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 checklist  Chart note |
| Collect/review/update locator information | MATRIX-003 Retention Sheet (collect/update)  Visit checklist (review) |
| Provide reimbursement | Visit checklist |
| Schedule next visit | Visit checklist  Chart note |
| COUNSELING | |
| Contraceptive counseling | MATRIX-003 Protocol Counseling Guide and Worksheet  chart note |
| Protocol counseling | MATRIX-003 Protocol Counseling Guide and Worksheet  chart note |
| HIV/STI risk reduction counseling | MATRIX-003 Protocol Counseling Guide and Worksheet  chart note |
| HIV pre- and post-test counseling | MATRIX-003 Protocol Counseling Guide and Worksheet  chart note |
| Study Product Use counseling | MATRIX-003 Protocol Counseling Guide and Worksheet  chart 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 Log  Adverse Events Log  **MATRIX-003 Baseline Medical History Review Guide** (for Baseline Medical and Menstrual History)  Updated Medical and Menstrual History  Chart note |
| Concomitant medications | Concomitant Medications Log  Chart note |
| Physical examination, including height, weight, and blood pressure | Screening Physical Exam and vital signs  PRN Symptom-directed 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 results report (HIV 5th Gen Ag/Ab Assay) |
| Vaginal pH | Pelvic Exam |
| Saline/KOH wet mount microscopy | Pelvic Exam |
| Gram stain collection  Vaginal swab collection for microbiota | Site-specific lab requisition/transmittal form  Specimen Storage  Visit checklist |
| 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-003 Protocol Counseling Guide and Worksheet  Visit checklist |
| Provision of study vaginal ring insertion instructions  Provision of study vaginal ring removal instructions | MATRIX-003 Protocol Counseling Guide and Worksheet  Chart note  Visit checklist |
| Insertion of vaginal ring | **Post-insertion Acceptability (FU1) Form**  **Clinical Observations for Insertion (COI) CRF**  Chart note  Visit checklist |
| Genital exam to check vaginal ring placement | **Clinical Observations for Insertion (COI) CRF**  Visit checklist  Chart 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 note  Visit checklist |
| OTHER | |
| Protocol Deviations | Protocol Deviation Log  Chart note |
| Contacts, and attempted contacts, with participant | MATRIX-003 Study Participant Contact Log  PRN Missed Visit  Chart note |
| Participant Demographics & Background | Demographic (DEM) Form |
| Sexual Partner Demographics | Sexual Partner Demographic (SPDEM) Form |
| Study Product Discontinuations | Study Product Hold/Discontinuation Log  Chart note |
| Pregnancy (following Enrollment) | Pregnancy Report and Outcome  Chart note |