needed, the digital exam may be repeated.* |  |
|  | RING INSERTION TIME: |  |
|  | Provide opaque bag from pharmacy to store ring if removed/expelled and copy of RING USE INSTRUCTIONS to participant for home use if needed. |  |

|  |  |  |
| --- | --- | --- |
| **X** | **PROCEDURE** | **Initials** |
|  | **RING REMOVAL** – complete the following as applicable for this INTERIM visit. If ring removal is not applicable, staff may strikethrough, initial and mark this section as N/A. | |
|  | 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. |  |

|  |  |  |
| --- | --- | --- |
| **X** | **PROCEDURE** | **Initials** |
|  | Conduct counseling as indicated per MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET:   * Protocol counseling * Contraceptive counseling for participants of childbearing potential^ * HIV post-test counseling and HIV/STI risk reduction counseling^ * Counseling on vaginal activity restrictions (no intravaginal products/practices for duration of study, no penetrative vaginal sex for first 14 days after each ring is placed)   *^Provide referrals if needed/requested per site SOP and detail in chart notes* |  |
|  | Review/provide test results and findings to participant.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Performed** | **Test result** | **Provided by** | **Date** | **Note** | |  | HIV |  |  | *See notes below and/or refer to protocol* | |  | Pregnancy |  |  | |  | GC/CT/TV |  |  | |  | Syphilis |  |  | |  | Hematology & Chemistry |  |  | |  | Pap smear |  |  | |  | 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. Section 9.5: Syndromic treatment is permitted. Single dose treatment is preferred. Consult PSRT if STI and plan is to discontinue.* |  |
|  | If diagnosed with symptomatic BV, symptomatic yeast or UTI, offer treatment consistent with WHO recommendations or referral for treatment |  |
|  | 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] |  |
|  | Document visit in a detailed chart note |  |
|  | Provide any other study informational materials, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit |  |
|  | Perform QC1 review while participant is still present, including:   * Visit checklist to ensure all relevant procedures were completed during the visit |  |
|  | Complete PSRT QUERY FORM, if PSRT guidance is needed |  |
|  | Perform QC2 review, including REDCap and paper forms   * Ensure findings identified during genital, pelvic and/or physical examinations and medical history review are consistent with Concomitant Medications Log and PRE-EXISTING CONDITIONS LOG * Review chart notes to ensure completeness and accuracy |  |

Comments: