



SERIOUS ADVERSE EVENT REPORT FORM

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

SECTION 1

Principal Investigator: (Name)	
CGHMC RERB Protocol No.	Sponsor Protocol No.
Date Submitted	Signature
Study Title:	
Study Site: (Name & Address)	
Name of the study medicine/device:	Report Date:
	<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up
Onset Date:	
Sponsor:	Date of first use of drug/device:
Title of the Report	
Subject's Number:	Age: <input type="checkbox"/> Male <input type="checkbox"/> Female
Subject's history:	Laboratory findings:
SAE:	Treatment Outcome: <input type="checkbox"/> Resolved <input type="checkbox"/> On-going
Seriousness: <input type="checkbox"/> Death <input type="checkbox"/> Life Threatening Hospitalization: <input type="checkbox"/> Short-stay <input type="checkbox"/> Prolonged <input type="checkbox"/> Disability/Incapacitated <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Others	Relation to <input type="checkbox"/> Drug <input type="checkbox"/> Device Study <input type="checkbox"/> Not related <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Definitely related <input type="checkbox"/> Unknown
Name and Signature of PI	Date

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



SECTION 2 (to be filled up by the designated SAE Subcommittee reviewer)

Document received by the RERB Secretariat	Signature	Date
Reviewer's Name/Signature:		Date: (dd/mm/yyyy)

Changes to the protocol recommended? Comments:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Changes to the informed consent form recommended? Comments:	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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

Name of RERB Reviewer:	Signature	Date (dd/mm/yyyy)
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