



PHILIPPINE CHILDREN'S MEDICAL CENTER
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE
(IR-EC)

PROTOCOL DEVIATION AND VIOLATION REPORT FORM

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

Protocol Title: _____

Principal Investigator/s: _____ Contact no.: _____

Sponsor : _____ Contact no.: _____
Reported by : _____ Contact no.: _____

Name of study medicine/ device: _____

Type of Research: Clinical Trial Clinical Research Public Health
 Genetic Research Sociobehavioural Laboratory Research

Description: _____

Reason for deviation: _____

_____ Principal Investigator's Deviation/Violation Major Minor
_____ Participant Non-compliance
_____ Others : _____

Corrective/ Preventive Action taken: _____

**use extra paper, if more space is required
Provide pertinent document/s, if needed*

To be filled-up by the IR-EC:

Reviewer's Assessment

Reviewer/s Recommendations:

Reviewer's Name : _____
Signature : _____
Date : _____

IR-EC Final Action:

** Request further information
Take note and no further action is needed
Correction and/or corrective actions are required
Site visit needed
Others:

Type of review: _____ Expedited review _____ Full board review
Date of meeting: _____

Name of Member/Secretary: _____
Signature : _____
Date : _____