**Checklist Instructions:** Enter your own 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 = OpenClinica Instrument (direct data entry unless otherwise specified in site Source Document SOP) GREEN TEXT = MATRIX-001 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| Confirm participant identity and PTID, *per site SOP* |  |
| Review/update locator information, *per site SOP* |  |
| Confirm participant (by self-report) is not having menses-like bleeding today*NOTE: If bleeding, reschedule after cessation of menses per IoR discretion and if within visit window* |  |
| Confirm participant is still willing to participate |  |
| Confirm visit is within window period |  |
| Log into OpenClinica and select the appropriate PTID |  |
| Review/update medical and menstrual history by completing/updating MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms. Providetreatment as indicated |  |
| Review/update PRE-EXISTING CONDITIONS LOG |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Collect urine sample (15-60 mL) and perform:* perform pregnancy test, *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] |  |
| Collect Blood [site may add collection order/tubes/volumes per site’s standards]:* Plasma PK
* HIV\*
* CBC\*
* Serum creatinine\*
* AST/ALT\*

\*as indicated or per local standard of care; document reason for performing in chart note |  |
| Check vital signs and weight. Perform directed physical exam, *only if indicated or per local standard of care*. Record on VITAL SIGNS AND PHYSICAL EXAMReview exam findings with participant*Note: document reason for performing PE in chart note* |  |
| Perform external genital exam and pelvic exam. Collect genital samples with speculum in place in the following order:* GC/CT/TV NAAT test\*
* NSS/KOH wet mount for candidiasis and/or BV\*
* CVF for PK
* Vaginal pH/Gram stain
* CVF for PD Anti-HIV
* CVF for PD Anti-HSV2
* PSA

  |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| * Vaginal swab(s) for microbiota
* CVL for secreted soluble markers
* Rectal swabs for PK (ONLY IF PARTICIPANT CONSENTS)

\*as indicated or per local standard of care; document reason for performing in chart noteRecord on PELVIC EXAM FORM. |  |
| Complete SPECIMEN STORAGE |  |
| **Procedure: Self Insertion of Study Product** |
| **AT VISIT 5**: Complete MATRIX-001 PRESCRIPTION for assigned insert (4th dose). Provideprescription to PoR/designee with Randomization print out from OpenClinica. |  |
| **AT VISIT 6**: Complete MATRIX-001 PRESCRIPTION for assigned inserts (doses 5-10). Provideprescription to PoR/designee with Randomization print out from OpenClinica. |  |
| Provide 1 insert to participant for self-insertion in clinic (at both V5 and V6). Have participant attempt self-insertion in clinic. **[All samples must be collected prior to self-insertion at both Visits 5 and 6.]***Note: staff should be available to answer questions (i.e., in same room behind a curtain; outside door).** If participant has any difficulty with self-insertion of study insert, clinician may assist if necessary
 |  |
| Complete CLINICAL OBSERVATIONS for both V5 and V6 |  |
| Provide product use counseling using MATRIX-001 PROTOCOL COUNSELING GUIDE &WORKSHEET |  |
| Provide/review Vaginal Insert Guide with participant |  |
| **AT VISIT 6**: Dispense study inserts for alternate day dose phase to participant for home self-insertion |  |
| Return unused insert(s) to pharmacy |  |
| PROCEDURE |  |
| Assess for AEs. Document on ADVERSE EVENT LOG if applicable |  |
| Counseling per MATRIX-001 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling including prohibited vaginal and anal activities
* Contraceptive counseling for participants of childbearing potential^

*^Provide referrals if needed/ requested per site SOP/detail in chart notes* |  |
| Complete POC TESTS/LAB RESULTS if indicated |  |
| Complete VISIT SUMMARY FORM |  |
| 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 |  |
| Schedule next visit/contactEnter Visit Date into MATRIX-001 PARTICIPANT VISIT CALENDAR TOOL to calculate next visit date*[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]* |  |
| Provide any other study informational materials, site contact information, and instructions tocontact the site for additional information and/or counseling if needed before the next visit |  |

|  |  |
| --- | --- |
| Perform QC2 review, including OpenClinica and paper forms:* Evaluate findings identified during genital, pelvic and/or physical examinations and medical history review. Document in chart notes and update PRE-EXISTING CONDITIONS LOG and CONCOMITANT MEDICATIONS LOG, if applicable.
* Review chart notes to ensure completeness and accuracy
 |  |

Comments: