ManilaMed
A MOUNT GRACE HOSPITAL

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

Principal Investigator	

Study Title		Protocol No.	

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: ☐ Male ☐ Female	Age:
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.

FOR MMERC:

RECOMMENDATION

DECISION	☐	No further action
	☐	Request further information
	☐	Request further action (e.g. Amendment to the protocol or the consent form)
	☐	Suspend or terminate the study

Reviewer's Name		Date	
Signature			