PHILIPPINE CHILDREN'S MEDICAL CENTER
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE
(IR-EC)

FINAL REPORT FORM

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

Protocol Title: _____
_____
Principal Investigator/s: _____
Telephone Number:_____ Mobile:_____. E-mail
Address:_____ _
Study Site (Name and address):_____
Sponsor, if any : _____
Sponsor's Contact Person:
Telephone:_____Mobile:_____Email:_____

Type of Research: [ ] Clinical Trial [ ] Clinical Research [ ] Public Health
[ ] Genetic Research [ ] Sociobehavioural [ ] Laboratory Research
_____
Study Duration: _____
Name of study medicine/ device:_____ Number of study arms:_____

_____Accrual ceiling set for this site
_____Total number of patients screened
_____Total number of participants accrued since protocol began
_____Total number of patients lost to follow up
_____Total number withdrawn from the study
_____Total number of participants who experienced SAEs/SUSARs
_____Total number of patients completed the study:

Any amendments to the original protocol? _____ Date of approval:_____
Summary of benefits to the participant:_____

Summary of onsite SAEs reported: _____

Summary of indemnifications of study-related injury (if applicable)_____

Summary of participants complaints or grievances documented regarding conduct of study
_____
Summary of Protocol Deviations/ Violations:_____
_____

If terminated early, specify number and reason/s for termination:_____
_____

Progress reports submitted (with dates of approval):_____

Informed consent form used (with version no./date) _____Attach most recent version

Summary objectives and summary of results :_____
_____
_____
_____
_____
_____

Principal Investigator : _____
(Signature over printed name)
Date : _____

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

To be filled-up by the IR-EC:

Reviewer/s Comments/Recommendations: i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)
_____
_____
_____

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

IR-EC Final Action:
_____
_____
** Acknowledged / Accepted
Request further information specify)
Recommend further action (specify)
Pending, if major clarifications are required before a decision can be made
Others:
_____

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

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