Republic of the Philippines
PHILIPPINE HEART CENTER
East Avenue, Quezon City 1100, Philippines
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CONTINUING REVIEW FORM

DIRECTIONS FOR SUBMITTING A CONTINUING REVIEW FORM

- This form must be submitted six weeks before the expiration date of the approved protocol.
- Request for continuation of a current approved research protocol will be reviewed at a regularly convened meeting of the ERB/ERC that issued the original approval.
- Continuation forms will not be accepted for studies **60 days** past the expiration date of a study; a new submission is required. Studies that are expired are lapsed in IERB approval and considered as noncompliance.
- Please ensure that the PI and all key personnel/s have completed the GCP within the last 3 years.
- Once you received the initial approval to conduct research, it is the PI's responsibility to gain approval to continue the research at the interval set by the IERB for your study as well as to close the study by submitting a closure form at the end of the study
- Please call us if you have any questions along the way: 9252401 loc.3899

WHAT TO SUBMIT

All required documents must be submitted six(6) weeks prior to the expiration date

- Submit one copy single-sided of the Continuing Review Form with original signature
- Two, clean, single sided, unstamped copies, of the informed consent/assent/information sheet currently in use (if applicable)
- 1 copy of the completed and signed original **Investigator's Progress Report**.
- 1 copy of the most recently approved **Consent/Assent Form.** If the study is closed to enrollment, do not send a consent form. If using an addendum consent form for currently enrolled participants, send 1 copy for review.
- 1 copy of the revised consent/assent form, if applicable, with changes highlighted. Please use underlining or shading to highlight changes.
- 1 copy of all **approved amendments/revisions** since their last renewal. copy of each previously submitted **Investigator's Progress Report**
- 1 copy of any progress report/s submitted to the sponsoring/funding agency since last renewal, if applicable.

PRINCIPAL INVESTIGATOR (PI)

Name of PI			
PI's Signature		Specialization	
Mobile no.		Email add.	

Has any potential and/or financial conflict of interest arisen since the last IERB review? If yes, a detailed financial conflict of interest disclosure must be submitted to the IERB annually or when a change occurs.	☐ Yes ☐ No

STUDY INFORMATION

IERB No.		Protocol No.		DETR No.	
Sponsor/CRO					
Protocol Title					
a) Original Approval Date		Expiration Date			
b) Date of Submission					
c) Is the submission date after or on the expiration date?	☐ Yes If **yes**, please answer below ☐ No				
If **yes**, your study has a lapse in IERB approval. Please indicate whether or not any research activities have taken place during the lapse in IERB approval.	☐ Yes, I did conduct research activities during the lapse in approval ☐ No research activities occurred during the lapse				

Note: *If your protocol does not receive approval prior to the expiration date, no participants can be enrolled, no data can be collected or used for research if collected during the period of lapsed approval.*
Repeat lapses of IERB approval are deemed non-compliance.

C. STATUS OF PROJECT

Any amendment since the last review? (Describe briefly.)	☐ No	☐ Yes
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes.)	☐ No	☐ Yes
Any change in the Informed Consent process or documentation since the last review? (Please explain.)	☐ No	☐ Yes

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.)	☐ No	☐ Yes
Any complaints about the research from subjects enrolled at the local site since the last IRB review (Describe.)	☐ No	☐ Yes
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.)	☐ No	☐ Yes
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)	☐ No	☐ Yes
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.)	☐ No	☐ Yes

Summary of protocol participants:

- ☐ Accrual ceiling set by IERB
- ☐ New participants accrued since last review
- ☐ Total participants accrued since protocol began

Accrual Exclusions:

- ☐ None
- ☐ Male
- ☐ Female
- ☐ Others (Specify) _____

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. ☐ No ☐ Yes

Impaired Participants:

- ☐ None
- ☐ Physically
- ☐ Cognitively
- ☐ Both

Action Requested:

- ☐ Renew - New participant accrual to continue
- ☐ Renew - Enrolled participant follow up only
- ☐ Terminate - Protocol discontinued

To be filled up by IERB

Date received:		Received by:
		Signature over Printed Name	

Recommendations

- ☐ Approve
- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting: _____

Recommended

Changes to the protocol :

Changes to the informed consent form :

IERB Final Decision:	

Primary Reviewer :	Approved by : IERB Chair
Signature over Printed Name / Date	*Signature over Printed Name / Date*

Date IERB Approval Expires (One year from approval date):	