SAN JUAN DE DIOS EDUCATIONAL FOUNDATION, INC.
INSTITUTIONAL REVIEW BOARD

SERIOUS ADVERSE EVENT/S REPORT FORM (SJDEFIIRB FORM 3.5)

Section 1. To be accomplished by the Principal Investigator. Documents relevant to the SAE should be submitted together with this form.

IRB Reference Code				
Protocol No.				
Submission Date				
Study Protocol Title				
Principal investigator				
Sponsor				
PATIENT INFORMATION				
Investigational Product	Report Date ❑ Initial ❑ Follow-up	Onset Date		Date of First Use
Patient Initials/No.		Age		❑ Male ❑ Female
Date of Birth		Weight		Height
Relevant Medical History				

REACTION INFORMATION	
_____ (Use CIOMS definition) Relevant test results:	Check all appropriate ❑ Patient died ❑ Involved or prolonged hospitalization ❑ Involved persistence or significant disability or incapacity ❑ Life-threatening

SUSPECT DRUG/S INFORMATION

Suspect Drug/s (include generic and brand name)				Did reaction abate after stopping drug? ❑ YES ❑ NO ❑ N/A
Dose		Route		
Indication				Did reaction appear after reintroduction? ❑ YES ❑ NO ❑ N/A
Start Date		End Date		
Treatment given for adverse event				Is this reaction ❑ Expected ❑ Unexpected

Causality assessment by investigator (WHO-UMC Causality Assessment System)

- ❑ Certain
- ❑ Probable
- ❑ Possible
- ❑ Unlikely
- ❑ Unclassifiable

Outcome of reaction/event at the time of last observation

- ❑ Recovered
- ❑ Recovering
- ❑ Recovering with sequelae
- ❑ Not recovering
- ❑ Death
- ❑ Unknown

CONCOMITANT DRUG/S

MANUFACTURER'S INFORMATION

Name and Address	

Section 2. FOR IRB USE ONLY

RECOMMENDATIONS		
Changes to the protocol recommended ☐No ☐ Yes Comments:		
Changes to the ICF recommended ☐No ☐ Yes Comments:		
SAE REVIEWER	Signature	Date

IRB FINAL ACTION

- ❑ Uphold original approval with no further action
- ❑ Request information

_____
_____
_____

- ❑ Recommend further action

_____
_____
_____

MEMBER-SECRETARY	Signature	Date
CHAIR	Signature	Date