LUNG CENTER OF THE PHILIPPINES
INSTITUTIONAL ETHICS REVIEW BOARD
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CONTINUING REVIEW APPLICATION / PROGRESS REPORT FORM

Section 1 *(To be filled-up by PI))*

LCP-IERB CODE		Submission Date	
Sponsor Protocol Number		Approval Date	

Protocol Title	

Name		Mobile / Phone / Fax Number	Email Address
Principal Investigator			
Sponsor			

ACTION REQUESTED	☐ Renewal: New participant accrual to continue ☐ Renewal: Enrolled participant follow up only

Any amendment since the last review? (Describe briefly)	☐ Yes	☐ No
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes)	☐ Yes	☐ No
Any change in the Informed Consent process or documentation since the last review? (Please explain)	☐ Yes	☐ No
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.)	☐ Yes	☐ No
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.)	☐ Yes	☐ No

Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)	☐ Yes	☐ No
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.)	☐ Yes	☐ No
Were there protocol deviation/violation reports? (Summarize)	☐ Yes	☐ No
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.	☐ Yes	☐ No

Summary of protocol participants: (Number)	☐ New participants accrued since last review ☐ Total participants accrued since protocol began	☐ Male ☐ Female
Accrual Exclusions (Number)	☐ Male ☐ Female	☐ None Reason/s for exclusion: _____
Impaired Participants (Number)	☐ None ☐ Physically	☐ Cognitively ☐ Both

Principal Investigator's Signature		Date	

Please take note of the following documents to be submitted on or before the expiration date of the approval:

- Four (4) copies of the completed and signed original copy of the Investigator's Progress Report (use LCPIERB Form 3 (C) – 2018 : Continuing Review Application / Progress Report Form
- Four (4) copies of the recently approved consent / assent form if applicable, with changes underlined and Bold-Faced to highlight changes.
- Four (4) copies of the recently approved amendments/ revision since their last renewal and copy of each previously submitted Progress Report.

Section 2 *(For IERB Use only)*

Received by *(Signature over printed name)*		Date Received	

Assessment by the Primary Reviewer	Yes	No	Comments
Do the risks to the study participants remain reasonable in relation to anticipated benefits?	☐	☐	
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?	☐	☐	
Is there a need to revise the ICF?	☐	☐	
Is there a need to reconsent subjects enrolled in the study?	☐	☐	
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third-party complaints, etc.) or institutional commitment that may affect patient safety?	☐	☐	
Are there concerns about participants safety, inability to comply with the protocol, high dropout rate that affect study implementation?	☐	☐	

Note: Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol violation/deviation) submitted by the PI.

Recommendations	☐ Approve ☐ Requests an amendment to the protocol or the consent form ☐ Request further information ☐ Suspend or terminate the study ☐ Disapprove renewal

Primary Reviewer/s	Signature	Date

IERB Final Decision		Type of Review ☐ Expedited review ☐ Full board review
		Date of Meeting

LCP-IERB Chairman	Signature	Date