**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-002 [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 |  |
|  | 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

Document result on site specific form |  |
|  | HIV Pre-test Counseling per 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
* Syphilis serology
 |  |
|  | 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 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
* GC/CT/TV NAAT test
* NSS/KOH wet mount for candidiasis and/or BV
* Pap test

Discuss exam findings with participant  |   |
|  | Perform bimanual exam if indicated |  |
|  | Complete SPECIMEN STORAGE |  |
|  | Review/update locator information, *per site SOP* |  |
|  | Conduct counseling as indicated per MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Contraceptive counseling for participants of childbearing potential^
* HIV post-test counseling and HIV/STI risk reduction counseling^
* “Pelvic rest” in Month 1 (after first film is inserted)

*^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 |  |
|  | Complete HIV, STI and Urine Test Results |  |
|  | Complete HEMALOGY AND CHEMISTRY |  |
|  | 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: