**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** |
| **\*MUST BE PERFORMED PRIOR TO RANDOMIZATION\*** |
|  | [sites: Re-check Enrollment Consent and associated documents (ICCA, coversheet, consentaddendums, etc.) if IRB/IEC requires two separate consents, including 2nd verifier of ICF] |  |  |
| Confirm Randomization Visit is within 10-14 days of Visit 2 (not less than 10 days) |  |
| 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 |  |
| 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 if indicated. Assess for AEs. Document on ADVERSE EVENT LOG if applicable |  |
| Review/update PRE-EXISTING CONDITIONS LOG |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Explain procedures to be performed at today’s visit |  |
| Check vital signs and weight. Perform directed physical exam, *only if indicated or per local standard of care*. Record on VITAL SIGNS AND PHYSICAL EXAM FORM*Note: document reason for performing PE in chart note* |  |
| Collect urine sample (15-60 mL) and perform:* perform pregnancy test (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-001 PROTOCOL COUNSELING GUIDE &WORKSHEET |  |
| Collect Blood [site may add collection order/tubes/volumes per site’s standards]:* HIV [*or saliva test if approved*]
 |  |
| 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/Gran stain
* CVF for PD Anti-HIV
* CVF for PD Anti-HSV2
 |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| * PSA
* 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 FORM |
| Provide HIV post-test counseling and HIV/STI risk reduction counseling using MATRIX-001PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| **Confirm participant remains eligible from above assessments prior to randomization** |  |
| **RANDOMIZATION** (only after above assessments have been completed and confirmed) |
| **AFTER POINT OF CARE HIV AND PREGNANCY TEST RESULTS** Complete MATRIX-001RANDOMIZATION in OpenClinica |  |
| Complete MATRIX-001 PRESCRIPTION for assigned insert(s). Provide prescription toPoR/designee with Randomization print out from OpenClinica |  |
| Obtain study inserts from pharmacy using MATRIX-001 Study Product Dispensation and ReturnLog |  |
| **SELF-INSERTION ATTEMPT** |
| Provide product use counseling using MATRIX-001 PROTOCOL COUNSELING GUIDE &WORKSHEET |  |
| Provide/review Vaginal Insert Guide with participant |  |
| Provide 1 insert to participant. Have participant attempt self-insertion in clinic.*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
 |  |
| Administer INITIAL PRODUCT USE ASSESSMENT |  |
| Complete CLINICAL OBSERVATIONS |  |
| Provide study inserts for daily dosing phase to participant for self-insertion at home. |  |
| Counseling per MATRIX-001 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Contraceptive counseling for participants of childbearing potential^
* Offer male condoms

*^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 and participant gift (insert carriers) [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 study product insertion |  |
| Schedule next visit/contactEnter V3 date into MATRIX-001 PARTICIPANT VISIT CALENDAR TOOL to calculate V4 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]* |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| 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: