



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

Quezon Avenue Extension, Quezon City, Philippines 1100

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PROTOCOL AMENDMENT APPLICATION

Section 1 (To be filled-up by PI)

LCP-IERB CODE		Submission Date	
Sponsor Protocol Number		Initial Approval Date	

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

List of Amendment/s (Include Version and Version Date)	Reason/s
1.	
2.	
3.	

Principal Investigator's Signature		Date	
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Please take note of the following:

- Approval should be obtained from LCPIERB prior to implementation of an amendment.
- Amendment should be integrated into a revised STUDY PROTOCOL/PACKAGE.
- Submit this form, LCPIERB FORM 3(B)-2018: STUDY PROTOCOL AMENDMENT APPLICATION FORM, and related documents in four (4) printed copies and (1) electronic copy. Forms may be downloaded from the LCPIERB website: erc@lcp.gov.ph or E-mail: lcpierb@gmail.com;
- SUMMARIZE the amendment in a cover letter indicating in which page of the revised study protocol the respective revision may be found, attached to every submission package;
- Modified part should be **underlined and bold-faced**; and
- Include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol.

Section 2 (For IERB Use only)

Received by <i>(Printed Name and Signature)</i>		Date Received	
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Assessment by Primary Reviewers	Type of amendments: <input type="checkbox"/> Minor <input type="checkbox"/> Major
	Does the amendment increase the risks to participants? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Does the amendment increase the benefits to the participants? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Is there favorable benefit/risk balance? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Comments:
Recommendations	<input type="checkbox"/> Approve <input type="checkbox"/> Requests further information/ Modification <input type="checkbox"/> Others

Primary Reviewer/s	Signature	Date

LCP-IERB Decision / Action Taken	<input type="checkbox"/> Approve <input type="checkbox"/> Minor Modification <input type="checkbox"/> Major Modification <input type="checkbox"/> Disapprove	Type of Review <input type="checkbox"/> Expedited review <input type="checkbox"/> Full board review	
		<table border="1" style="width: 100%;"> <tr> <td style="background-color: #cccccc;">Date of Meeting</td> <td></td> </tr> </table>	Date of Meeting
Date of Meeting			

LCP-IERB Chairman	Signature	Date