SCMC-AEI Ethics Review Committee

Serious Adverse Event/s (SAE) / Suspected Unexpected Serious Adverse Reaction/s (SUSAR) Report Form

QR-ERC-002-14/02/10102025

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

Study/Protocol No. and Title:
Principal Investigator:
Study Site:

To Investigator: if more than one (1) SAE or SUSAR report will be submitted, kindly copy the whole report table, and relabel as report no. 2 and repeat as needed.

REPORT NO. 1:		
Report Date:		
MFR Control No.:		
Report Status: ☐ **Initial Report** ☐ **Follow Up Report No. _____**		
Event Name:		
Name of Investigational Product:		
Mark whichever is applicable: ☐ Death ☐ Involved persistent or significant disability or incapacity ☐ Medically important event ☐ Involved or prolonged inpatient hospitalization ☐ Life threatening		
Country:	**Sex:**	**Age:**
Onset Date of SAE/SUSAR: dd/mmm/yyyy		
Outcome: ☐ Ongoing ☐ Resolved without sequelae ☐ Resolved with sequelae ☐ No possible resolution ☐ Others: _____		
Stop Date: dd/mmm/yyyy		
Date Drug/Device Started: dd/mmm/yyyy **Status of Study Drug/Device:** ☐ No change ☐ Investigational Product permanently stopped/removed. Stop date: _____ ☐ Investigational Product temporarily paused		

Document Date (dd/mmm/yyyy)		**ERC Number:**	
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☐ Change medication/device. Specify details: _____

☐ Increase/decrease study drug dose/frequency. Specify details: _____

☐ Others: _____

Comorbidities:
Causality Assessment of Investigator:
Causality Assessment of Sponsor:
Other relevant details related to the event: (if applicable)

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

RECOMMENDATIONS (for SCMC-AEI ERC use only)

COMMENTS / ASSESSMENT OF SAE/SUSAR REPORT
Report No. 1 (Event Name)

RECOMMENDED ACTION:	☐ **NO ADDITIONAL ACTION NECESSARY**

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	☐ **REQUEST FOR ADDITIONAL INFORMATION OR FOLLOW-UP REPORTS (APPLICABLE FOR ONSITE SAE REPORTS ONLY)**
	☐ **REQUEST AMENDMENT OF INFORMED CONSENT FORM** *(Indicate action)*

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