



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

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SERIOUS ADVERSE EVENT REPORT FORM

All SAE/SUSAR events in any research approved by the Lung Center of the Philippines – IERB must be reported by the principal investigator (PI) to the IERB.

Section 1 (to be filled up by PI)

Submission Date	
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LCP-IERB CODE		Sponsor Protocol Number	
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Protocol Title	
Principal Investigator	

Name of the Study Medicine / Device	Report Date
	<input type="checkbox"/> Initial <input type="checkbox"/> Follow up <u>(no.)</u> . Onset Date: _____

Sponsor	Date of Randomization
Title of the Report	Date of the Report

Subject Initial Number	Age	Gender
		<input type="checkbox"/> Male <input type="checkbox"/> Female

Subject's History	
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Laboratory Findings	
SAE	
Treatment	Outcome: <input type="checkbox"/> Resolved <input type="checkbox"/> On-going

Seriousness		Relation to		
<input type="checkbox"/> Death	<input type="checkbox"/> Life Threatening	<input type="checkbox"/> Drug	<input type="checkbox"/> Device	<input type="checkbox"/> Study
<input type="checkbox"/> Hospitalization		<input type="checkbox"/> Not related		
<input type="checkbox"/> Initial	<input type="checkbox"/> Prolonged	<input type="checkbox"/> Possibly		
<input type="checkbox"/> Disability/Incapacity		<input type="checkbox"/> Probably		
<input type="checkbox"/> Congenital Anomaly		<input type="checkbox"/> Definitely related		
<input type="checkbox"/> Others		<input type="checkbox"/> Unknown		
Note: PI should attach standard SAE report form (CIOMS) to this IERB form.				

Principal Investigator's Signature		Date	
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Section 2 (For LCP-IERB use only)

Received by <i>(Signature over Printed Name)</i>		Date Received	
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Assessment by the SAE Subcommittee Primary Reviewer	
Comments	
Recommendations	<input type="checkbox"/> No further action/report on file <input type="checkbox"/> Amendment to the protocol/ICF <input type="checkbox"/> Request further information <input type="checkbox"/> Suspend enrolment of new participants until further review <input type="checkbox"/> Take note and continue monitoring <input type="checkbox"/> Suspend all trial related procedures <input type="checkbox"/> Conduct site visit <input type="checkbox"/> Termination of study

Primary Reviewer	Signature	Date
SAE Subcommittee Chairman	Signature	Date

LCP-IERB Decision		Type of Review
		<input type="checkbox"/> Expedited review
		<input type="checkbox"/> Full board review
		Date of Meeting

LCP-IERB Chairman	Signature	Date