

Subject ID		Subject DOB	
Date Consent Signed		Date Enrolled	
Valid Consent Version	Activation Date:	Expiration Date:	
Version Signed	Activation Date:	Expiration Date:	

	YES	NO
▪ Is the consent process documented in study files (source documentation)?	<input type="checkbox"/>	<input type="checkbox"/>
▪ Was an invalid consent form signed?	<input type="checkbox"/>	<input type="checkbox"/>
<i>If YES, were there any approved changes in the valid consent? could any of these changes affect the subject's decision to participate?</i>	<input type="checkbox"/>	<input type="checkbox"/>
↳ <i>If YES, PI must submit as a Significant Deviation to CCI/IRB</i>		
↳ <i>If NO, PI must submit as a Minor Deviation to CCI/IRB at next continuing review</i>		

Check the required signatures below, and then complete the appropriate information:

<input type="checkbox"/> Subject Consent	Date signed:
<input type="checkbox"/> Subject Assent <small>▪If req'd, but not obtained, reason?</small>	Date signed: Reason:
<input type="checkbox"/> Parent/Guardian	Date signed: Relationship:
<input type="checkbox"/> Parent/Guardian	Date signed: Relationship:
<input type="checkbox"/> PI/PI Associate	Date signed:
<input type="checkbox"/> Witness	Date signed:

	YES	NO
▪ Were all required signatures obtained?	<input type="checkbox"/>	<input type="checkbox"/>
▪ Did all required signors correctly date their own signature?	<input type="checkbox"/>	<input type="checkbox"/>
<i>If NO, explain below:</i>		

	YES	NO
▪ Are all adverse events correctly documented and reported w/adequate follow-up?	<input type="checkbox"/>	<input type="checkbox"/>
▪ Are all deviations/exceptions correctly documented and reported w/adequate follow-up?	<input type="checkbox"/>	<input type="checkbox"/>
<i>If NO, explain below:</i>		

Subject Eligibility: Inclusion/Exclusion Criteria

Inclusion Criteria: does subject meet the following criteria:

	YES	NO
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>

If NO, explain below:

Exclusion Criteria: does subject meet the following criteria:

	YES	NO
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>
▪	<input type="checkbox"/>	<input type="checkbox"/>

If NO, explain below:
