**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-003 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* |  |
| Inquire about bleeding; ideally V2 is scheduled when participant is not menstruating |  |
| 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 UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms and social harms. If applicable, record social harms on SOCIAL HARMS AND BENEFITS ASSESSMENT LOG CRF |  |
| Review/update PRE-EXISTING CONDITIONS LOG |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Administer BASELINE BEHAVIORAL ASSESSMENT [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-003 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]
* 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 symptom directed physical exam, *only if indicated or per local standard of care*. Record on PRN SYMPTOM-DIRECTED 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 POLY
* GC/CT/TV NAAT test\*
* NSS/KOH wet mount for candidiasis and/or BV\*
* Vaginal swab(s) for microbiota x 2 CALG
* Vaginal swab for archive x1 CALG

\*as indicated or per local standard of care; document reason for performing in chart noteRecord on PELVIC EXAM. 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 |  |  |
|  | 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-003 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| Review/update locator information, *per site SOP* |  |
| Evaluate findings identified during genital, pelvic and/or physical examination and medical history review. Document in chart notes and update PRE-EXISTING CONDITIONS LOG and CONCOMITANT MEDICATION LOG, if applicable |  |
| Confirm eligibility from above assessments & prior to randomization IoR/designee to review and sign enrollment EligibILIty Criteria |  |
| **RANDOMIZATION** (only after above assessments have been completed and confirmed) |
| Provide product use counseling using MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| Provide/review MATRIX-003 IVR USE INSTRUCTIONS with participant  |  |
| Assign next (sequential) randomization envelope by completing Randomization LogOpen sealed envelope and complete Participant Randomization Form*NOTE: Randomization = Enrollment*  |  |
| Complete MATRIX-003 PRESCRIPTION for assigned ring. Provide prescription to PoR with completed PARTICIPANT RANDOMIZATION FORM |  |
| Complete MATRIX-003 RANDOMIZATION |  |
| Obtain ring from pharmacy |  |
| After washing and drying hands, have participant remove ring from package in front of clinician. Clinician to visually inspect ring (both sides).  |  |
| IVR Insertion. Provide assigned ring to participant. The same ring is used for multiple attempts. * Inserted on 1st self-insertion attempt
* Inserted on 2nd self-insertion attempt
* Inserted by clinician
 |  |
| Perform digital exam to check IVR placement. *Note: The participant should be asked to walk around the room to assess comfort. If needed, the digital exam may be repeated.*  |  |
| Once the ring is inserted, provide/review removal instructions in MATRIX-003 IVR USE INSTRUCTIONS with participant and have participant attempt removal. If two unsuccessful attempts at removal, clinician to assist. * Removed on 1st self-removal attempt
* Removed on 2nd self-removal attempt
* Removed by clinician
 |  |
| Re-review insertion instructions in MATRIX-003 IVR USE INSTRUCTIONS with participant (as necessary). Have participant repeat IVR insertion:* Inserted on 1st self-insertion attempt
* Inserted on 2nd self-insertion attempt
* Inserted by clinician
 |  |
| Perform digital exam to check IVR placement. *Note: The participant should be asked to walk around the room to assess comfort. If needed, the digital exam may be repeated.*  |  |
| FINAL RING INSERTION TIME:  |  |
| Provide opaque bag from pharmacy to store ring if removed/expelled and copy of RING USE INSTRUCTIONS to participant for home use if needed. |  |
| Administer post-insertion acceptability ASSESSMENT [fu1] crf |  |
| Complete CLINICIAN-COMPLETED OBSERVATION: INSERTION [COI] CRF  |  |
| Assess for AEs.  Document on ADVERSE EVENT LOG if applicable |  |
| Additional counseling per MATRIX-003 PROTOCOL COUNSELING GUIDE & WORKSHEET: * Protocol counseling
* Contraceptive counseling
* Counseling on vaginal activity restrictions
 |  |
| Complete HIV, STI and Urine Test Results |  |
| Complete HEMATOLOGY AND CHEMISTRY RESULTS, if applicable |  |
| 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 ring insertion |  |
| Schedule next visit/contact [sites may add details]Enter V2 date into MATRIX-003 Participant Visit Calendar Tool to calculate V3-V5 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]*  |  |
| If applicable, provide any other study informational material 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: