**Checklist Instructions:** Enter your own 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 = OpenClinica Instrument (direct data entry unless otherwise specified in site Source Document SOP) GREEN TEXT = MATRIX-001 Tool/Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| Confirm participant identity and PTID, *per site SOP* |  |
| Review/update locator information, *per site SOP* |  |
| Confirm visit is within protocol specified window of 24 hrs + 4hrs post 3rd dose |  |
| Confirm participant (by self-report) is not having menses-like bleeding today  *NOTE: If bleeding, reschedule after cessation of menses per IoR discretion and if within visit window* |  |
| Confirm participant is still willing to participate |  |
| Log into OpenClinica and select the appropriate PTID |  |
| Review/update medical and menstrual history by completing/updating MEDICAL AND MENSTRUAL HISTORY, including assessment for current RTI/STI/UTI symptoms. Provide  treatment if indicated |  |
| Review/update PRE-EXISTING CONDITIONS LOG |  |
| Review/update CONCOMITANT MEDICATION LOG |  |
| Administer Product Use Questionnaire |  |
| Explain procedures to be performed at today’s visit |  |
| Check vital signs and weight. Perform directed physical exam, *only if indicated or per local standard of care*. Record on VITAL SIGNS AND PHYSICAL EXAM FORM  *Note: document reason for performing PE in chart note* |  |
| Collect urine sample (15-60 mL) and perform:   * perform pregnancy test, *only if indicated and/or per local SOC* * 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] |  |
| Collect Blood [site may add collection order/tubes/volumes per site’s standards]:   * Plasma PK * HIV\* * CBC\* * Serum creatinine\* * AST/ALT\*   \*as indicated or per local standard of care; document reason for performing in chart note |  |
| Provide Biopsy procedural counseling per MATRIX-001 PROTOCOL COUNSELING GUIDE &  WORKSHEET |  |
| Perform external genital exam and pelvic exam. Collect genital samples with speculum in place in the following order:   * GC/CT/TV NAAT test\* * NSS/KOH wet mount for candidiasis and/or BV\* * CVF for PK * Vaginal pH/Gram stain |  |

|  |  |
| --- | --- |
| **PROCEDURE** | **Initials** |
| * CVF for PD Anti-HIV * CVF for PD Anti-HSV2 * PSA * Vaginal swab(s) for microbiota * CVL for secreted soluble markers * BXV for PK * BXC for HIV (EVMS ONLY) * Rectal swabs for PK (ONLY IF PARTICIPANT CONSENTS)   \*as indicated or per local standard of care; document reason for performing in chart note  Record on PELVIC EXAM FORM. |  |
| Complete SPECIMEN STORAGE FORM |  |
| Assess for AEs. Document on ADVERSE EVENT LOG if applicable |  |
| Counseling per MATRIX-001 PROTOCOL COUNSELING GUIDE & WORKSHEET:   * Protocol counseling * Contraceptive counseling for participants of childbearing potential^ * Post Biopsy procedural counseling * Offer male condoms if indicated   *^Provide referrals if needed/ requested per site SOP/detail in chart notes* |  |
| Complete POC TESTS/LAB RESULTS as indicated |  |
| Complete VISIT SUMMARY FORM |  |
| 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 |  |
| Schedule next visit/contact  Enter V4 date into MATRIX-001 PARTICIPANT VISIT CALENDAR TOOL to calculate V5 date  *[NOTE: V5 has to be at least 10 days after bx and shortly after menstrual flow ceases for cycling participants to ensure the 14 days of product use do not occur during a menstrual cycle. 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 OpenClinica and paper forms:   * Evaluate findings identified during genital, pelvic and/or physical examinations and medical history review. Document in chart notes and update PRE-EXISTING CONDITIONS LOG and CONCOMITANT MEDICATIONS LOG, if applicable. * Review chart notes to ensure completeness and accuracy |  |

Comments: