



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

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STUDY PROTOCOL NON-COMPLIANCE REPORT FORM (VIOLATION / DEVIATION)

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	
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Name	Mobile / Phone / Fax Number	Email Address
Principal Investigator		
Sponsor		
Reported by		

<input type="checkbox"/> PI Deviation from protocol <input type="checkbox"/> Major <input type="checkbox"/> Minor	<input type="checkbox"/> Participant Non-Compliance
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Description	
Action/s Taken	

Principal Investigator's Signature		Date	
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Noted by (Secretariat)		Date	
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Section 2 (For IERB Use only)

Assessment by the SAE Subcommittee Primary Reviewer

Comments			
Recommendations	<input type="checkbox"/> Noted (no further action required) <input type="checkbox"/> Request additional information from the PI; specify, _____ <input type="checkbox"/> Corrective action required; specify, _____ <input type="checkbox"/> Site visit needed		
Primary Reviewer/s	Signature	Date	
SAE Subcommittee Chairman	Signature	Date	

LCP-IERB Decision	<input type="checkbox"/> Noted and acknowledged <input type="checkbox"/> Request additional information / further action; _____	Type of Review
	<input type="checkbox"/> Suspension of study/enrolment of participants <input type="checkbox"/> Termination of study <input type="checkbox"/> Conduct site visit	<input type="checkbox"/> Expedited review <input type="checkbox"/> Full board review
		Date of Meeting

LCP-IERB Chairman	Signature	Date