PHILIPPINE CHILDREN'S MEDICAL CENTER
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE
(IR-EC)

CONTINUING REVIEW FORM

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

Protocol Title: _____
_____
_____

Principal Investigator: _____

Study Site: _____
Duration of study: _____
Anticipated duration of participation per enrollee:_____
Date of IR-EC Initial Approval: _____
Date Started: _____ Date of last Progress Report:_____
Date of this Report:_____
Total Number of target study participants: _____ No. of study Arms: _____
Number of participants enrolled to date : Global site :_____ Local Site: _____

Action Requested:
_____ Renew – New participant accrual to continue
_____ Renew – Enrolled participant follow-up only
_____ Terminate – Protocol discontinued

1. Any amendment since the last review? (Describe briefly)
   _____ **No** _____ **Yes**

2. Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes)
   _____ **No** _____ **Yes**; _____

3. Any difficulty in recruiting patients? (Briefly explain why)
   _____ **No** _____ **Yes**; _____

4. Are there plans to increase the number of recruitment into the study? (Please explain)
   _____ **No** _____ **Yes;** _____

5. Any change in the Informed Consent process or documentation since the last review? (Please explain)
   _____ **No** _____ **Yes;** _____

6. Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative)
   _____ **No** _____ **Yes**

7. Any unexpected complication or side effect noted since the last review? (Summarize, include corrective actions taken)
   _____ **No** _____ **Yes**

8. Did the adverse event / SAE occur in the expected frequency and level of severity as indicated in the protocol, ICF or Investigator's Brochure? (Discuss adverse event /SAE)
   _____ **No** _____ **Yes**

9. Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)
   _____ **No** _____ **Yes**

10. Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the Curriculum Vitae/s of new investigator/s)
    _____ **No** _____ **Yes**; Name(s): _____

11. Summary of protocol participants:
    _____ Accrual ceiling set by the IR-EC
    _____ Number of new participants accrued since last review
    _____ Total number of participants accrued since protocol began

12. Accrual Exclusions:
    _____ None
    _____ Number of participants who are lost to follow up
    _____ Number of participants withdrawn by the investigator from the study (Summarize reason)
    _____ Number of participants who decided to withdraw from the study. (Summarize reason)
    _____ Others (specify) _____

13. Are there any new collaborating sites that have been added or deleted since the last review? (Please identify the sites and note the addition or deletion)
    _____ **No** _____ **Yes**

Principal Investigator : _____
(Signature over printed name)

Date : _____

Note: Principal Investigator should provide covering letter for this form.

To be filled-up by the IR-EC:

Assessment by the Primary Reviewer/Designated Member/Chair:

1. Do the risks to the study participants remain reasonable in relation to anticipated benefits?
   _____ No _____ Yes. Comments:

2. Are there new findings in the Investigator's Brochure or literature (eg. Important toxicity or adverse event information) that need to be included in the informed consent?
   _____ No _____ Yes. Comments:

3. Is there a need to revise the ICF?
   _____ No _____ Yes. Comments:

4. Is there a need to reconsent subjects enrolled in the study?
   _____ No _____ Yes. Comments:

5. Are there concerns about the conduct of the research team (eg. Suspension of medical license, frequent protocol deviation, patient or third party complants, etc) or institutional commitment that may affect patient safety?
   _____ No _____ Yes. Comments:

6. Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?
   _____ No _____ Yes. Comments:

Reviewer/s Recommendations:

_____
_____

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

IR-EC Final Action:

_____
_____

** Renew Approval
Request an amendment to the protocol or the Informed Consent Form
Request further information or action, specify
Suspend: enrollment of new subjects, or research procedures in currently enrolled subjects, or both
Disapprove renewal
Others:

_____

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

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