



SCMC-AEI Ethics Review Committee

Early Study Termination Application Form

QR-ERC-002-16/01/10102025

Document Date (dd/mmm/yyyy)		ERC Number:	
		Protocol Number:	

INSTRUCTIONS TO 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. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in letter size paper; then date and sign this Form before submission.

Study/ Protocol No.:		
Study/ Protocol Title:		
Initial Approval Date:		List all the dates of re-approval received:
Principal Investigator:		
Mobile:	Telephone:	E-mail:
Contract Research Organization:		Sponsor:
Contract Research Organization Contact Person:		
Mobile:	Telephone:	E-mail:
Sponsor Contact Person:		
Mobile:	Telephone:	E-mail:
Study Site:		
Study Site Address:		
Study Details		
1. Start Date:		
2. Proposed Termination Date:		
3. Total Subjects Enrolled:		
4. Total Subjects Randomized/Treated:		
5. Total Subjects who have early exited from the study:		
6. Total Number of SAEs:		
7. Total Number of SUSARs:		
8. Total Number of Protocol Deviation Reports:		
9. Reason for Termination with Justification:		



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10. Proposed disposition of all subjects enrolled in the study:

CERTIFIED CORRECT:			
Principal Investigator	Signature:		Date: (dd/mmm/yyyy)
	Printed Name:		

RECOMMENDATIONS (for SCMC-AEI ERC use only)

COMMENTS OF PRIMARY REVIEWER (i.e. implication on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants)

RECOMMENDED ACTION:	<input type="checkbox"/> ACCEPTED. NO FURTHER ACTION REQUIRED
	<input type="checkbox"/> REQUEST INFORMATION <i>(Indicate information)</i>
	<input type="checkbox"/> RECOMMENDED FURTHER ACTION <i>(Indicate action)</i>

CERTIFIED CORRECT:			
Primary Reviewer	Signature:		Date: (dd/mmm/yyyy)
	Printed Name:		