SJD Institutional Review Board

Title: Progress Report
Code: SJDIRB Form 10.2
Version: 00

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

SJDIRB Ref. Code		**Date of Submission**	DD Month YYYY
Protocol Code		**SJDIRB Code**	
Protocol Title			
Principal Investigator		**Sponsor/CRO**	
Approval Date	DD Month YYYY	**Start Date**	DD Month YYYY

Study has not started due to:	**Has any information appeared in the literature, or evolved from this or similar research that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?**
	○ **No** ○ **Yes** (Discuss and attach a separate paper for the narrative)

Summary of protocol participants:		**Investigational New Drug/Device**		
	Accrual ceiling set by SJDIRB	○ **None**	**FDA No.:**	
	New participants accrued since last review	○ **IDE**	**Name:**	
	Total participants accrued since protocol began	○ **IND**	**Sponsor:**	
	Total Number of onsite PD/PV		**Holder:**	
	Total Number of onsite SAE/SUSAR			

Any amendment since the last review?	○ No	○ Yes (Describe briefly)		
Any change in participant population, recruitment or selection criteria since the last review?	○ No	○ Yes (Explain the changes)		
Any change in the Informed Consent process or documentation since the last review?	○ No	○ Yes (Explain Briefly)		
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study?	○ No	○ Yes (Described Briefly)		
Any unexpected complication or side effect noted since the last review?	○ No	○ Yes (Described Briefly)		
Were there protocol deviation/violation reports? Summarize. What corrective actions were taken?	○ No	○ Yes (Described Briefly)		
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.	○ No ○ Yes	**Are there any new collaborating sites that have been added or deleted since the last review?**	○No ○Yes (Please Identify the sites and note the addition or deletion)	

Name of Principal Investigator	**Signature**	**Date**

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

Indicators	Fact	Remarks/Comments
Do the risks to the study participants remain reasonable in relation to anticipated benefits?	O No O Yes	
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?	O No O Yes	
Is there a need to revise the ICF?	O No O Yes	
Is there a need to re-consent subjects enrolled in the study?	O No O Yes	
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?	O No O Yes	

Decision Points	Recommendation
O **Renew Approval** O **Recommend Further Action** O **Request Additional Information** O **Site Visit** O **Pending** (if substantial clarifications are necessary prior to reaching a decision)	O **Expedited review only** O **For Full Board Review on** DD Month YYYY 1. 2.

Primary Reviewer	Signature	Date

SJDIRB Final Action

Final Decision	Recommendation/Comments
O **Renew Approval** O **Recommend Further Action** O **Request Additional Information** O **Site Visit** O **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			