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**	DD Month YYYY
Protocol Code		**SJREB Code**	
Protocol Title			
Principal Investigator			
Sponsor/CRO			
Approval Date	DD Month YYYY	**Start Date**	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 *(attach CAPA & other related documents)*		

Name of Reporter	**Signature**	**Date**

Section 2: FOR SJDIRB USE ONLY

(To be filled by the Primary Reviewer: Please use the drop down for the action - Complete; Not Applicable; For Clarificatory)

Risk Assessment	Evaluation of whether the event increases risks to subjects.	**Complete**
	Assessment of whether the event alters the risk-benefit ratio.	**Not Applicable**
	Identification of whether additional safeguards are needed.	**For Clarificator**
Protocol and Consent	Determination of whether the event involves noncompliance with the approved protocol.	**Complete**
	Assessment of whether the informed consent process or document needs revision.	**Complete**
	Consideration of whether re-consent of participants is necessary.	**Complete**
Corrective and Preventative Actions	Review of proposed corrective actions by the investigator.	**Complete**
	Review of preventive measures to avoid recurrence.	**Complete**
	Determination of whether the corrective action plan is adequate.	**Complete**

(CAPA)		
Impact on Study Participants	Determination of whether participants were notified	**Complete**
	Assessment of whether participants require medical follow-up or additional support.	**Complete**
	Review of how the event was communicated to affected parties.	**Complete**
Compliance with Regulations	Verification that the report aligns with institutional policies.	**Complete**
	Assurance of compliance with national and international guidelines (e.g., FDA, GCP, HHS).	**Complete**

Decision Points	**Recommendation**
○ Recommend further action ○ Request additional information ○ Site visit ○ Ask for corrective action ○ Others; _____	1. . 2. . 3. .

Primary Reviewer	**Signature**	**Date**

SJDIRB Final Action

Final Decision	**Recommendation/Comments**
○ Recommend further action ○ Request additional information ○ Site visit ○ Ask for corrective action ○ 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			