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 checklistChart note |
| Collect/review/update locator information | Site locator documents (collect/update)Visit checklist (review) |
| Provide reimbursement | Visit checklistSite-specific reimbursement log/processChart note |
| Schedule next visit | Visit checklistChart note |
| COUNSELING |
| Contraceptive counseling | MATRIX-002 Protocol Counseling Guide and Worksheetchart note |
| Protocol counseling | MATRIX-002 Protocol Counseling Guide and Worksheetchart note |
| HIV/STI risk reduction counseling | MATRIX-002 Protocol Counseling Guide and Worksheetchart note |
| HIV pre- and post-test counseling | MATRIX-002 Protocol Counseling Guide and Worksheetchart 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 LogAdverse Events Log**MATRIX-002 Baseline Medical History Review Guide** (for Baseline Medical and Menstrual History)Updated Medical and Menstrual HistoryReview of Medical RecordsChart note |
| Concomitant medications | Concomitant Medications LogChart note |
| Physical examination, including height, weight, and blood pressure | Screening Physical Exam and vital signsPRN Targeted Physical ExamChart note |
| Pelvic exam with speculum | Pelvic ExamChart note |
| Provide available test results | Visit checklistChart note |
| AE assessment | Adverse Events LogChart note |
| Social Harms and Benefits | Social Harms and Benefits Assessment LogChart note |
| Treat or prescribe treatment for UTIs/RTIs/STIs or refer for other findings | Chart notePrescriptionReferral letter |
| LABORATORY |
| Urine pregnancy testUrine dip/cultureNAAT for GC/CT/TrichCBCChemistries (serum creatinine, AST/ALT)Syphilis serology | Site-specific lab requisition formLab results form |
| Plasma archive | Visit checklistLab transmittal form |
| HIV Test (serology or saliva) | Site-specific lab requisition formSite 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 CRFsVisit checklistChart note |
| Saline/KOH wet mount microscopy | Site testing log/results report |
| Gram stain collectionVaginal swab collection for microbiota | Site-specific lab requisition/transmittal formSpecimen StorageVisit checklistChart note |
| Endocervical sample collection for Pap test | Visit checklistSite-specific lab requisition formChart note |
| Pap test interpretation | Lab results report |
| STUDY PRODUCT/SUPPLIES |
| Offer male condoms | MATRIX-002 Protocol Counseling Guide and WorksheetVisit checklist |
| Provision of study vaginal film instructions | MATRIX-002 Protocol Counseling Guide and WorksheetChart noteVisit checklist |
| Participant self-insertion of vaginal film | Post-insertion acceptability (FU1) FormChart note |
| Clinician inserted vaginal film | Clinician Observations (CO) FormChart note |
| External genital exam to check film placement | Clinician Observations (CO) FormVisit checklistChart note  |
| Removal of residual film | Pelvic examChart note |
| OTHER |
| Protocol Deviations | Protocol Deviation LogChart note |
| Contacts, and attempted contacts, with participant | Site-specific contact/outreach/retention logs PRN Missed VisitChart 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 OutcomeChart note |