

PTID:		Visit Date:	
Screening Attempt:		Visit Code: 2.0	
Initials		Procedures	
		Confirm participant identity and PTID per site SOPs.	
		Check for co-enrollment in other studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study ⇒ CONTINUE. <input type="checkbox"/> Enrolled in another study ⇒ NOT ELIGIBLE ⇒ STOP.	
		Review documentation from previous visit.	
		Verify current screening attempt number and, based on date of screening informed consent, confirm the last possible enrollment date for this screening attempt: <div style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div>	
		Provide and explain all prior screening test results. Provide post-test counseling if HIV WB was performed between Screening Part 1 and this visit.	
		<p>Explain to the participant her current eligibility status and procedures to be performed at today's visit:</p> <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE but reasonably likely to meet eligibility criteria within this screening attempt ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP screening but provide clinical management as needed. Document in chart notes.	
		Review/update locator information and re-assess adequacy of information per site SOPs: <input type="checkbox"/> Adequate locator information ⇒ CONTINUE. <input type="checkbox"/> Inadequate locator information ⇒ PAUSE and re-assess: <input type="checkbox"/> Adequate information likely to be available prior to enrollment ⇒ CONTINUE. <input type="checkbox"/> Adequate information NOT likely to be available ⇒ NOT ELIGIBLE ⇒ STOP.	
		Administer the Screening Part 2/Enrollment Behavioral Eligibility form: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP.	
		Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant ⇒ CONTINUE. <input type="checkbox"/> Pregnant ⇒ NOT ELIGIBLE ⇒ STOP.	

Comment [JAC1]: Need site input on whether it is useful to list this item here.

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	<input type="checkbox"/> If 1+ for protein or glucose at Screening Part 1 or if participant has urinary symptoms, perform dipstick urinalysis; complete testing logs and transcribe results onto Safety Laboratory Results form. <ul style="list-style-type: none"> • If 2+ or greater for protein OR glucose ⇒ NOT ELIGIBLE ⇒ STOP. • If 1+ for protein at this visit and 1+ for protein at Screening Part 1 ⇒ NOT ELIGIBLE ⇒ STOP. • If 1+ for glucose at this visit and 1+ for glucose at Screening Part 1 ⇒ NOT ELIGIBLE ⇒ STOP. • If 1+ for protein at this visit but normal or trace for protein at Screening Part 1, dipstick must be repeated at Enrollment ⇒ CONTINUE. • If 1+ for glucose at this visit but normal or trace for glucose at Screening Part 1, dipstick must be repeated at Enrollment ⇒ CONTINUE. • If positive for nitrites or leukocytes, provide treatment and/or additional UTI work-up per site SOPs; document in chart notes. If UTI is diagnosed, participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE. 		
	<input type="checkbox"/> Retain remaining urine for possible gonorrhea and chlamydia SDA; refrigerate prior to testing.		
	Collect baseline medical and menstrual history with documentation of current medications; document per site SOPs.		
	Perform physical exam with measurement of height and weight; document per site SOPs.		
	Perform and document pelvic exam per the Screening Pelvic Exam Checklist.		
	Provide and explain available exam and lab test results.		
	If STI/RTI is diagnosed, provide treatment and offer STI testing and/or treatment for partners if indicated ⇒ participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE.		
	If indicated, prepare urine for gonorrhea and chlamydia SDA.		
	If indicated, collect and prepare blood for syphilis serology.		
	If indicated, collect and prepare blood for other testing needed to determine eligibility (specify):		

Comment [JAC2]: Need site input on the timing of this procedure – would they be aware of urinary symptoms at this time?

Comment [JAC3]: The Non-DataFax Baseline Medical and Menstrual History form and the Concomitant Medications Log DataFax form are the recommended source documents for this procedure. Need input on whether all sites are planning to use these forms as source. If so, we will list them as part of this item on the checklist.

Comment [a4]: The Non-DataFax Physical Exam form is the recommended source document for this procedure. Need input on whether all sites are planning to use this form. If so, we will list the form as part of this item on the checklist.

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	Assess participant's current eligibility status: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE but reasonably likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule Enrollment Visit when participant is likely to be eligible. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP screening but provide clinical management as needed. Document in chart notes.		
	Provide HIV/STI risk reduction counseling and condoms. Offer HIV counseling and testing for partner(s).		
	Verify current contraceptive method (see Screening Part 2 Behavioral Eligibility form and medical history documentation), review study contraception requirements, and provide contraceptive counseling; document in chart notes.		
	Provide contraception if indicated per site SOPs.		
	Provide study informational material.		
	Provide contact information and instructions to contact the site for additional information and/or counseling if needed before the next visit.		
	Schedule next visit.		
	Provide reimbursement.		
	Document the visit in a signed and dated chart note.		
	Complete and review all required visit documentation.		

Comment [JAC5]: Need site input about the timing of this procedure. Since the study contraception requirements are discussed in the Screening Part 2 Behavioral Eligibility form, should contraception counseling occur immediately after completing that form, or is it preferred to wait until later in the visit, after eligibility is further determined?

Comment [JAC6]: Need site input on what would be given at this visit.