

PTID	Visit Date	Visit Code 01.0
Initials	Procedures	
	Explain, conduct, and document the informed consent process per site SOP (mark one): <input type="checkbox"/> Participant willing and able to provide written informed consent ⇒ <b>CONTINUE</b> <input type="checkbox"/> Participant NOT willing and/or able to provide written informed consent ⇒ <b>STOP; provide reimbursement, complete Enrollment Status form, and document visit in a signed and dated chart note.</b>	
	Review VOICE study records to confirm HIV and pregnancy status (mark one): <input type="checkbox"/> HIV uninfected and not pregnant per VOICE records ⇒ <b>CONTINUE</b> <input type="checkbox"/> HIV infected and/or pregnant per VOICE records ⇒ <b>STOP; provide reimbursement, complete Enrollment Status form, and document visit in a signed and dated chart note.</b>	
	Determine eligibility and complete Inclusion and Exclusion Criteria Form (mark one): <input type="checkbox"/> Eligible ⇒ <b>CONTINUE</b> <input type="checkbox"/> Not eligible ⇒ <b>STOP; provide reimbursement, complete Enrollment Status form, and document visit in a signed and dated chart note.</b>	
	Assign PTID.	
	Collect locator information.	
	Administer Demographics form.	
	Assign next sequential Randomization Envelope to participant per site SOPs.	
	Give completed randomization assignment to participant to bring to pharmacy to obtain Wisebag. <input type="checkbox"/> Complete Product Dispensation and Accountability Log	
	Provide protocol adherence counseling and Wisebag instructions per Wisebag Instruction Checklist <input type="checkbox"/> Provide Diary Card(s) and practice opening/closing Wisebag and placing sticker on Diary Card	
	Schedule follow-up visit.	
	Provide site contact information.	
	Provide reimbursement.	
	Complete Enrollment Status form.	
	Document the visit in a signed and dated chart note.	