



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\_\_\_\_\_ Total number withdrawn from the study  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 : \_\_\_\_\_