SJD Institutional Review Board

Title: Annual Report
Code: SJDIRB Form 10.1
Version: 08

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**	
Protocol Code		**SJREB Code**	
Protocol Title			
Principal Investigator		**Sponsor/CRO**	
Approval Date	DD Month YYYY	**Start Date**	DD Month YYYY
Action Requested	○ **RENEW** -New participant accrual to continue ○ **TERMINATE** -Protocol discontinued ○ **RENEW** -Enrolled participant follow up only ○ **Others, Specify:** _____		
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:		**Accrual exclusions**	○ **None** ○ **Male** ○ **Female** ○ **Others,** specify: _____
	Accrual ceiling set by SJDIRB		
	New participants accrued since last review	**Impaired participants**	
	Total participants accrued since protocol began	○ **Physically** ○ **Cognitive** ○ **Both** ○ **None**	
	Total Number of onsite PD/PV		
	Total Number of onsite SAE/SUSAR	**Ionizing radiation use** (X-rays, radioisotopes, etc)	○ **None** ○ **Medically indicated only**
Investigational New Drug/Device			
○ **None** ○ **IDE** ○ **IND**	**FDA No.:**	**Have any participants withdrawn from this study since the last SJDIRB approval?**	
	Name:	○ **No** ○ **Yes** (explain in separate document)	
	Sponsor:		
	Holder:		

Have any participating investigators been added or deleted since the last review?	**Have any unexpected discomforts, complications, or side effects been noted since last review?**
○ **No** ○ **Yes** (Identify all changes in the attached narrative)	○ **No** ○ **Yes** (Describe briefly)
Have there been any changes in the participant population, recruitment or selection criteria since the last review?	**Have there been any amendments since the last review?**
○ **No** ○ **Yes** (explain in separate document)	○ **No** ○ **Yes** (Describe briefly)
Have there been any changes in the informed consent process or documentation since the last review?	**Have any new collaborating sites (institutions) been added or deleted since the last review?**
○ **No** ○ **Yes** (explain changes in attached narrative)	○ **No** ○ **Yes** (identify all changes and provide an explanation of changes in the attached narrative)

Change in medical advisor/investigator?		**Have any investigators developed equity or consultative relationships with a source related to this protocol which might be considered a conflict of interest?**
○**None**		
○**Delete**		
○**Add**		○ **No** ○ **Yes** (append a statement of disclosure)

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)	1. . 2. . 3. .

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			