

<b>PTID:</b>		<b>Visit Date:</b>	
<b>Screening Attempt:</b>		<b>Visit Code: 3.0</b>	
<b>Initials</b>	<b>Procedures</b>		
	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 visits.		
	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.		
	Explain the participant's current eligibility status and procedures to be performed at today's visit: <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 and schedule participant for another Enrollment Visit. <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 and document HIV counseling and testing per site SOPs: <input type="checkbox"/> Provide HIV pre-test counseling <input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms <input type="checkbox"/> Collect blood: <div style="margin-left: 20px;"> <input type="checkbox"/> 1 x 4 mL lavender top (EDTA) tube <span style="background-color: #ffff00; padding: 2px;">4 mL is approximate. Tailor to reflect site-specific volume.</span>  <input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube ⇒ REFRIGERATE pending enrollment                 </div> <input type="checkbox"/> Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results. <input type="checkbox"/> Provide rapid HIV test results and post-test counseling: <ul style="list-style-type: none"> <li>• If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE.</li> <li>• If both tests positive ⇒ INFECTED ⇒ NOT ELIGIBLE ⇒ STOP.</li> <li>• If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ defer further screening until HIV status is clarified.</li> </ul> <input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s). <input type="checkbox"/> Transcribe results onto Screening and Enrollment HIV Test Results form.		

**Comment [JAC1]:** Need site input on whether blood for plasma archive would be collected at this time, prior to eligibility confirmation, or would a second blood draw be done after final eligibility confirmation?

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	<p>Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:</p> <p><input type="checkbox"/> NOT pregnant ⇒ CONTINUE.</p> <p><input type="checkbox"/> Pregnant ⇒ NOT ELIGIBLE ⇒ STOP.</p> <hr style="border-top: 1px dashed black;"/> <p><input type="checkbox"/> If 1+ for protein or glucose at Screening Part 2, or if participant has urinary symptoms, perform dipstick urinalysis; complete testing logs and transcribe results onto Safety Laboratory Results form.</p> <ul style="list-style-type: none"> <li>• If 2+ or greater for protein OR glucose ⇒ NOT ELIGIBLE ⇒ STOP.</li> <li>• If 1+ for protein at this visit and 1+ for protein at Screening Part 1 OR Screening Part 2 ⇒ NOT ELIGIBLE ⇒ STOP.</li> <li>• If 1+ for glucose at this visit and 1+ for glucose at Screening Part 1 OR Screening Part 2 ⇒ NOT ELIGIBLE ⇒ STOP.</li> <li>• If 1+ for protein at this visit but normal or trace for protein at Screening Part 1 AND Screening Part 2 ⇒ CONTINUE.</li> <li>• If 1+ for glucose at this visit but normal or trace for glucose at Screening Part 1 AND Screening Part 2 ⇒ CONTINUE.</li> <li>• 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 is NOT ELIGIBLE ⇒ STOP.</li> </ul> <hr style="border-top: 1px dashed black;"/> <p><input type="checkbox"/> Retain remaining urine for possible gonorrhea and chlamydia SDA; refrigerate prior to testing.</p>
	<p>Review/update locator information and re-assess adequacy of information per site SOPs:</p> <p><input type="checkbox"/> Adequate locator information ⇒ CONTINUE.</p> <p><input type="checkbox"/> Inadequate locator information ⇒ NOT ELIGIBLE ⇒ STOP.</p>
	<p>Administer the Screening Part 2/Enrollment Behavioral Eligibility form:</p> <p><input type="checkbox"/> ELIGIBLE ⇒ CONTINUE.</p> <p><input type="checkbox"/> NOT ELIGIBLE ⇒ STOP.</p>
	<p>Reinforce co-enrollment restrictions and provide associated information and counseling as needed; document in chart notes.</p>
	<p>Actively review the participant's baseline medical and menstrual history and current medications to verify and/or update all information recorded at Screening Part 2. Document all updates on relevant source documents and case report forms.</p>
	<p>Review study contraception requirements and provide contraceptive counseling; document in chart notes.</p>
	<p>Provide contraception if indicated per site SOPs.</p>

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	<p>If clinically indicated or otherwise required to confirm eligibility, perform pelvic exam and associated lab tests:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No exclusionary findings identified ⇒ CONTINUE.</li> <li><input type="checkbox"/> Exclusionary finding(s) identified but reasonably likely to resolve within the current screening attempt ⇒ NOT ELIGIBLE ⇒ PAUSE ⇒ perform and document all clinically indicated procedures and schedule participant for another Enrollment Visit.</li> <li><input type="checkbox"/> Exclusionary finding(s) identified and NOT reasonably likely to resolve within the current screening attempt ⇒ NOT ELIGIBLE ⇒ STOP screening but provide clinical management as needed. Document in chart notes.</li> </ul>
	Provide and explain available exam and lab test results.
	Provide any clinically indicated treatment; offer STI testing and/or treatment for partners if indicated.
	<p>Review all screening documentation, complete Enrollment Medical Eligibility form, and determine eligibility:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ELIGIBLE ⇒ CONTINUE ⇒ Proceed to eligibility confirmation per site SOPs.</li> <li><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 participant for another Enrollment Visit when she is likely to be eligible.</li> <li><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.</li> </ul>
	<p>Verify participant eligibility per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ELIGIBLE ⇒ CONTINUE ⇒ Proceed to enrollment informed consent process.</li> <li><input type="checkbox"/> NOT ELIGIBLE ⇒ STOP screening but provide clinical management as needed. Document in chart notes.</li> </ul>
	<p>Explain, conduct, and document the informed consent process for study participation per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE.</li> <li><input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ NOT ELIGIBLE ⇒ STOP.</li> </ul>
	Explain, conduct, and document the informed consent process for specimen storage and possible future research testing per site SOPs.
	<p>If participant is susceptible (HBsAg- and HBsAb-), offer Hepatitis B vaccine:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Participant accepted and vaccine was administered.</li> <li><input type="checkbox"/> Participant refused and refusal was documented per site SOPs.</li> </ul>
	Administer Baseline Behavior Assessment form.
	Administer Baseline ACASI Questionnaire.

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	Verify written consent for study participation and assign the next sequential Clinic Randomization Envelope to the participant per site SOPs.
	Open the assigned envelope and confirm that the envelope number printed on the prescription contained in the envelope corresponds with the number on the outside of the envelope. Inform the participant of her assignment (gel or tablets).
	Complete the prescription. Give the completed white original prescription to the participant to bring to the pharmacy to obtain product supplies. Retain the envelope and the yellow clinic copy of the prescription in the participant's study notebook.
	Complete LDMS Specimen Tracking Sheet and prepare blood (10 mL lavender top tube) for processing and plasma archive.
	Obtain confirmation of receipt of blood for plasma archive at the local lab per site SOPs.
	After the participant returns from the pharmacy with her product supplies, provide instructions for product use. Then ask the participant to take her first tablets or insert her first applicatorful of gel at the clinic. <b>DO NOT HANDLE OR INSPECT GEL APPLICATORS THAT HAVE BEEN REMOVED FROM THEIR WRAPPERS.</b>
	Debrief with the participant about her first product use; provide additional information and instructions as needed.
	Provide study product adherence counseling.
	Schedule next visit. Remind the participant to bring all unused study product supplies and any medications she is taking to the next visit.
	Provide contact information and instructions to contact the site to report symptoms and/or to request for additional information, counseling, product supplies, or condoms, if needed, before the next visit.
	Provide reimbursement.
	Document the visit in a signed and dated chart note.
	Complete and review all required visit documentation.

**Comment [JAC2]:** Need site input on whether all participants will bring prescriptions to the pharmacy

**Comment [JAC3]:** Need site input on the timing of this procedure

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	<input type="checkbox"/> Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <li><input type="checkbox"/> Screening Consent</li> <li><input type="checkbox"/> Demographics</li> <li><input type="checkbox"/> Screening and Enrollment HIV Test Results (completed at Screening Part 1)</li> <li><input type="checkbox"/> Screening and Enrollment HIV Test Results (completed at Enrollment)</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Screening and Enrollment Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK (completed at Screening Part 2)</li> <li><input type="checkbox"/> Specimen Storage/PK (completed at Enrollment)</li> <li><input type="checkbox"/> Enrollment</li> <li><input type="checkbox"/> Pre-Existing Conditions</li> <li><input type="checkbox"/> Concomitant Medications Log</li> <li><input type="checkbox"/> Baseline Family Planning</li> <li><input type="checkbox"/> Baseline Behavior Assessment</li> </ul>		

**Comment [JAC4]:** Need site input on this item: given that forms are not usually faxed on the day of the visit, is it a problem to have an item like this on the checklist, because this item will need to be initialed and dated separate from all other visit procedures?