**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) in the comments section or chart notes; initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in comments section.

| **Procedure** | **Staff Initials** |
| --- | --- |
|  | Confirm identity, age, and PTID |  |
|  | Check for co-enrollment * NOT currently or recently enrolled in another study 🡪 CONTINUE.
* Currently or recently enrolled in another study 🡪 STOP. Assess eligibility to continue. Consult PSRT, if needed.

*NOTE: Participation in studies involving drugs, medical devices, genital products, or vaccines within 30 days of enrollment is exclusionary. Participation in any research study involving rectal products* ***ever*** *is exclusionary.*   |  |
|  | Confirm participant is within 45-day screening window* WITHIN 45 days from screening visit 🡪 CONTINUE.
* OUTSIDE 45 days from screening visit 🡪 STOP. Not eligible to enroll during this screening attempt 🡪 If willing, schedule for rescreening
 |  |
|  | Review/update locator information and re-assess adequacy:* Adequate locator information 🡪 CONTINUE.
* Inadequate locator information 🡪 STOP. NOT ELIGIBLE.
 |  |
|  | Review elements of informed consent. Reconfirm participant is still willing to participate and document review in chart notes. * Willing to participate 🡪 CONTINUE.
* NOT willing to participate 🡪 STOP. NOT ELIGIBLE.
 |  |
|  | Explain procedures to be performed at today’s. Provide and explain all Screening test results, if not done already.  |  |
|  | Assess behavioral eligibility by administering the **Enrollment Behavioral Eligibility Worksheet** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |
|  | Log into Medidata Rave and select the appropriate PTID. Open the Enrollment Visit folder to begin CRF data entry. |  |
|  | Collect mid-stream catch urine (15-60 mL) and perform tests:* **FOR INDIVIDUALS WHO CAN GET PREGNANT:** Qualitative hCG (pregnancy)
* NOT pregnant 🡪 CONTINUE.
* Pregnant 🡪 STOP. NOT ELIGIBLE.
* ***If indicated***: NAAT for GC/CT/TV
* ***If indicated***: Dipstick urinalysis and/or culture per site SOP.

**For individuals who can get pregnant**, document pregnancy test results on local testing log and the **Pregnancy Test Results eCRF**. *If applicable, document GC/CT/TV test results on the* ***STI Test Results eCRF****.*  |  |
|  | **FOR INDIVIDUALS WHO CAN GET PREGNANT:** Review study contraception requirements and provide contraceptive counseling per protocol. Confirm current contraceptive method. Effective study methods, per protocol, include: * hormonal methods (≥30 days prior to Enrollment)
* intrauterine device (IUD) (≥30 days prior to Enrollment)
* sterilization of participant or partner
* Receptive vaginal-penile intercourse (RVI) abstinence (≥90days prior to Enrollment)
* Meets contraceptive requirements ⇒ CONTINUE.
* DOES NOT meet contraceptive requirements ⇒ STOP. NOT ELIGIBLE.

Prescribe/provide/refer for contraception if needed. If applicable, document contraceptive method on **Concomitant Medications Log eCRF** orin **chart notes (RVI abstinence or sterilization)** or *[add site-specific form if desired]***.** |  |
|  | Review/update baseline medical and medications history to verify and/or update all information previously recorded. Document all updates as needed onthe Medical History Summary/Log eCRFs and Concomitant Medications Summary/Log eCRFs. |  |
|  | Provide and document HIV pre-test and HIV/STI risk reduction counseling, including offering male condoms, using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |
|  | Collect the following amounts of blood and send to lab for testing or storage:* HIV-1/2 (rapid test[s] required)
	+ [X] mL [color] top [additive/no additive] tube
* Plasma for archive
	+ [X] mL [color] top [additive/no additive] tube

***If indicated:**** Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube

Document collection of plasma storage on **Specimen Storage eCRF** and **LDMS Tracking Sheet.** Document syphilis results on the **Syphilis Serology eCRF**, if applicable. |  |
|  | Perform and document HIV test (s) per site SOPs and in accordance with HIV Testing Algorithm.*The following applies to sites running one EIA:* * If negative 🡪 UNINFECTED 🡪 CONTINUE.
* If positive or indeterminate 🡪RESCHEDULE VISIT**→** Perform HIV confirmation test actions per HIV testing algorithm.
* POSITIVE→STOP →INELIGIBLE
* NEGATIVE OR INDETERMINATE→CONSULT LC

*The following applies to sites running two rapid tests:** If both tests negative → UNINFECTED → CONTINUE.
* If both tests positive OR discordant → RESCHEDULE VISIT**→** Perform HIV confirmation test actions per HIV testing algorithm.
* POSITIVE→STOP →INELIGIBLE
* NEGATIVE OR INDETERMINATE→CONSULT LC

Document results on **HIV Test Results eCRF.**  |  |
|  | Provide HIV test results in the context of post-test counseling and document on **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.** Provide referrals for care and treatment, if applicable, per site SOPs.  |  |
|  | Perform targeted physical exam and complete the **Vital Signs eCRF** and **Physical Exam eCRF.** |  |
|  | *If clinically indicated, collect pharyngeal sample for NAAT for GC/CT. Document results on STI Tests eCRF.*  |  |
|  | *If clinically indicated, for individuals with a natural phallus or neo-phallus, perform genital examination per Genital Exam Checklist and document findings on the Genital Exam eCRF.*  |  |
|  | *If clinically indicated, for individuals with a natural vagina or neo-vagina, perform pelvic examination and/or collect vaginal swab per Pelvic Exam Checklist. Document results on STI Test Results eCRF and exam findings on the Pelvic Exam Diagrams Form and Pelvic Exam eCRF.* |  |
|  | Perform anorectal exam per anorectal Exam Checklist and document findings on the **Anorectal Exam eCRF**.  |  |
|  | Evaluate findings identified during rectal and physical examinations (if applicable, genital and pelvic exams) and medical history review. Determine whether participant has current RTI/STI/UTI symptoms:* No symptoms 🡪 CONTINUE.
* Symptom(s) present 🡪 evaluate per site SOPs. 🡪 STOP. MAY BE INELIGIBLE.

 *If symptomatic and diagnosed with an RTI/STI/UTI, t*reat or refer for treatment *if indicated, per site SOP. The participant must complete treatment and all symptoms must resolve to be eligible for enrollment.*  |  |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  |
|  | Document referral in chart notes and update **Concomitant Medications Log** **eCRF**, if treatment provided or prescribed. Document relevant ongoing conditions on the **Medical History Log** **eCRF**.  |  |
|  | Conduct confirmation and final determination of eligibility status by review/completion of **Eligibility Checklist.** * ELIGIBLE 🡪 CONTINUE 🡪 sign the **Eligibility Checklist** and proceed to eligibility verification.
* NOT ELIGIBLE 🡪 STOP. DO NOT enroll. 🡪 Pause and evaluate whether participant is:
	+ NOT ELIGIBLE but likely to meet eligibility criteria during this screening attempt 🡪 PAUSE🡪perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.
* NOT ELIGIBLE and NOT likely to meet eligibility criteria during this screening attempt 🡪 STOP. Provide clinical management as needed. Complete the **Inclusion/Exclusion Criteria eCRF.**
 |  |
|  | Verify participant eligibility by review of **Eligibility Checklist** (done by IoR/designee [must be different staff member from above step]): * ELIGIBLE 🡪 CONTINUE. Complete the Inclusion/Exclusion Criteria eCRF with eligibility status.
* NOT ELIGIBLE 🡪 STOP. DO NOT RANDOMIZE. Provide clinical management as needed. Complete the **Inclusion/Exclusion Criteria eCRF** with ineligibility status.
 |  |
|  | Administer the Baseline Behavioral Assessment and document on the **Behavioral Assessments Summary** and **CASI Tracking eCRFs**. |  |
|  | Randomize the participant to product sequence. Complete **Randomization eCRF.** Once the randomization date and time are auto-populated on the CRF, the participant is officially enrolled in the study. |  |
|  | Complete the **Enrollment** **eCRF.** |  |
|  | Complete a **Study** **Prescription** for assigned product sequence. Deliver the top (white) copy [along with the site-specific form, if applicable] to the pharmacy. Retain yellow copy of prescription in participant’s binder.  |  |
|  | Provide written product use instructions, review instructions on how to use and store assigned product, and instructions to return any unused study product to the clinic at the PUEV. Provide assigned product (and lubricant if needed) and have participant self-administer first dose for Period 1.  |  |
|  | Perform QC1 with participant still present. Review the following for completion and clear documentation:* Visit and Rectal Exam checklist (if indicated, pelvic and genital exam checklists) to ensure all required procedures were completed.
* LDMS Specimen Tracking Sheet and **Specimen Storage eCRFs**.
* **Medical History Log** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently.
* **Enrollment eCRF**, chart notes, **Eligibility Checklist**, **Enrollment Behavioral Eligibility Worksheet,** and **Inclusion/Exclusion Criteria eCRF** to ensure all items are complete and accurate.
* All CRFs for completeness and accuracy, based on participant responses and clinical findings.
 |  |
|  | Program/initiate short message service SMS/IM Reporting System. Review instructions and training on how to receive and respond to SMS/IM. |  |
|  | Schedule next visit and provide condoms (if needed) and any other study informational materials, site contact information, and instructions to contact the site for additional information, study product and/or counseling if needed before the next visit: *[add site-specific list if desired]* |  |
|  | Update **Screening and Enrollment Log.**  |  |
|  | Provide reimbursement. |  |

|  |  |  |
| --- | --- | --- |
|  | Perform QC2. Review participant chart contents, paper forms and EDC data: **Required eCRFs:*** Vital Signs
* Physical Exam
* Anorectal Exam
* Behavioral Assessment Summary
* CASI Tracking
* HIV Test Results
* Randomization
* Specimen Storage
* Pregnancy Test Results (for individuals who can get pregnant)
* Inclusion/Exclusion Criteria
* Enrollment

**Required Paper Forms:*** Eligibility Checklist
* Screening and Enrollment Log
* Enrollment Behavioral Eligibility Worksheet
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet
* LDMS Tracking Sheet
* Pelvic Exam Diagrams, *if applicable*

***If indicated/applicable:**** Genital Exam
* Pelvic Exam
* Medical History Summary/Log
* Concomitant Medications Summary/Log
* STI Tests Results
* Protocol Deviations Log
* Syphilis Serology
* Social Impact Summary/Log

For failed screening attempts, the only CRF that requires completion is the Inclusion/Exclusion Criteria eCRF. Other CRFs that were completed during the failed screening attempt up until the point that ineligibility was determined may remain in the study database. |  |
| **Comments:** |
|   |