Note: The items in **bold** are required source documents for the listed study procedures/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** **Informed Consent Comprehension Assessment**Chart note |
| Assign a unique Participant Identification (PTID) number | **MATRIX-003 PTID Assignment Log** MATRIX-003 Participant Screening and Enrollment Log  |
| Assess and/or confirm eligibility | **MATRIX-003 Eligibility Checklist** |
| Randomization | **MATRIX-003 Participant Randomization Assignment Record** |
| Confirm permission to include sexual partner for IDI (subset) | **Signed and Dated Informed Consent forms**Visit checklistChart note |
| Collect/review/update locator information | MATRIX-003 Retention Sheet (collect/update)Visit checklist (review) |
| Provide reimbursement | Visit checklist |
| Schedule next visit | Visit checklistChart note |
| COUNSELING |
| Contraceptive counseling | MATRIX-003 Protocol Counseling Guide and Worksheetchart note |
| Protocol counseling | MATRIX-003 Protocol Counseling Guide and Worksheetchart note |
| HIV/STI risk reduction counseling | MATRIX-003 Protocol Counseling Guide and Worksheetchart note |
| HIV pre- and post-test counseling | MATRIX-003 Protocol Counseling Guide and Worksheetchart note |
| Study Product Use counseling | MATRIX-003 Protocol Counseling Guide and Worksheetchart note |
| BEHAVIORAL |
| Behavioral assessments | Completed interviewer administered CRFs: **Baseline Behavioral (BEH) CRF** **Baseline Acceptability (BL) CRF****Post Insertion Acceptability (FU1) CRF****Brief Acceptability (FU2) CRF****Follow up Behavioral and Acceptability (FU3) CRF****Follow up Behavioral and Acceptability (FU4) CRF** |
| Additional Behavioral forms | **Clinical Observations for Insertion (COI) CRF****Clinical Observations for Removal (COR) CRF** |
| 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-003 Baseline Medical History Review Guide** (for Baseline Medical and Menstrual History)Updated Medical and Menstrual HistoryChart note |
| Concomitant medications | Concomitant Medications LogChart note |
| Physical examination, including height, weight, and blood pressure | Screening Physical Exam and vital signsPRN Symptom-directed 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 results report (HIV 5th Gen Ag/Ab Assay) |
| Vaginal pH | Pelvic Exam |
| Saline/KOH wet mount microscopy | Pelvic Exam |
| Gram stain collectionVaginal swab collection for microbiota | Site-specific lab requisition/transmittal formSpecimen StorageVisit checklist |
| 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-003 Protocol Counseling Guide and WorksheetVisit checklist |
| Provision of study vaginal ring insertion instructionsProvision of study vaginal ring removal instructions | MATRIX-003 Protocol Counseling Guide and WorksheetChart noteVisit checklist |
| Insertion of vaginal ring | **Post-insertion Acceptability (FU1) Form****Clinical Observations for Insertion (COI) CRF**Chart noteVisit checklist |
| Genital exam to check vaginal ring placement | **Clinical Observations for Insertion (COI) CRF**Visit checklistChart note  |
| Removal of vaginal ring | **Follow up Behavioral and Acceptability (FU3) CRF****Follow up Behavioral and Acceptability (FU4) CRF** **Clinical Observations for Removal (COR) CRF**Chart noteVisit checklist |
| OTHER |
| Protocol Deviations | Protocol Deviation LogChart note |
| Contacts, and attempted contacts, with participant | MATRIX-003 Study Participant Contact LogPRN Missed VisitChart note |
| Participant Demographics & Background | Demographic (DEM) Form |
| Sexual Partner Demographics | Sexual Partner Demographic (SPDEM) Form |
| Study Product Discontinuations | Study Product Hold/Discontinuation LogChart note |
| Pregnancy (following Enrollment) | Pregnancy Report and OutcomeChart note |