



PHILIPPINE CHILDREN'S MEDICAL CENTER
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE
(IR-EC)

UNEXPECTED EVENT AND UNANTICIPATED RISK REPORT FORM

IR-EC Protocol Number: _____
Sponsor Protocol Number: _____ Approval Date: _____

Protocol Title: _____

Principal Investigator/s: _____

Institute : _____

Sponsor : _____

Name of study medicine/ device: _____

Principal Investigator/s' signature: _____

This report covers the period from _____ to _____

Remarks : _____

Details for the use of study drug/device:

Subject's initials/ no.	Age/ Gender	Site (Onsite/ Offsite)	Description	On-set date	Start – End of treatment	Related to the study (Yes/No)	Intervention	Outcome

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

To be filled-up by the IR-EC:

Reviewer/s Recommendations:

Changes to the protocol recommended? No Yes

Comments :

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

Comments :

Reviewer's Name : _____

Signature and Date : _____

Date : _____

IR-EC Final Action:

** Request an amendment to the protocol or the Informed Consent Form

Request further information

Suspend or terminate the study

Take note and no further action is needed

Others:

Type of review: Expedited review Full board review

Date of meeting: _____

Name of Member/Secretary: _____

Signature : _____

Date : _____