| **Screening Visit Checklist**  PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_  Visit Type: Screening Visit Code: 1.0 | |
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| **Procedure** | **Staff Initials** |
| **Confirm participant’s identity and age 18 through 45 years (inclusive) years of age at screening**   * Yes ==> CONTINUE. * No ==> STOP. NOT ELIGIBLE.   *Note: [If on menses, reschedule screening visit within the window.]* |  |
| Confirm whether the participant is co-enrolled in another study.  🞎 No ==> CONTINUE. 🞎 Yes ==> STOP. NOT ELIGIBLE. |  |
| Determine screening attempt (Verify if PTID has previously been assigned)  🞎 First attempt 🞎 Second attempt ==> CONTINUE (Note: max of two attempts allowed). |  |
| Explain procedures to be performed at today’s visit. |  |
| Explain, conduct and document written informed consent, complete ***Informed Consent Coversheet***and***Comprehension Assessment.*** |  |
| Assign PTID => complete ***Screening and Enrollment Log*** *and* ***PTID Name Linkage Log*** |  |
| Determine last possible enrollment date for this screening attempt using visit calendar tool **(+45 days):**  Date : \_\_ \_\_ / \_\_ \_\_ \_\_/ \_\_ \_\_ |  |
| Obtain locator information and complete site specific locator form. Determine adequacy of locator information:   * Adequate locator information ==> CONTINUE * **Inadequate** locator information ==> Adequate information likely to be available prior to enrollment ==>   CONTINUE and RE-ASSESS at enrollment.   * **Adequate information NOT likely to be available ==> STOP. NOT ELIGIBLE**. |  |
| Collect demographic information using the ***Demographics CRF*** |  |
| Administer ***Screening Behavioral Eligibility Worksheet***  🞎 Eligible ==> CONTINUE.  🞎 **Not Eligible** but **likely** to meet eligibility criteria within this screening attempt ==> PAUSE ==> Schedule  Enrollment Visit when participant is likely to be eligible.  🞎 **Not Eligible** and **Not likely** to meet eligibility criteria within this screening attempt ==> STOP |  |
| Provide and document contraceptive counseling *using* ***Contraceptive Counseling Worksheet*** |  |
| Obtain baseline medical, menstrual and medications history. Document on the  ***Baseline Medical History Questions Sheet, Pre-existing Conditions CRF and Concomitant Medications Log CRF*** |  |
| Collect urine (15-60 mL):   * **hCG** * **Dipstick urinalysis** * *urine culture (if indicated)*   Document dipstick urinalysis results on the ***Safety Laboratory Results CRF***.  Pregnant: 🞎 NO==> CONTINUE 🞎 YES==> **STOP**. NOT ELIGIBLE. |  |
| Provide and document HIV pre- test and risk reduction counseling *using* ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet*** |  |
| Collect blood:  **❒ Complete blood count (CBC) with differential and platelets**  **❒ HIV-1 serology**  **Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.**  **❒ HBsAg**  **❒ Coagulation (INR)**  **❒ Anti-HCV**  **❒ Chemistries (AST, ALT, creatinine)**  **❒ Syphilis serology**  Review lab results when available and transcribe results on the ***Safety Laboratory Results CRF***. Add any grade 1 or higher labs to ***Pre-Existing Conditions CRF***. |  |
| Provide and document available test results/post-test counseling using ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet.*** |  |
| Perform and document full physical examination on the ***Physical Exam CRF*.** Add relevant findings to ***Pre-Existing Conditions CRF.*** |  |
| Perform and document pelvic examination on the ***Pelvic Exam Checklist, Pelvic Exam CRF*** and ***Pelvic Exam Diagrams non-DataFax CRF***. Add relevant findings to ***Pre-Existing Conditions CRF***. |  |
| 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.  ***Note****: Participant must complete treatment and symptoms resolved prior to enrollment (see protocol for exclusionary STIs i.e. GC/CT and syphilis).* |  |
| Review last possible day the participant may be enrolled. Schedule next visit taking into consideration the length of time required to receive lab results and participant’s menses, as applicable. Advise participant of potential length of next visit. |  |
| Provide and document protocol adherence counseling using [site to insert (i.e. study information booklet)]. Offer a copy of the booklet to the participant. |  |
| 🞎 If participant will not proceed to Enrollment, complete ***Eligibility Checklist*** and complete and fax ***Eligibility Criteria CRF*** ==> End of Visit  🞎 If participant will proceed to Enrollment, move ***Eligibility Checklist*** and ***Eligibility Criteria CRF*** to Enrollment Visit form packet and complete at Enrollment Visit ==> CONTINUE |  |
| Provide reimbursement |  |

**Complete and assemble all CRFs from the Screening Visit and complete QC 1 to ensure all items are completed (while the participant is still in the clinic). Do not fax forms until participant has enrolled (randomized).**

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| **Case Report Forms** |
| Demographics CRF |
| Pelvic Exam CRF |
| Physical Exam CRF |
| Pre-Existing Conditions CRF |
| Concomitant Medications Log CRF |
| Safety Laboratory Results CRF |
| Pelvic Exam Diagrams (non-DataFax) CRF |
| Eligibility Criteria CRF (as needed) |
| **Other Tools and Worksheets** |
| Screening Behavioral Eligibility Worksheet |
| Baseline Medical History Questions Sheet |
| HIV Pre/Post Test and Risk Reduction Counseling Worksheet |
| Contraceptive Worksheet |
| Calculated Creatinine Clearance Worksheet |
| Informed Consent Comprehension Assessment |
| Informed Consent Coversheet |
| PTID Name Linkage Log |
| Screening and Enrollment Log |
| Eligibility Checklist (as needed) |

QC1 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

QC2 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_