**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** | **Visit**  | **Staff Initials** |
| --- | --- | --- |
|  | Prepare for exam: * Exam equipment, documentation, and specimen collection supplies; label as needed.
 | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly Visits
 |  |
|  | Prepare for participant: * Explain exam procedures to participant and answer any questions.
* Position and drape participant comfortably.
 | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:All other Monthly Visits |  |
|  | Palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.  | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly Visits
 |  |
|  | Perform naked eye examination of the external genitalia including the perineum, perianal area, and the epithelial lining of the introitus.  | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly visits
 |  |
|  | Insert speculum, using warm water as lubricant if needed. Perform naked eye exam of the vagina and cervix, if applicable.  | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly Visits
 |  |
|  | Collect vaginal fluid for **Trichomonas** **rapid test** at local lab.* 1 swab from lateral vaginal wall.
 | Required:* Screening (V1)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* Enrollment (V2)
* All other Monthly Visits
 |  |
|  | Collect vaginal fluid for **microbiota analyses (qPCR)** at MTN LC. * 3 flocked swabs from lateral vaginal wall.
 | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16
 |  |
|  | Collect vaginal fluid for **pH assessment** in clinic.* 1 swab from lateral vaginal wall. Swab fluid onto pH strip and assess results.

Note: same swab can be used for wet prep mount if needed | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20

If indicated:* Screening (V1)
* All other Monthly Visits
* PUEV (V23)
 |  |
|  | *If clinically indicated (symptomatic),* use swab collected for pH assessment (if done) for **wet prep/KOH wet mount** for evaluation of candidiasis and/or BV at local lab/clinic.Note: If a swab for vaginal pH gets contaminated or does not have enough vaginal fluid for wet mount, then collect a swab from the lateral vaginal wall. | If indicated: All clinic visits |  |
|  | Collect vaginal fluid for **Gram stain analysis** at MTN LC**.**  * 1 swab from lateral vaginal wall; turn swab 3x. Roll swab across two labeled slides and air dry.
 | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)
 |  |
|  | Collect vaginal fluid for **biomarker analyses** at MTN LC. * 1 swab from posterior fornix.

*NOTE: Self-collected at visits when no pelvic exam is performed [see Monthly Follow-Up Checklist].* | Required:* Enrollment (V2)
* All Monthly Visits
* PUEV (V23)
 |  |
|  | Collect cervical fluid for **GC/CT NAAT test** at local lab.* 1 swab from the endocervical canal.

 | Required:* Screening (V1)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* Enrollment (V2)
* All other Monthly Visits
 |  |
|  | Collect cervical fluid for **biomarker analyses** at MTN LC. * 1 swab from the endocervical canal.
 | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)
 |  |
|  | Collect cervical specimen **flow cytometry** at local lab. * Place cervical cytobrush in the cervix os and perform 2 turns.

*Note: At designated site(s) only with capacity* | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)
 |  |
|  | Collect cervicovaginal lavage (CVL) for **biomarker analyses** at MTN LC. * From cervix/ upper-end of vagina using syringe technique.
 | Required:* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)
 |  |
|  | Remove speculum; and perform bimanual exam, if indicated. | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly Visits
 |  |
|  | 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 **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**. | Required:* Screening (V1)
* Enrollment (V2)
* Monthly Visits 6, 9, 13, 16, 20
* PUEV (V23)

If indicated:* All other Monthly Visits
 |  |

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