ManilaMed
A MOUNT GRACE HOSPITAL

MMERC

Onsite Serious Adverse Event Report Form

Whenever there is any SAE is any research approved by the ManilaMed ERC, it has to be reported by the principal investigator (PI) to the ERC. Section 1 of this form should be filled out by the PI.

Section 1

Study Title	

Principal Investigator		MMERC Protocol No.	

Type of Review	☐ Full board ☐ Expedited

Name of the Study Medicine/Device	Report Date
	☐ Initial Onset ☐ Follow-Up

Sponsor	Date of First Use

Title of Report	Date of the Report

Subject's Initial/Number: _____ Age: _____ Gender: ☐ Male ☐ Female

Subject History	Laboratory Findings

SAE	Treatment Outcome
	☐ Resolved ☐ On-going

Seriousness	Relation to:
☐ Life Threatening ☐ Death ☐ Hospitalization ☐ Initial ☐ Prolonged ☐ Disability ☐ Congenital Anomaly ☐ Others	☐ Drug ☐ Device ☐ Study ☐ Not Related ☐ Possibly ☐ Probably ☐ Definitely Related ☐ Unknown
Causality (by SAE point person) Certain, Probable, Possible, Unlikely, Conditional, Unclassifiable	

Note: PI Should attach standard SAE report form to this ERC form.

Comments of Primary Reviewer: _____
_____
_____

FOR MMERC

RECOMMENDATION

Decision	☐ No further action ☐ Request Further Information ☐ Require Specific Action, (e.g. Amendment to the protocol or the consent form) ☐ Suspend or terminate the study

Reviewer's Name		Date	
Signature			