



SCMC-AEI Ethics Review Committee

Protocol and ICF Amendment Submission Form

QR-ERC-002-06/02/10102025

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

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: A Protocol Amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the SCMC-AEI ERC that issued the Ethical Clearance or Approval prior to the implementation of an amendment. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in letter size paper; then date and sign this Form before submission.

Study/Protocol No.:		
Study/Protocol Title:		
Approval Date:		
Principal Investigator:		
Mobile:	Telephone:	E-mail:
Address:		
Co-Investigator/s:		
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:		
<p>1.1 List all the protocol versions and approval dates: <input type="checkbox"/> not applicable</p> <p style="padding-left: 40px;">Current version of protocol for review: <input type="checkbox"/> not applicable</p> <p>1.2 List all the informed consent form versions and approval dates: <input type="checkbox"/> not applicable</p> <p style="padding-left: 40px;">Current version and date of informed consent for review: <input type="checkbox"/> not applicable</p>		
<p>2.1 State Nature of Protocol Amendment: <input type="checkbox"/> not applicable</p> <p><small>(list all the changes made and cite protocol section and page where amendment is found)</small></p>		



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2.2 State Changes in the Informed Consent Form: not applicable
 (List all the changes made and cite the section and page on the ICF where the amendment is found) -

Reviewer to complete the section below:

3. TYPE OF REVIEW:

3.1. EXPEDITED REVIEW FOR AMENDMENTS THAT:

- Do not involve significant change in the study populations
- Do not involve the collection of stigmatizing information
- Do not change approved use of anonymized or archived samples
- Do not involve further recruitment of participants
- Involve study protocols previously classified under expedited review
- Are administrative in nature (such as contact details of study personnel)
- Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants

3.2. FULL BOARD REVIEW for any amendments not cited under EXPEDITED REVIEW

CERTIFIED CORRECT:

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

RECOMMENDATIONS (for SCMC-AEI ERC use only)

COMMENTS OF PRIMARY REVIEWER

1. Effect of amendment on feasibility of the study

2. Effect of amendment on safety and well-being of subjects

3. Effect of amendment on overall risk-benefit ratio



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RECOMMENDED ACTION:	<input type="checkbox"/> APPROVED
	<input type="checkbox"/> MINOR MODIFICATION/S (modification is required in 1 or more documents)
	<input type="checkbox"/> MAJOR MODIFICATION/S (modification is required in 1 or more documents)
	<input type="checkbox"/> PENDING (request for further information/clarification)
	<input type="checkbox"/> DISAPPROVED State the reasons for the disapproval:

CERTIFIED CORRECT:

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