SERIOUS ADVERSE EVENT/S REPORT

Principal Investigator:		RIHS ERC Code:
Study Protocol Title:		
Name of the study medicine/device	Report Date: ☐ Initial ☐ Follow-up Onset date:	Place of Occurence:
Sponsor:		Date of first use:
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth:	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 ☐Related ☐Unrelated		
Treatment given for Adverse Event:		
Outcome of reaction/event at the time of last observation: ☐ Recovered ☐ Recovering with sequelae ☐ Death ☐ Recovering ☐ Not recovering ☐ Unknown		

III. CONCOMITANT DRUG/S AND HISTORY:

Concomitant drug/s and dates of administration (exclude drug used to treat reaction)
Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. **MANUFACTURER'S INFORMATION**:

Name and address of manufacturer		
Manufacturer control no.		
Date received by manufacturer:	Report source ☐ Study ☐ Literature ☐ Health professional	
Date of this report:	Report type ☐ Initial ☐ Follow-up	

RECOMMENDED ACTION: *(for RIHS ERC use only)*

- ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION
- ☐ REQUEST INFORMATION: (indicate information regarding subject status)
- ☐ RECOMMEND FURTHER ACTION: (indicate action)
- ☐ FORWARD TO AE SUBCOMMITTEE

SAE SUBCOMMITTEE PRIMARY REVIEWER	Signature	
Date:	Name	
SAE SUBCOMMITTEE CHAIR	Signature	
Date:	Name	
RIHS ERC CHAIR	Signature	
Date:	Name	