

## **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 Co	de			Date of Su	ubmission		
Protocol Code				SJREE	3 Code		
Protocol Title							
Principal Investigator							
Sponsor/CRO				Ciant Data		D Mara (	
Approval Date		Month YYYY and/or Violation		Start Date	D	D Month	<u> </u>
O PD/PV Related to St				<b></b>			#
		Total Number of Participants					
O PD/PV Related to Sa		Total Number of DD/DV					
O PD/PV Related to <b>Eligibility</b> O PD/PV Related to <b>ICF Process</b>				Total Number of PD/PV			
		iation and	or Violation				
	Action Take	en (Attach CAPA a	nd other re	lated Docum	nents)		
		-					
Name of Repo	orter	Si	gnature			Date	
Name of Repo							
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Section 2: FOR SJDIR Deci O Recommend further a O Request additional inf	B USE ONLY ision Points action		he Primary 1. Manda for the	Recon ate Good Clin e study team.	ical Practic	n se (GCP)	•
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SJDIRB Final Action								
Final Pan	el Decision	Re	Recommendation/Comments					
O Recommend further acti	on							
O Request additional infor	nation	(e.g. Proceed with the recommendation of the						
O Site visit		reviewer or full board meeting last						
O Warn PI about halting cl	inical procedures and	)						
delaying vaccination s	chedule for failure of CRO to							
pay PI								
O Ask for corrective action								
0 Others;								
SJDIRB Officer	Name		Signature	Date				
Board/Panel Secretary								
Chair/Panel Lead								



