**Checklist Instructions:** Enter your 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-002 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| Confirm participant identity and PTID, *per site SOP* |  |
| Confirm visit is within window period, *per SSP* |  |
| Location of visit* Study clinic
* Off-site visit: document continued understanding of Consent for Off-site Visit and agreement in a chart note
 | [site may delete row if off-site visits NA] |
| Confirm participant (per self-report) is not having menses-like bleeding today   *NOTE**: If menses-like bleeding, ideally reschedule after cessation of menses like bleeding, per protocol.*  |  |
| Explain procedures to be performed at today’s visit  |  |
| Confirm willingness to continue |  |
| Log into REDCap and select the appropriate PTID |  |
| Review and verify consent choice for IDI and Permission to Contact Sexual Partner*Note: If participant changes original choice, include in chart note and follow local guidelines regarding re-consent. Update* ICF SUMMARY*.* |  |
| Review and update locator information |  |
| Conduct behavioral assessment by administering FOLLOW-UP BEHAVIORAL AND ACCEPTABILITY [FU3] CRF  |  |
| Review/update UPDATED MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| 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-002 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]:* 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 |  |
| Provide HIV post-test counseling and HIV/STI risk reduction counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET  |  |
| Perform targeted physical exam, if indicated or per local standard of care. Record on PRN TARGETED PHYSICAL EXAMReview exam findings with participant.*Note: document reason for performing PE in chart note* |  |
| Perform external genital exam and pelvic exam with speculum* Remove any residual film prior to sample collection
* Collect genital samples in the following order:
* Vaginal pH
* Vaginal Gram stain x 2
* Vaginal swab(s) for microbiota x 2
* GC/CT/TV NAAT test
* NSS/KOH wet mount for candidiasis and/or BV\*

\*as indicated or per local standard of care; document reason for performing in chart noteRecord on PELVIC EXAMINATION. 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, refer to Protocol Section 7.4* |
| x | Pregnancy |  |  |
| x | 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.* |  |
| Assess for AEs.  Document on ADVERSE EVENT LOG if applicable |  |
| **FILM INSERTION**  |
| Provide product use counseling using MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET |  |
| Provide/review film insertion instructions with participant  |  |
| Confirm randomization (film) assignment from V2 |  |
| Complete MATRIX-002 PRESCRIPTION for assigned film  |  |
| Obtain films from pharmacy |  |
| 1st SELF-INSERTION ATTEMPT: Provide film to participant. Have participant attempt first self-insertion. *Note: staff should be available to answer questions (i.e. in same room behind a curtain; outside door).*  |  |
| Perform external genital exam to assess film placement, per protocol.* 1st SELF INSERTION ATTEMPT “SUCCESSFUL” (more than 50% of film is in vagina)

If “SUCCESSFUL” but some film is visible, provide feedback and ask the participant to tuck in visible film, per SSP. Clinician steps away and then re-evaluates. If any additional visible film, clinician to tuck. à skip to POST-INSERTION ACCEPTABILITY [FU1] CRF * 1st SELF INSERTION ATTEMPT “UNSUCCESSFUL” (equal to/less than 50% of film in vagina) à remove film
 |  |
| 2nd SELF-INSERTION ATTEMPT: Provide new film to participant. Have participant attempt second self-insertion. *Note: staff should be available to answer questions (i.e. in same room behind a curtain; outside door).*  |  |
| Perform external genital exam to assess film placement, per protocol.* 2nd SELF INSERTION ATTEMPT “SUCCESSFUL” (more than 50% of film is in vagina)

If “SUCCESSFUL” but some film is visible, provide feedback and ask the participant to tuck in visible film, per SSP. Clinician steps away and then re-evaluates. If any additional visible film, clinician to tuck. à skip to POST-INSERTION ACCEPTABILITY [FU1] CRF* 2nd SELF INSERTION ATTEMPT “UNSUCCESSFUL” (equal to/less than 50% of film in vagina) à remove film; clinician to insert film
 |  |
| CLINICIAN FILM INSERTION: Provider inserts new film with speculum, per SSP  |  |
| FILM (SUCCESSFUL) INSERTION TIME:  |  |
| Return unused film(s) to the pharmacy |  |
| Administer POST-INSERTION ACCEPTABILITY [FU1] CRF  |  |
| Complete CLINICIAN OBSERVATION/ADMINISTRATION [CO] CRF |  |
| Counseling per MATRIX-002 PROTOCOL COUNSELING GUIDE & WORKSHEET:* Protocol counseling
* Contraceptive counseling for participants of childbearing potential^
* No restrictions on sex or vaginal products following second film
* Discuss optional Sexual partner IDI component including sexual partner involvement and how partner will be contacted

*^Provide referrals if needed/ requested per site SOP/detail in chart notes* |  |
| Offer male condoms  |  |
| Complete HIV, STI and Urine Test Results |  |
| 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 narrative chart note.  |  |
| Schedule next visit/contact Note: Enter V6 date into MATRIX-002 Participant Visit Calendar Tool to calculate V7 – V9 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]*  |  |
| Provide any other study informational materials, 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 accuracy and completeness of REDCap and paper forms |  |

Comments: