



INSTITUTIONAL ETHICS AND REVIEW BOARD
12th Floor, Our Mother of Perpetual Succour Medical Specialty Center
Perpetual Succour Hospital
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Tel No/Fax No: +63-32-342-0853

Serious Adverse Event and SUSAR Report Form	PSH-IERB Form 4D
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PSH-IERB Code:		Date Submitted:	
Protocol Number/Study Title:			
Sponsor:		Sponsor's Local Address:	
Principal Investigator:	Sub-Investigator:	Study Coordinator:	
Email address:		Contact No.:	

<input type="checkbox"/> SAE	<input type="checkbox"/> On-site	<input type="checkbox"/> Initial
<input type="checkbox"/> SUSAR	<input type="checkbox"/> Off-site	<input type="checkbox"/> Follow-up # _____
		<input type="checkbox"/> Final
Date of SAE		Date of Site Awareness
SAE Term		<input type="checkbox"/> Related
		<input type="checkbox"/> Not Related
		<input type="checkbox"/> Expected
		<input type="checkbox"/> Unexpected
Subject's History:		
Treatment:		
Action Done by PI		Outcome

Submitted by: SIGNATURE OVER PRINTED NAME	DATE
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FOR IERB MEMBERS: PLEASE INDICATE DECISION:

<input type="checkbox"/> May continue study <input type="checkbox"/> Request an amendment to the protocol or informed consent form (pls specify) _____ _____ <input type="checkbox"/> Request further information (pls specify) _____ _____ <input type="checkbox"/> Suspended (state reason) _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____	<input type="checkbox"/> May continue study <input type="checkbox"/> Request an amendment to the protocol or informed consent form (pls specify) _____ _____ <input type="checkbox"/> Request further information (pls specify) _____ _____ <input type="checkbox"/> Suspended (state reason) _____ _____ _____ Reviewer's signature over printed name Date reviewed: _____
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