



SERIOUS ADVERSE EVENT REPORT FORM

Whenever there is any SAE event in any research approved by the PHC-IERB, it has to be reported by the principal investigator (PI) to the IERB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:

Study Title: Protocol No.:

Name of the study medicine/device:

Report Date:
 Initial Follow-up :
 Onset Date: _____

Date Site was Informed: _____

Sponsor:

Date of first use:

Title of the Report

Date of the report

Subject's initial/number: _____ Age: _____ Male Female

Subject's history:

Laboratory findings:

SAE:

Treatment:
 Outcome: Resolved On-going

Seriousness:

Death Life Threatening

Hospitalization:
 Initial Prolonged

Disability/Incapacity

Congenital Anomaly

Others

Relation to

Drug Device Study

Not related

Possibly

Probably

Definitely related

Unknown

Action Taken as the result of the report

Signature over Printed Name of PI / Date



PHILIPPINE HEART CENTER

Institutional Ethics Review Board

8/F Medical Arts Building

East Avenue, Quezon City, 1100 Philippines

Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

PHC-IERB-FR-29-05

Note: PI should attach standard SAE report form to this IERB form.



SECTION 2 (to be filled up by the designated IERB representative)
 Document receipt by the IERB

Name (IERB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended No Yes
 Comments:

Changes to the informed consent form recommended? No Yes
 Comments:

<p>IERB Final Action:</p> <p><input type="checkbox"/> Request an amendment to the protocol <input type="checkbox"/> or the consent form.</p> <p><input type="checkbox"/> Request further information.</p> <p><input type="checkbox"/> Suspend or terminate the study</p> <p><input type="checkbox"/> Take note and no further action is needed.</p>	<p>Type of review:</p> <p><input type="checkbox"/> Expedited review <input type="checkbox"/> Full board review</p> <p>Date of meeting _____</p>
<p><input type="checkbox"/> Others: _____</p>	