



# ST. PAUL'S HOSPITAL OF ILOILO, INC.

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## PROTOCOL REPORT UPDATES FORM (SAE/SUSARS Form 4.7)

IRB Protocol No.	<input type="text"/>	Date Received (D/M/Y):	<input type="text"/>
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Protocol Title:	<input type="text"/>	Sponsor:	<input type="text"/>
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Principal & Sub Investigators:	<input type="text"/>	Type of SAE	<input type="checkbox"/> SAE	<input type="checkbox"/> SUSAR
		Site of SAE	<input type="checkbox"/> On-site	<input type="checkbox"/> Off site (International)

**A: TITLE OF REPORT:** \_\_\_\_\_ **Date of Event:** \_\_\_\_\_

**B. SUMMARY OF SIGNIFICANT DATA:**

With Full Document Attachment       With Partial Data Attachment

Name of the study medicine/device	Report Date: dd/mm/yyyy IREB Submission Date: dd/mm/yyyy <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up Onset date: dd/mm/yyyy	
Date of first use:	<input type="text"/>	
Patient's Initial/Number:	Age:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Patient's Date of Birth: dd/mm/yyyy	Weight:    kg	Height:    cm
Relevant medical history and concurrent conditions:		

**I. REACTION INFORMATION:**

Check all appropriate to adverse reaction: <input type="checkbox"/> Patient died <input type="checkbox"/> Involved or prolonged inpatient hospitalization <input type="checkbox"/> Involved persistence or significant disability or incapacity	<input type="checkbox"/> Life threatening <input type="checkbox"/> Congenital anomaly
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**II. SUSPECT DRUG/S INFORMATION:**

Suspect drug/s (include generic name)		Did reaction abate after stopping drug? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Daily dose/s:	Route/s of administration:	Did reaction appear after reintroduction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Indication/s for use:		
Therapy date/s: (from/to)	Therapy duration:	
Is this reaction <input type="checkbox"/> Unexpected <input type="checkbox"/> Expected		
Treatment given for Adverse Event:		
Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System) <input type="checkbox"/> Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Unclassifiable		
Outcome of reaction/event at the time of last observation: <input type="checkbox"/> Recovered <input type="checkbox"/> Recovering with sequelae <input type="checkbox"/> Death <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovering <input type="checkbox"/> Unknown <input type="checkbox"/>		

**INVESTIGATOR'S ATTESTATION**

I certify that the information provided in this report is complete and accurate.	
_____	_____
Signature Over Printed Name of Principal Investigator	Date

<i>(IRB Use only)</i> Received by:	
_____	_____
Signature Over Printed Name	Date

**SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER**

Type of Review

Expedited

Full Board

Reviewer's  
Comments:

Final Action:

- ( ) Request an amendment to the protocol or the consent form.
- ( ) Request further information
- ( ) Recommend further Action (indicate action)
- ( ) Take Note and No Further Action needed
- ( ) Others: \_\_\_\_\_

Acknowledged by:

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**Name of Reviewer**  
IRB Member-Secretary

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**Signature**

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**Date**