



## SJD Institutional Review Board

### Title: Early Termination Form

Code: SJDIRB Form 16

Version: 02

**6Section 1.** To be filled up by the Principal Investigator. (This form is required to apply for premature termination or suspension of a study and refers to ICH-GCP Section 4.12: PREMATURE TERMINATION OR SUSPENSION OF A TRIAL.)

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
Date of last Continuing Review/Approval:	DD Month YYYY	Proposed Termination Date	DD Month YYYY
Participants Enrolled to Date		PI Telephone No.	
		PI Mobile No.	
SUMMARY OF RESULTS TO DATE:			
ACCRUAL DATA:			
REASON FOR TERMINATION with JUSTIFICATION:			
ADDITIONAL INFORMATION			
<b>THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR</b>			
<ol style="list-style-type: none"><li>1. Fill in the form and email an electronic copy to:</li><li>2. Print two copies of the completed form, sign and date</li><li>3. Send one signed copy to SJDIRB</li><li>4. Put one signed copy in your Trial Master File in the Pharmacovigilance section</li><li>5. Receipt will be acknowledged by email</li></ol>			
Name of Primary Investigator	Signature		Date



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<b>Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)</b>					
<b>Decision Points</b>		<b>Recommendation</b>			
<input type="radio"/> Approve <input type="radio"/> Recommend further action <input type="radio"/> Request additional information <input type="radio"/> Site Visit <input type="radio"/> Pending (if substantial clarifications are necessary prior to reaching a decision)		1. . 2. . 3. .			
<b>Primary Reviewer</b>		<b>Signature</b>		<b>Date</b>	
<b>SJDIRB Final Action</b>					
<b>Final Decision</b>			<b>Recommendation/Comments</b>		
<input type="radio"/> Approve <input type="radio"/> Recommend further action <input type="radio"/> Request additional information <input type="radio"/> Site Visit <input type="radio"/> 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 _____)		
<b>SJDIRB Officer</b>	<b>Name</b>		<b>Signature</b>	<b>Date</b>	
<b>Board/Panel Secretary</b>					
<b>Chair/Panel Lead</b>					