



SJD Institutional Review Board

Title: Reportable Negative Events Form

Code: SJDIRB Form 14

Version: 02

Section 1. To be filled up by the Principal Investigator. Documents relevant to the RNE 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		Start Date	
DD Month YYYY		DD Month YYYY	
Number of Enrolled Participants		No. of Required Participants	
Negative Event Report			
Description of Negative Events (e.g. harms, risks)		Actions taken to prevent future RNEs, interventions and Outcomes	
Involving Participants			
Involving Members of the Study Team			
Involving Data safety and integrity			
Recommendations			
Name of Reporter		Signature	
Date			

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

Decision Points		Recommendation	
<ul style="list-style-type: none"> No further action Recommend further action Request additional information Site Visit Pending (if substantial clarifications are necessary prior to reaching a decision) 		<ol style="list-style-type: none"> . . . 	
Primary Reviewer		Signature	
Date			
SJDIRB Final Action			
Final Decision		Recommendation/Comments	



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<ul style="list-style-type: none">● No further action● Recommend further action● Request additional information● Site Visit● Pending (if substantial clarifications are necessary prior to reaching a decision)		(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			