



SJD Institutional Review Board
Title: Pregnancy Report Form
Code: SJDIRB Form 16
Version: 00

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

SJDIRB Reference Code		Date of Submission		DD Month YYYY	
Protocol Code		SJREB Code			
Protocol Title					
Principal Investigator					
Sponsor/CRO					
Approval Date		DD Month YYYY		Start Date	
				DD Month YYYY	
SUSPECT DRUG/S INFORMATION					
Suspect Drug/s (include generic and brand name)				Did reaction abate after stopping the drug?	
Dose		Route			
Indication				<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
				Did reaction appear after reintroduction?	
Start Date		DD Month YYYY		End Date	
				DD Month YYYY	
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"/> Possible		<input type="checkbox"/> Unclassifiable	
<input type="checkbox"/> Probable		<input type="checkbox"/> Unlikely			
Outcome of reaction/event at the time of last observation					
<input type="checkbox"/> Recovered		<input type="checkbox"/> Recovering		<input type="checkbox"/> Recovering w/ sequelae	
<input type="checkbox"/> Not Recovering		<input type="checkbox"/> Death		<input type="checkbox"/> Unknown	
CONCOMITANT DRUG/S					
MANUFACTURER'S INFORMATION					
Name and Address					
Name of Primary Investigator		Signature		Date	

Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)



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Decision Points		Recommendation	
<input type="checkbox"/> No further action <input type="checkbox"/> Recommend further action <input type="checkbox"/> Request additional information <input type="checkbox"/> Site Visit <input type="checkbox"/> Pending (if substantial clarifications are necessary prior to reaching a decision)	1. . 2. . 3. .		
Primary Reviewer		Signature	
		Date	
SJDIRB Final Action			
Final Decision		Recommendation/Comments	
<input type="checkbox"/> No further action <input type="checkbox"/> Recommend further action <input type="checkbox"/> Request additional information <input type="checkbox"/> Site Visit <input type="checkbox"/> Pending (if substantial clarifications are necessary prior to reaching a decision)	(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)		
SJDIRB Officer	Name	Signature	Date
Board/Panel Secretary			
Chair/Panel Lead			