



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:

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:

** Approve

Request further information / modification

Disapprove

Others: _____

Type of review: ___ Expedited review ___ Full board review

Date of meeting: _____

Name of Member/Secretary: _____

Signature : _____

Date : _____