

**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  <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up	Onset Date	Date of First Use
Patient Initials/No.		Age	<input type="checkbox"/> Male <input type="checkbox"/> Female
Date of Birth		Weight	Height
Relevant Medical History			
REACTION INFORMATION			
<div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> (Use CIOMS definition)  Relevant test results:		Check all appropriate  <input type="checkbox"/> Patient died  <input type="checkbox"/> Involved or prolonged hospitalization  <input type="checkbox"/> Involved persistence or significant disability or incapacity  <input type="checkbox"/> Life-threatening	

SUSPECT DRUG/S INFORMATION				
Suspect Drug/s (include generic and brand name)			Did reaction abate after stopping drug?	
Dose			<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	
Route			Did reaction appear after reintroduction?	
Indication			<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	
Start Date			End Date	
Treatment given for adverse event			Is this reaction	
			<input type="checkbox"/> Expected <input type="checkbox"/> Unexpected	
Causality assessment by investigator (WHO-UMC Causality Assessment System)				
<input type="checkbox"/>			Certain	
<input type="checkbox"/>			Probable	
<input type="checkbox"/>			Possible	
<input type="checkbox"/>			Unlikely	
<input type="checkbox"/>			Unclassifiable	
Outcome of reaction/event at the time of last observation				
<input type="checkbox"/>			Recovered	
<input type="checkbox"/>			Recovering	
<input type="checkbox"/>			Recovering with	
<input type="checkbox"/> sequelae			Not recovering	
<input type="checkbox"/>			Death	
<input type="checkbox"/>			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
-------	-----------	------