ANGELES UNIVERSITY FOUNDATION
INSTITUTIONAL ETHICS REVIEW COMMITTEE

Serious Adverse Event Report

Principal Investigator:	AUF-IERC Code:	
Study Protocol Title:		
Name of the study medicine/device	Report Date: dd/mm/yyyy ☐ Initial ☐ Follow-up Onset date: dd/mm/yyyy	
Sponsor:	Date of first use:	
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth: dd/mm/yyyy	Weight: kg	Height: cm
Relevant medical history and concurrent conditions:		

I. REACTION INFORMATION:

_____ (use CIOMS definition) List all relevant tests/ lab data:	Check all appropriate to adverse reaction: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity ☐ Life threatening

II. SUSPECT DRUG/S INFORMATION:

Suspect drug/s (include generic name)		Did reaction abate after stopping drug? ☐ Yes ☐ No ☐ NA
Daily dose/s:	Route's of administration:	Did reaction appear after reintroduction? ☐ Yes ☐ No ☐ NA
Indication/s for use:		
Therapy date/s: (from/to)	Therapy duration:	
Is this reaction ☐ Unexpected ☐ Expected		
Treatment given for Adverse Event:		
Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System) ☐ Certain ☐ Probable ☐ Possible		