



# SJD Institutional Review Board

## Title: Protocol Deviation/ Violation Form

Code: SJDIRB Form 11

Version: 06

**Section 1. To be filled up by the Principal Investigator. Documents relevant to the Deviation and/or Violation should be submitted together with this form**

SJDIRB Reference Code		Date of Submission	
Protocol Code		SJREB Code	
Protocol Title			
Principal Investigator			
Sponsor/CRO			
Approval Date		DD Month YYYY	Start Date
			DD Month YYYY
Nature of Deviation and/or Violation			#
<input type="radio"/> PD/PV Related to <b>Study Procedure</b> <input type="radio"/> PD/PV Related to <b>Safety</b> <input type="radio"/> PD/PV Related to <b>Eligibility</b> <input type="radio"/> PD/PV Related to <b>ICF Process</b>		Total Number of Participants	
		Total Number of PD/PV	
		Description of the Deviation and or Violation	
Action Taken (Attach CAPA and other related Documents)			
Name of Reporter	Signature		Date

### Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)

Decision Points	Recommendation
<input type="radio"/> Recommend further action <input type="radio"/> Request additional information <input type="radio"/> Site visit <input type="radio"/> Warn PI about halting clinical procedures and delaying vaccination schedule for failure of CRO to pay PI <input type="radio"/> Ask for corrective action <input type="radio"/> Others; _____	<ol style="list-style-type: none"> <li>1. Mandate Good Clinical Practice (GCP) retraining for the study team.</li> <li>2. Request follow-up on the safety status of affected participants.</li> <li>3. Prohibit the PI from using data from ineligible participants in the analysis.</li> <li>4. Issue a warning to the PI about the potential for halting clinical procedures and delaying vaccination schedules due to failure of the Clinical Research Organization (CRO) to fulfill payment obligations.</li> </ol>
Primary Reviewer	Signature
	Date



## SJD Institutional Review Board

### Title: Protocol Deviation/ Violation Form

Code: SJDIRB Form 11

Version: 06

SJDIRB Final Action			
Final Panel Decision		Recommendation/Comments	
<input type="radio"/> Recommend further action <input type="radio"/> Request additional information <input type="radio"/> Site visit <input type="radio"/> Warn PI about halting clinical procedures and delaying vaccination schedule for failure of CRO to pay PI <input type="radio"/> Ask for corrective action <input type="radio"/> Others; _____		(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)	
SJDIRB Officer	Name	Signature	Date
Board/Panel Secretary			
Chair/Panel Lead			