



**INSTITUTIONAL ETHICS AND REVIEW BOARD**  
**12<sup>th</sup> Floor, Our Mother of Perpetual Succour Medical Specialty Center**  
**Perpetual Succour Hospital**  
**Gorordo Avenue, Cebu City**  
**Tel No/Fax No: +63-32-342-0853**

<b>Serious Adverse Event and SUSAR Report Form</b>	<b>PSH-IERB Form 4D</b>
--	-----------------------------

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

Submitted by: SIGNATURE OVER PRINTED NAME	DATE
--	------

**FOR IERB MEMBERS: PLEASE COMMENT AND INDICATE DECISION:**

<input type="checkbox"/> Causality _____ _____ <input type="checkbox"/> Expectedness of the event _____ <input type="checkbox"/> Description of how the PI managed the event _____ _____ _____ _____ _____	<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: _____
---	--