

PTID:	Visit Date:
Screening Attempt:	Visit Code: 1.0
Initials	Procedures
	Confirm identity per site SOPs and determine whether a VOICE PTID has previously been assigned to the participant.
	Determine screening attempt number: <input type="checkbox"/> First attempt ⇒ determine recruitment source and document per site SOPs. <input type="checkbox"/> Second or other attempt ⇒ CONTINUE.
	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.
	Determine whether the participant is of legal age to provide informed consent for research per site SOPs: <input type="checkbox"/> Of legal age ⇒ CONTINUE. <input type="checkbox"/> NOT of legal age ⇒ NOT ELIGIBLE ⇒ STOP.
	Explain, conduct and document the screening informed consent process per site SOPs: <input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE. <input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ NOT ELIGIBLE ⇒ STOP.
	Assign a VOICE PTID (if not done during a previous screening attempt).
	Based on the 56-day screening and enrollment window, determine the participant's last possible enrollment date for this screening attempt: <div style="text-align: center;"> </div>
	Obtain locator information and determine 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 Demographics form.
	Administer the Screening Part 1 Eligibility form: <input type="checkbox"/> ELIGIBLE far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP.
	Measure and document participant weight per site SOPs.
	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 timing of this procedure

Comment [JAC2]: Need site input on timing of this procedure.
 Also, is there consensus among sites on where weight will be source documented? In chart notes? On other worksheet?

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	<input type="checkbox"/> Perform dipstick urinalysis for protein, glucose, nitrites and leukocyte esterase; 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 OR glucose, dipstick must be repeated at Screening Part 2 ⇒ 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"/> Prepare remaining urine for gonorrhea and chlamydia SDA; refrigerate prior to testing.		
	Provide and document HIV counseling and testing per site SOPs: <ul style="list-style-type: none"> <input type="checkbox"/> Provide HIV pre-test counseling <input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms <input type="checkbox"/> Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> 1 x 6 mL lavender top (EDTA) tube <input type="checkbox"/> 1 x 5 mL red top (no additive) tube <input type="checkbox"/> 1 x 10 mL red top (no additive) tube <div style="border: 1px solid black; background-color: #90EE90; padding: 5px; width: fit-content; margin-left: 100px;"> Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. </div> <ul style="list-style-type: none"> <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"> • If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE. • If both tests positive ⇒ INFECTED ⇒ NOT ELIGIBLE ⇒ STOP. • If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ continue screening OR defer further screening procedures until HIV status is clarified. <input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s). <input type="checkbox"/> Transcribe rapid results onto Screening and Enrollment HIV Test Results form. 		
	Prepare remaining blood for required testing: <ul style="list-style-type: none"> • Complete blood count (see protocol Section 7.11) • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Syphilis serology • Hepatitis B surface antigen (HBsAg) • Hepatitis B surface antibody (HBsAb) 		

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	Determine whether the participant has current RTI/STI symptoms: <input type="checkbox"/> No symptoms ⇒ CONTINUE. <input type="checkbox"/> Symptom(s) present ⇒ evaluate per site SOPs and document in chart notes ⇒ CONTINUE.
	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 ⇒ participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE.
	Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document in chart notes.
	Provide contraception if indicated per site SOP.
	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 [JAC3]: Need site input on the timing of this procedure. Since the study contraception requirements are discussed in the Screening Part 1 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 [JAC4]: Need site input on what would be given at this visit.