

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	Confirm participant identity and PTID per site SOPs.	
	Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section X. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule the participant to return when a response from PSRT is expected.	
	Instruct participant to return her unused study product supplies to the pharmacy.	
	Review documentation from previous visit.	
	Review elements of informed consent as needed.	
	Explain the content and sequence of procedures for today’s visit.	
	Review/update locator information.	
	Administer Oral or Vaginal Product Adherence and Behavior Assessment form.	
	Administer Quarterly ACASI Questionnaire (oral or vaginal).	
	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: <input type="checkbox"/> 1 x 5 mL red top (no additive) tube <input type="checkbox"/> 1 x 5 mL lavender top (EDTA) tube <input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube <div style="background-color: #90EE90; padding: 2px; display: inline-block; margin-left: 20px;">             Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.           </div>  <input type="checkbox"/> Perform and document rapid HIV test(s) per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.	
	<input type="checkbox"/> Provide rapid HIV test results and post-test counseling: <input type="checkbox"/> All tests negative. <input type="checkbox"/> At least one test positive ⇒ inform the participant that she must stop product use; arrange to collect her product supplies if she did not bring all supplies to this visit.	
	<input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s). <input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.	

**Comment [DD1]:** Need site input on whether one or two rapid tests are planned to be done at follow-up visits.

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	Prepare remaining blood for required testing: <ul style="list-style-type: none"> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Plasma archive</li> </ul>	
	Record blood collected for plasma archive on the LDMS Specimen Tracking Sheet.	
	Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <ul style="list-style-type: none"> <li><input type="checkbox"/> NOT pregnant.</li> <li><input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit.</li> <li><input type="checkbox"/> Pregnant, pregnancy newly identified at this visit:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Complete a Pregnancy Report and History form.</li> <li><input type="checkbox"/> Inform the participant that she must stop product use; arrange to collect her product supplies if she did not bring all supplies to this visit.</li> <li><input type="checkbox"/> Initiate use of a Pregnancy Management Worksheet to track and document additional requirements related to this pregnancy.</li> </ul> </li> </ul>	
	<input type="checkbox"/> Perform dipstick urinalysis for protein and glucose; complete testing logs and transcribe results onto Safety Laboratory Results form. If 1+ or greater, product hold may be required. Refer to protocol Sections 9.6 and 9.7.	
	<input type="checkbox"/> If clinically indicated, perform dipstick urinalysis for nitrites and leukocyte esterase; complete testing logs and transcribe results onto Safety Laboratory Results form. If positive, provide treatment and/or additional UTI work-up per site SOPs; document additional work-up in chart notes.	
	<input type="checkbox"/> Retain remaining urine for possible gonorrhea and chlamydia SDA; refrigerate prior to testing.	
	Collect interval medical and menstrual history with documentation of current medications; document per site SOPs.	
	Provide contraceptive counseling; document in chart notes.	
	Provide contraception if indicated per site SOPs.	
	Perform physical exam including weight measurement; document per site SOPs.	
	If clinically indicated, perform and document pelvic exam per the Follow-Up Pelvic Exam Checklist.	
	Provide and explain all available findings and results.	
	If RTI/STI is diagnosed, provide treatment and offer STI testing and/or treatment for partners if indicated.	
	If indicated, administer Hepatitis B vaccine.	
	If required based on all available information, complete AE Log form(s).	

**Comment [JAC2]:** The Non-DataFax Follow-up 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 [JAC3]:** Need site input on the timing of this procedure. Would this be done as shown here, or more toward the end of the visits?

**Comment [JAC4]:** 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 eligibility to continue product use: <input type="checkbox"/> Eligible to continue product use ⇒ complete a Study Product Request Slip marked RE-SUPPLY. <input type="checkbox"/> NOT eligible to continue product use ⇒ complete a Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE and complete a Product/Hold Discontinuation form.	
	Provide product use instructions and adherence counseling per site SOPs. Document in chart notes.	
	Give the completed white original Study Product Request Slip to the participant to bring to the pharmacy to obtain product supplies. Retain the yellow clinic copy in the participant's study notebook.	
	Schedule next visit. Remind the participant to bring unused product supplies and any medications she is currently taking to the next visit.	
	Provide contact information and instructions to contact the site to report symptoms and/or request 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.	
	Fax all required DataFax forms to SCHARP DataFax: <input type="checkbox"/> Follow-up Visit <input type="checkbox"/> Oral or Vaginal Product Adherence and Behavior Assessment <input type="checkbox"/> Follow-up HIV Rapid Test Results <input type="checkbox"/> Follow-up Family Planning <input type="checkbox"/> Product Returns and Dispensations <input type="checkbox"/> Specimen Storage/PK <input type="checkbox"/> Safety Laboratory Results  If Applicable: <input type="checkbox"/> Follow-up Pelvic Exam <input type="checkbox"/> Vaginal Test Results <input type="checkbox"/> Pap Test Results <input type="checkbox"/> STI Laboratory Results <input type="checkbox"/> HIV Western Blot Test Results <input type="checkbox"/> Seroconverter Laboratory Test Results <input type="checkbox"/> Product Hold/Discontinuation Log <input type="checkbox"/> Adverse Experience Log <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Pregnancy Outcome	