| Enrollment Visit Checklist | | |
| --- | --- | --- |
| Procedures | | Staff Initials |
|  | Confirm participant identity and PTID.  [Note: If female and on menses, reschedule enrollment visit within the window, if applicable] |  |
|  | Verify 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 |  |
|  | Check for co-enrollment in other studies per site SOPs:   * NOT enrolled in another study ⇒ CONTINUE. * Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY. CONSULT PSRT as needed |  |
|  | Review/update locator information and re-assess adequacy per site SOPs.   * Adequate locator information ==> CONTINUE. * NO adequate locator information ==> STOP. NOT ELIGIBLE. |  |
|  | Review elements of informed consent. Explain procedures to be performed at today’s visit. Confirm participant is still willing to participate and document in chart notes:   * Willing to participate ==> CONTINUE. * NOT willing to participate==> STOP. NOT ELIGIBLE. |  |
|  | Provide and explain all prior screening test results. |  |
|  | Assess behavioral eligibility and document on **Enrollment Behavioral Eligibility Worksheet**   * Eligible ==> CONTINUE. * Not Eligible but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> Reschedule Enrollment Visit when participant is likely to be eligible. * Not Eligible and Not likely to meet eligibility criteria within this screening attempt ==> STOP |  |
|  | Administer **Baseline CASI Questionnaire**. Document administration on the **CASI Summary and CASI Tracking CRFs**.  *Note: The administration of the CASI Questionnaire may be placed elsewhere in the visit flow; however, administration must occur prior to randomization.* |  |
|  | Complete the **Sexual Lubricant CRF.** |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. As needed, make updates to **Baseline Medical History Questions Sheet**, **Baseline Medical History Summary/Log CRF** and **Concomitant Medications Summary/Log CRF**. |  |
|  | Females participants: determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs. Prescribe/provide/refer for contraception if indicated per site SOP. Document contraceptive counseling using Contraceptive Counseling Worksheet. |  |
|  | Perform and document targeted physical examination on the **Physical Exam CRF**. Add relevant findings to **Baseline Medical History Log CRF**. |  |
|  | Obtain vitals and document on **Vital Signs CRF** |  |
|  | Collect urine (15-60 mL) for:   * Qualitative hCG (Female participants)   If indicated:   * Dipstick urinalysis and/or urine culture * NAAT for GC/CT   Enter results onto **Pregnancy Test CRF** (required for female participants) and **STI Tests CRF** (if indicated). |  |
|  | Female participants: Perform pregnancy test:   * NOT pregnant ⇒ CONTINUE. * Pregnant ⇒ STOP. NOT ELIGIBLE. |  |
|  | Provide and document HIV/STI risk reduction counseling using HIV Pre/Post Test and Risk Reduction Counseling Worksheet. |  |
|  | Collect blood samples for:   * Plasma for archive \_\_\_ mL [tube type] * HIV serology \_\_\_ mL [tube type]   Document plasma for archive on [specify source doc, such as LDMS Tracking Sheet and/or Specimen Storage CRF]. Enter results onto **HIV Test Results CRF** once available.  If clinically indicated:   * AST, ALT \_\_\_ mL [tube type] * Syphilis serology \_\_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type] * CBC with differentials and platelets \_\_\_ mL [tube type]   Enter results onto **Local Laboratory Results CRF, Hematology CRF,** and/or **STI Tests CRF** (if indicated). |  |
|  | Provide test results and post-test counseling using HIV Pre/Post Test and Risk Reduction Counseling Worksheet; provide/document referrals if needed/requested. |  |
|  | Perform and document genital examination on the **Genital Exam Checklist**, **Anorectal Exam CRF**, **Pelvic Exam CRF** and **Pelvic Exam Diagrams form**. Add relevant findings to **Baseline Medical History Log CRF**. |  |
|  | Provide and explain available exam and lab test results. |  |
|  | Evaluate any abnormal findings. Explain test results and exam findings. If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document provision of results, treatments and referrals in chart notes.   * Symptom(s) present ⇒evaluate per site SOPs. If treatment is required ⇒STOP. MAY BE INELIGIBLE. * No symptoms⇒CONTINUE. |  |
|  | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist:   * ELIGIBLE ⇒ CONTINUE. Document date and time of checklist and complete sign-off. * NOT ELIGIBLE ⇒ STOP. Provide clinical management as needed. Document in chart notes. Enter data into study database for Eligibility Criteria CRF. |  |
|  | Randomize the participant as follows: complete the Eligibility Criteria CRF in the study database, then complete the Randomization CRF. Once the participant’s randomization date and time auto-populate on the Randomization CRF, the participant is randomized. ONCE A PARTICIPANT IS RANDOMIZED, S/HE IS OFFICIALLY ENROLLED IN THE STUDY. |  |
|  | Provide and document protocol adherence counseling using protocol counseling worksheet. Review and offer a copy of the informational booklet to the participant (if not already provided). |  |
|  | Perform QC1: while participant is still present, review the following:   * Review Enrollment Behavioral Eligibility Worksheet, Eligibility Checklist, and chart notes to ensure completeness and accuracy * Review LDMS Specimen Tracking Sheet to ensure completeness * Review Cervical Specimen Storage (LMP items), Sexual Lubricant, Baseline Medical History Log CRF, and Concomitant Medications Log CRF to ensure all conditions and medications are captured consistently * Review Pelvic Exam, Anorectal Exam, Vital Signs, and Physical Exam CRFs (or other source documents), Pelvic Exam Diagrams to ensure all findings are clearly documented |  |
|  | Update Screening and Enrollment Log. Generate participant visit calendar if not done already. Review study schedule using visit schedule tool. Schedule next visit and advise participant of potential length of next visit. |  |
|  | Provide contact information and instructions to report symptoms and/or request information, counseling, study product before next visit. |  |
|  | Provide reimbursement. |  |
|  | For enrolled participants, ensure that data is entered into the study database (and perform QC2 review, if applicable) for the following required CRFs:   * Enrollment * Randomization * CASI Summary * CASI Tracking * Eligibility Criteria * Vital Signs * Physical Exam * Anorectal Exam * Pregnancy Test (female participants only) * Specimen Storage * HIV Test Results * Sexual Lubricant * Cervical Specimen Storage (female participants) * Pelvic Exam (female participants only) * Pelvic Exam Diagrams (female participants only)   Log CRFs (complete/update as applicable)   * Baseline Medical History Summary/Log * Concomitant Medications Summary/Log * Protocol Deviations Summary/Log   For failed screening attempts, the only CRF that requires completion is the Eligibility Criteria CRF. Other CRFs that were completed during the failed screening attempt may remain in the study database. |  |

**Additional Notes/Comments/Referrals:**