**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” 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 procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Visits Required**  | **Staff Initials** |
| --- | --- | --- |
|  | Prepare for exam: * Exam equipment, documentation, and specimen collection supplies; label as needed.
* Explain exam procedures to participant and answer any questions.
* Position and drape participant comfortably.
 | * Visits 1-9
* If indicated at Visit 10
 |  |
|  | Collect cervicovaginal fluid (CVF) for **TFV level testing** (for MTN LC). * Using 1 vaginal swab near, but not touching the VR

Record pre- and post-collection weights.*Note: Collect blood, rectal fluid, CVF samples for TFV level testing in as close time proximity as possible (within 30 minutes).* | * Enrollment (V2)

*Note: Taken 1 and 4 hrs after VR insertion. Collection timepoints are documented on Enrollment checklist.** Visits 3, 4, 5, 6, 8, 9, 10

*Note: V9 – taken prior to and 4 hrs after VR removal. Post-removal collection time point is documented on the Visit 9 Checklist*  |  |
|  | Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.  | * Visits 1-9
* If indicated at Visit 10
 |  |
|  | Perform naked eye examination of the external genitalia including the perineum, perianal area, and the epithelial lining of the introitus.  | * Visits 1-9
* If indicated at Visit 10
 |  |
|  | Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the vagina and cervix, if applicable.  | * Visits 1-9
* If indicated at Visit 10
 |  |
|  | Perform visual confirmation of VR in place and document on **Pelvic Exam CRF.** | * Visits 3-8
* Visit 9 *prior to ring removal*
 |  |
|  | Collect vaginal fluid for **Trichomonas** **NAAT test** at local lab.* 1 swab from lateral vaginal wall.
 | * Screening (V1)
* If indicated at Visits 2-9
 |  |
|  | Collect vaginal fluid for **GC/CT NAAT test** at local lab.* 1 swab from lateral vaginal wall.
 | * Screening (V1)
* If indicated at Visits 2-9
 |  |
|  | Collect vaginal fluid for **microbiota analyses** (for MTN LC). * 2 flocked swabs from lateral vaginal wall (for q-PCR)
* 2 swab from lateral vaginal wall (for culture)
 | * Enrollment (V2)
* Visits 6 & 8
* Visit 9 *prior to VR removal*
 |  |
|  | *If clinically indicated (symptomatic),* collect vaginal fluid for **wet prep/KOH wet mounts with pH** for evaluation of candidiasis and/or BV at local lab/clinic.* 1 swab from lateral vaginal wall.
 | * If indicated at all visits
 |  |
|  | Collect vaginal fluid for **gram stain analysis** (for MTN LC)**.**  * 1 swab from lateral vaginal wall; turn swab 3x. Roll swab across two labeled slides and air dry.
 | * Enrollment (V2)
* Visits 6 & 8
* Visit 9 *prior to VR removal*
 |  |
|  | If participant (over age 21) is unable to provide documentation of a satisfactory Pap test within 3 yrs prior to enrollment, collect and perform **Pap Test** at local lab.* Ecto- and endocervical cells per site SOP.
 | * Screening (V1) if indicated
 |  |
|  | Collect cervicovaginal fluid (CVF) for **biomarkers** (for MTN LC). * Using 1 vaginal swab near, but not touching the VR
 | * Enrollment (V2) *prior to ring insertion*
* Visits 3-8
* Visit 9 *prior to VR removal*
 |  |
|  | Collect cervicovaginal fluid (CVF) for **anti-HSV-2 activity** for MTN LC). * Using 1 vaginal swab near, but not touching the VR
 | * Enrollment (V2) *prior to ring insertion*
* Visits 6 & 8
 |  |
|  | Collect cervicovaginal lavage (CVL) for **PK, PD and** **biomarker analyses** (for MTN LC). * From cervix/ upper-end of vagina using syringe technique.

*Note: At V2, CVL is only for PD and biomarkers.* | * Enrollment (V2) *prior to VR insertion*
* Visits 6 & 8
 |  |
|  | Collect cervical tissue biopsy for **PK testing** (for MTN LC)* 2 biopsies, 3x5 mm in size, of cervical tissue taken from two different locations.

Record pre- and post-collection weights. | * Visits 5 & 6 *according to assigned biopsy collection schedule (schedule V5 & 8 or V6 & 9)*
 |  |
|  | Collect cervical tissue biopsy for **PK and** **PD testing** (for MTN LC)* 4 biopsies, 3x5 mm in size, of cervical tissue taken from two different locations.

Record pre- and post-collection weights for PK only (PD biopsy delivered to and weighed in Local PD Lab). | * Visit 8 & 9 *according to assigned biopsy collection schedule (schedule V5 & 8 or V6 & 9)*

*Note: collect prior to ring removal at Visit 9*  |  |
|  | Remove speculum; and perform bimanual exam, if indicated. | * Visits 1-9
* If indicated at Visit 10
 |  |
|  | Document all findings on **Pelvic Exam Diagrams** and **Pelvic Exam CRF,** and **STI Test Results CRF**, as applicable.Document storage of all specimens collected on the **(Timed)** **Cervical/** **Specimen Storage CRFs** and **LDMS Specimen Tracking Sheet**. | * Visits 1-10
 |  |

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| --- |
| **Comments** |
|  |