

Between Screening Part 1 and Screening Part 2 Worksheet

PTID:	Screening Attempt:
Initials & Date	Procedures
	Complete initial QC/QA review of Screening Part 1 visit documentation per site SOPs
	Receive, review, grade, and assess the clinical significance of Screening Part 1 lab results per site SOPs (mark each as completed) <ul style="list-style-type: none"> <input type="checkbox"/> Complete blood count <input type="checkbox"/> Liver and renal function tests (AST, ALT, phosphate, creatinine) <input type="checkbox"/> Syphilis serology <input type="checkbox"/> Hepatitis B surface antigen (HBsAg) <input type="checkbox"/> Hepatitis B surface antibody (HBsAb) <input type="checkbox"/> Gonorrhea SDA <input type="checkbox"/> Chlamydia SDA <input type="checkbox"/> If indicated, Western blot
	Assess eligibility based on lab results (mark one) <ul style="list-style-type: none"> <input type="checkbox"/> Eligible <input type="checkbox"/> Not Eligible ⇒ specify reason(s):
	Assess Hepatitis B status (mark one) <ul style="list-style-type: none"> <input type="checkbox"/> HBsAg+ and HBsAb- ⇒ not eligible for study ⇒ counsel and refer <input type="checkbox"/> HBsAg- and HBsAb- ⇒ Hep B susceptible ⇒ offer vaccine if enroll <input type="checkbox"/> HBsAg- and HBsAb+ ⇒ not Hep B susceptible ⇒ vaccine not indicated
	Assess clinical management and referral needs (mark one) <ul style="list-style-type: none"> <input type="checkbox"/> No action needed <input type="checkbox"/> Action needed ⇒ specify:
	Complete laboratory test result case report forms <ul style="list-style-type: none"> <input type="checkbox"/> Screening and Enrollment HIV Test Results <input type="checkbox"/> Safety Laboratory Results <input type="checkbox"/> STI Laboratory Results
	Complete additional QC/QA and eligibility reviews of Screening Part 1 visit documentation per site SOPs