



PHILIPPINE CHILDREN'S MEDICAL CENTER
Quezon Avenue, Quezon City

INSTITUTIONAL RESEARCH – ETHICS COMMITTEE
(IR-EC)

SITE VISIT FORM

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

Protocol Title: _____

Principal Investigator/s: _____ Telephone No. _____

Sponsor: _____ Telephone No: _____

Site: _____

Name of study medicine/ device: _____

Total number of expected subjects: _____

Total subjects enrolled : _____

1. Are site facilities appropriate? Yes No
Comment: _____
2. Are ICF complete? Yes No
Comment: _____
3. Are approved ICFs versions used? Yes No
Comment: _____
4. Are copies of the approved version of the protocol documents kept in the site?
 Yes No
Comment: _____
5. Does the site keep copies of all communication with the IRB-EC in the site?
 Yes No
Comment: _____
6. Are copies of adverse event reports kept? Yes No
Comment: _____
7. Any adverse events found? Yes No
Comment: _____
8. Are copies of protocol deviation/violation reports kept in the site? Yes No
Comment: _____
9. Any protocol deviation/ non-compliance/ violation? Yes No
Comment: _____
10. Are all case record forms up to date? Yes No

Comment: _____

11. Are storage of data and investigating products locked? Yes No

Comment: _____

12. Is there appropriate documentation of qualifications and roles of personnel?

Yes No

Comment: _____

13. Are investigator functions properly delegated to qualified research personnel?

Yes No

Comment: _____

14. Is there evidence of corrective action taken as recommended by the IRB-EC?

Yes No

Comment: _____

Duration of visit (hours): Starting from : _____ Finish: _____

Summary of Findings:

Recommendations:

Names of IR-EC member/ representatives and companion:

Report prepared by (Name and Signature); _____

Date : _____

IR-EC Final Action:

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

Request further information or action (Specify)

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 : _____