**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 = REDCap Instrument (direct data entry unless otherwise specified in site Source Document SOP)

GREEN TEXT = MATRIX-002 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| **\*MUST BE PERFORMED PRIOR TO RANDOMIZATION\*** |
| [sites: Add Enrollment Consent and associated documents (ICCA, coversheet, consent addendums, etc.) if IRB/IEC requires two separate consents, including 2nd verifier of ICF] |  |
| Confirm Enrollment Visit is within 45 days of Screening Visit  |  |
| Confirm participant identity and PTID, *per site SOP* |  |
| Confirm participant (by self-report) is not having menses-like bleeding today  *NOTE: If bleeding, reschedule enrollment after cessation of menses and within 45 days of screening* |  |
| Review elements of informed consent. Explain procedures to be performed at today’s visit |  |
| Confirm participant understanding and willingness to continue participation* Participant understands and is willing to continue participation
* Participant does not understand and/or is not willing to continue participation → STOP

and include details in chart note |  |
| Review/Provide Screening lab results*Note: Verify/document on Screening Visit Checklist* |  |
| Assess eligibility using the ELIGIBILITY CHECKLIST  |  |
| Log into REDCap and select the appropriate PTID |  |
| Review/update medical and menstrual history by completing UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms |  |
| Review/update PRE-EXISTING CONDITIONS LOG |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Administer BASELINE BEHAVIORAL [BEH] CRF |  |
| Administer BASELINE ACCEPTABILITY [BL] CRF |  |
| 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-002 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| [sites with CLIA certification: Have participant collect sample and perform HIV Saliva testDocument result on site specific form] |  |
| Collect Blood [site may add collection order/tubes/volumes per site’s standards]:* Plasma Archive [EDTA tube; site to include volume; minimum of 4mL required]
* 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 targeted physical exam, *only 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 external genital exam and pelvic exam. Collect genital samples with speculum in place in the following order:  * Vaginal pH
* Vaginal Gram stain x 2
* Vaginal swab(s) for microbiota x 2
* GC/CT/TV NAAT test
* NSS/KOH wet mount for candidiasis and/or BV\*

\*as indicated or per local standard of care; document reason for performing in chart noteRecord on PELVIC EXAMINATION. 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, participant is ineligible* |
| x | Pregnancy |  |  |
| x | 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. \*Result will not be available prior to Randomization* |  |
| Provide HIV post-test counseling and HIV/STI risk reduction counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| Review/update locator information, *per site SOP* |  |
| 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.  |  |
| Confirm eligibility from above assessments & prior to randomization IoR/designee to review and sign enrollment Eligiblity Criteria |  |
| **RANDOMIZATION** (only after above assessments have been completed and confirmed) |
| Provide product use counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| Provide/review FILM INSERTION INSTRUCTIONS with participant  |  |
| Assign next (sequential) randomization envelope by completing Randomization LogOpen sealed envelope and complete Participant Randomization Form*NOTE: Randomization = Enrollment*  |  |
| Complete MATRIX-002 PRESCRIPTION for assigned film. Provide prescription to PoR with completed PARTICIPANT RANDOMIZATION FORM |  |
| Complete MATRIX-002 RANDOMIZATION |  |
| Obtain films from pharmacy |  |
| 1st SELF-INSERTION ATTEMPT: Provide film to participant. Have participant attempt first self-insertion *Note: staff should be available to answer questions (i.e., in same room behind a curtain; outside door).*  |  |
| Perform external genital exam per SSP to assess film placement* 1st SELF-INSERTION ATTEMPT “SUCCESSFUL” (more than 50% of film is in vagina)

If “SUCCESSFUL” but some film is visible, provide feedback and ask the participant to tuck in visible film. Clinician steps away and then re-evaluates. If any additional visible film, clinician to tuck. à skip to POST-INSERTION ACCEPTABILITY [FU1] CRF* 1st SELF-INSERTION ATTEMPT “UNSUCCESSFUL” (equal to/less than 50% of film in vagina) à remove and dispose of film
 |  |
| 2nd SELF-INSERTION ATTEMPT: Provide new film to participant. Have participant attempt second self-insertion. *Note: staff should be available to answer questions (i.e. in same room behind a curtain; outside door).*  |  |
| Perform external genital exam to assess film placement* 2nd SELF-INSERTION ATTEMPT “SUCCESSFUL” (more than 50% of film is in vagina)

If “SUCCESSFUL” but some film is visible, provide feedback and ask the participant to tuck in visible film. Clinician steps away and then re-evaluates. If any additional visible film, clinician to tuck. à skip to POST-INSERTION ACCEPTABILITY [FU1] CRF* 2nd SELF-INSERTION ATTEMPT “UNSUCCESSFUL” (equal to/less than 50% of film in vagina) à remove and dispose of film
 |  |
| CLINICIAN FILM INSERTION: Provider inserts new film using speculum, per SSP  |  |
| FILM (SUCCESSFUL) INSERTION TIME:  |  |
| Return unused film(s) to pharmacy  |  |
| Administer POST-INSERTION ACCEPTABILITY [FU1] CRF  |  |
| Complete CLINICIAN OBSERVATION/ADMINISTRATION [CO] CRF |  |
| Assess for AEs.  Document on ADVERSE EVENT LOG if applicable |  |
| Counseling per MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Contraceptive counseling for participants of childbearing potential^
* Required “pelvic rest” in Month 1 (after first film is inserted) counseling

*^Provide referrals if needed/ requested per site SOP/detail in chart notes* |  |
| Complete HIV, STI and Urine Test Results |  |
| 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 film insertion |  |
| Schedule next visit/contact Enter V2 date into MATRIX-002 Participant Visit Calendar Tool to calculate V3-V6 dates*[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 to contact the site for additional information and/or counseling if needed before the next visit |  |
| 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: