Note: The items in **bold** are required source documents for the listed study procedure/evaluation [and should not be modified. Other items are listed as suggested source documents, but site should specify the actual source document to be used at their site. This sample document should be updated to reflect what is being used as source for the site or alternately should be detailed/included in a site Source Document SOP.]

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| --- | --- |
| **Evaluation/Procedure** | **Source Document(s)** |
| ADMINISTRATIVE AND REGULATORY | |
| Obtain informed consent(s) | **Signed and Dated Informed Consent forms**  Informed Consent Coversheet (or chart note)  **Informed Consent Comprehension Assessment** |
| Assign a unique Participant Identification (PTID) number | **MATRIX-002 PTID Assignment Log** (may also serve as the PTID-Name Linkage Log) |
| Assess and/or confirm eligibility | **MATRIX-002 Eligibility Checklist** |
| Randomization | **Participant Randomization Form** |
| Confirm permission to contact sexual partner for IDI (subset) | Visit checklist  Chart note |
| Collect/review/update locator information | Site locator documents (collect/update)  Visit checklist (review) |
| Provide reimbursement | Visit checklist  Site-specific reimbursement log/process  Chart note |
| Schedule next visit | Visit checklist  Chart note |
| COUNSELING | |
| Contraceptive counseling | MATRIX-002 Protocol Counseling Guide and Worksheet  chart note |
| Protocol counseling | MATRIX-002 Protocol Counseling Guide and Worksheet  chart note |
| HIV/STI risk reduction counseling | MATRIX-002 Protocol Counseling Guide and Worksheet  chart note |
| HIV pre- and post-test counseling | MATRIX-002 Protocol Counseling Guide and Worksheet  chart note |
| BEHAVIORAL | |
| Behavioral assessments | Completed interviewer administered CRFs:  **Baseline behavioral (BEH) Form**  **Baseline acceptability (BL) Form**  **Post-insertion acceptability (FU1) Form**  **Brief Acceptability (FU2) Form**  **Follow-up behavioral and acceptability (FU3) Form**  **Final Behavioral and Acceptability (FU4) Form** |
| Additional Behavioral forms | **Clinician Observations (CO) Form** |
| IDI – subset of participants | **IDI Recordings and transcripts** |
| IDI – sexual partners | **IDI Recordings and transcripts** |
| CLINICAL | |
| Medical and menstrual history | Pre-existing Conditions Log  Adverse Events Log  **MATRIX-002 Baseline Medical History Review Guide** (for Baseline Medical and Menstrual History)  Updated Medical and Menstrual History  Review of Medical Records  Chart note |
| Concomitant medications | Concomitant Medications Log  Chart note |
| Physical examination, including height, weight, and blood pressure | Screening Physical Exam and vital signs  PRN Targeted Physical Exam  Chart note |
| Pelvic exam with speculum | Pelvic Exam  Chart note |
| Provide available test results | Visit checklist  Chart note |
| AE assessment | Adverse Events Log  Chart note |
| Social Harms and Benefits | Social Harms and Benefits Assessment Log  Chart note |
| Treat or prescribe treatment for UTIs/RTIs/STIs or refer for other findings | Chart note  Prescription  Referral letter |
| LABORATORY | |
| Urine pregnancy test  Urine dip/culture  NAAT for GC/CT/Trich  CBC  Chemistries (serum creatinine, AST/ALT)  Syphilis serology | Site-specific lab requisition form  Lab results form |
| Plasma archive | Visit checklist  Lab transmittal form |
| HIV Test (serology or saliva) | Site-specific lab requisition form  Site testing log/results report (rapid test)  Lab result report (WB/HIV RNA) |
| Vaginal pH | Site testing log/results report  Screening STI Test Results/STI Test Results CRFs  Visit checklist  Chart note |
| Saline/KOH wet mount microscopy | Site testing log/results report |
| Gram stain collection  Vaginal swab collection for microbiota | Site-specific lab requisition/transmittal form  Specimen Storage  Visit checklist  Chart note |
| Endocervical sample collection for Pap test | Visit checklist  Site-specific lab requisition form  Chart note |
| Pap test interpretation | Lab results report |
| STUDY PRODUCT/SUPPLIES | |
| Offer male condoms | MATRIX-002 Protocol Counseling Guide and Worksheet  Visit checklist |
| Provision of study vaginal film instructions | MATRIX-002 Protocol Counseling Guide and Worksheet  Chart note  Visit checklist |
| Participant self-insertion of vaginal film | Post-insertion acceptability (FU1) Form  Chart note |
| Clinician inserted vaginal film | Clinician Observations (CO) Form  Chart note |
| External genital exam to check film placement | Clinician Observations (CO) Form  Visit checklist  Chart note |
| Removal of residual film | Pelvic exam  Chart note |
| OTHER | |
| Protocol Deviations | Protocol Deviation Log  Chart note |
| Contacts, and attempted contacts, with participant | Site-specific contact/outreach/retention logs  PRN Missed Visit  Chart note |
| Participant Demographics & Background | Demographic (DEM) Form |
| Sexual Partner Demographics | Sexual Partner Demographic (SPDEM) Form |
| Study Product Discontinuations | Discontinuation of Study Product  Chart note |
| Pregnancy (following Enrollment) | Pregnancy Report and Outcome  Chart note |