



SCMC-AEI Ethics Review Committee

Continuing Review Application/Progress Report Form

QR-ERC-002-12/02/10102025

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

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: An ethical clearance or approval is granted for a period of one year or less. Continuing review is required to be done at least once a year, corresponding to the risk assessment of the study protocol. The frequency of continuing review is indicated in the *Certificate of Approval*. For ethical clearance or approval approaching the expiry date and requiring renewal or extension, it is advisable to submit this Form (thirty) 30 days prior to expiry date. Obtain an electronic copy of this form and encode all the information required in the space provided. Print the report on 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:		
1. START DATE: 1.1. Date of Site Initiation or Date of First Patient First Visit: 1.2. Explanation, if not yet initialized as of date of this application:		



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<p>2. ACTION REQUESTED:</p> <p>2.1. <input type="checkbox"/> Renewal: Ongoing screening and recruitment of study participants/subjects</p> <p>2.2. <input type="checkbox"/> Renewal: Ongoing follow-up visits only (no new subjects will be enrolled)</p> <p>2.3. <input type="checkbox"/> Renewal: No screening and follow-up; ongoing database cleanup/ waiting for close-out visit</p> <p>2.4. <input type="checkbox"/> Renewal: Data analysis only</p> <p>2.5. <input type="checkbox"/> Other (specify):</p>
<p>3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?</p> <p>3.1. <input type="checkbox"/> No</p> <p>3.2. <input type="checkbox"/> Yes</p> <p>[Yes, list all Study Protocol Amendments and Date of Approval, include short description of the changes made]</p>
<p>4. SUMMARY OF STUDY PROTOCOL PARTICIPANTS:</p> <p>4.1. Number of Subject/s Screened (from start to present):</p> <p>4.2. Number of Subject/s Enrolled/Treated/Randomized:</p> <p>4.3. Number of Subject/s Who Exited Early and state the reason/s:</p>
<p>5. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL?</p> <p>5.1. <input type="checkbox"/> No</p> <p>5.2. <input type="checkbox"/> Yes</p> <p>[Yes, list all the Informed Consent Forms that were approved, date of approval and short description of change]</p>



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6. LIST ALL SAEs THAT WERE REPORTED
(include event name, date of submission to ERC, type of SAE, status and relationship to the investigational product):

7. LIST ALL SUSARs THAT WERE REPORT
(include MFR no., event name, relationship to the investigational product, country):

8. LIST ALL PROTOCOL DEVIATION REPORTS
(include date of submission and the deviation committed)

9. ANY CHANGES IN THE INVESTIGATORS, SITE STAFF AND STUDY SITE SINCE THE LAST REVIEW/ APPROVAL? (must submit a copy of the QR-ERC-XXX-XX Principal Investigator and Site Staff Information Sheet)

9.1. No

9.2. Yes



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10. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?
(must submit a copy of the QR-ERC-XXX-XX Principal Investigator and Site Staff Information Sheet)

10.1. No
 10.2. Yes

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

RECOMMENDATIONS (for SCMC-AEI ERC use only)

COMMENTS OF PRIMARY REVIEWER

RECOMMENDED ACTION:	<input type="checkbox"/> APPROVED
	<input type="checkbox"/> REQUEST INFORMATION <i>(Indicate information)</i>
	<input type="checkbox"/> RECOMMENDED FURTHER ACTION <i>(Indicate action)</i>
	<input type="checkbox"/> PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE <i>(Indicate major clarification)</i>

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