



PHILIPPINE CHILDREN'S MEDICAL CENTER  
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE  
(IR-EC)

**PROTOCOL AMENDMENT FORM**

Date of Submission: \_\_\_\_\_ IR-EC Protocol Number: \_\_\_\_\_

Sponsor Protocol Number: \_\_\_\_\_ Approval Date: \_\_\_\_\_

Protocol Title: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Principal Investigator/s: \_\_\_\_\_  
\_\_\_\_\_

Contact details: Telephone No. \_\_\_\_\_ Fax: \_\_\_\_\_ E-mail Address: \_\_\_\_\_

Institute : \_\_\_\_\_

Sponsor : \_\_\_\_\_

Name of study medicine/ device: \_\_\_\_\_

List of Amendment/s:	Reason/s:
1. _____	_____
2. _____	_____
3. _____	_____

*Note: Principal Investigator should attach pertinent document/s to this form.*

***\*\*Please highlight in bold letters the modifications/corrections done in the revised protocol and provide a summary of the changes made and on what page/paragraph number it can be found.***

To be filled-up by Technical Reviewer:	
Reviewer/s Recommendations:	
_____	
_____	
_____	
Reviewer's name and Signature: _____	Date: _____
Changes to the protocol recommended? _____ No _____ Yes	

To be filled-up by the IR-EC:

Assessment of Reviewer:

Type of amendment: \_\_\_ Minor \_\_\_ Major

Does the amendment change the risk/benefit ratio of the study? \_\_\_ Yes \_\_\_ No

Reviewer/s Recommendations:

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Changes to the protocol recommended? \_\_\_ Yes \_\_\_ No

Comments : \_\_\_\_\_  
\_\_\_\_\_

Changes to the Informed Consent Form and/or other documents recommended? \_\_\_ Yes \_\_\_ No

Comments : \_\_\_\_\_  
\_\_\_\_\_

Reviewer's Name : \_\_\_\_\_  
Signature : \_\_\_\_\_  
Date : \_\_\_\_\_

IR-EC Final Action:

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\*\* Approve

Request further information / modification

Disapprove

Others: \_\_\_\_\_

Type of review: \_\_\_ Expedited review \_\_\_ Full board review

Date of meeting: \_\_\_\_\_

Name of Member/Secretary: \_\_\_\_\_

Signature : \_\_\_\_\_

Date : \_\_\_\_\_