**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 test  Document 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 EXAM  Review 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 note  Record 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 Log  Open 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: