	DR. JOSE N. RODRIGUEZ MEMORIAL HOSPITAL AND SANITARIUM PhilHealth Accredited ● ISO 9001:2015 Certified	**FORM 12: SERIOUS ADVERSE EVENTS (SAEs) / SERIOUS ADVERSE REACTION (SUSARs)** Form Code: **SF.MCC.IRB.014.Rev1**

Coordinating Principal Investigator:	
IREB Protocol Code:	
Study Title:	
Sponsor:	
Name of Study Medicine	
Report Date:	
Onset Date	
Date of First Use:	

Patient Number	Age	Sex

Patient's History	
Laboratory Findings:	
SAE:	
Treatment Outcome:	
Management of Adverse Reaction:	

Please check the ones applicable:

Seriousness:		Relation to:					
	Life threatening		Drug		Device		Study
	Death		Not related				
	Hospitalization		Possibly				
	Disability. Incapacity		Probably				
	Congenital Anomaly		Definitely related				
	Others (Please specify)		Unknown				

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Name of Primary Investigator and signature

Date

Received by:

Name of IREB staff and Signature

Date

FOR IREB USE ONLY

Name of Primary Reviewer and signature

Date

Changes in the protocol recommended?	o	Yes	Comments:
	o	No	
Changes to the informed consent form recommended?	o	Yes	Comments:
	o	No	

IREB Final Action	
	Request an amendment to the protocol or the consent form
	Request further information
	Suspend enrolment of new research participants
	Suspend all trial-related procedures
	Termination of study
	Take note and continue monitoring
	Conduct study site visits
	Others (Please specify)