**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. |  |
|  | Administer the Baseline Behavioral Assessment and document on the **Behavioral Assessments Summary** and **CASI Tracking eCRFs**. |  |
|  | 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.
 |  |
|  | 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. 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:** |
|   |