



SJD Institutional Review Board

Title: Progress Report

Code: SJDIRB Form 11

Version: 07

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

SJDIRB Reference 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		<ul style="list-style-type: none"> ● RENEW - New participant accrual to continue ● RENEW - Enrolled participant follow up only ● TERMINATE - Protocol discontinued 	
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?	
		<ul style="list-style-type: none"> ● No ● Yes (Discuss and attach a separate paper for the narrative) 	
Have there been any amendments since the last review?		Have any unexpected discomforts, complications, or side effects been noted since last review?	
<ul style="list-style-type: none"> ● No ● Yes (Describe briefly) 		<ul style="list-style-type: none"> ● No ● Yes (Discuss briefly) 	
_____		_____	
_____		_____	
_____		_____	
_____		_____	
Summary of protocol participants:		Have any participants withdrawn from this study since the last IRB approval?	
_____	accrual ceiling set by IRB	<ul style="list-style-type: none"> ● No ● Yes (Discuss) 	
_____	new participants accrued since last review	_____	
_____	total participants accrued since protocol began	_____	
Investigational New Drug/Device		Ionizing radiation use (X-rays, radioisotopes, etc)	
<ul style="list-style-type: none"> ● None ● IDE ● IND 	FDA No.:	<ul style="list-style-type: none"> ● None ● Medically indicated only 	
	Name:		
	Sponsor:		
	Holder:		
Accrual exclusions		Have there been any changes in the participant population, recruitment or selection criteria since the last review?	
<ul style="list-style-type: none"> ● None ● Male ● Female 		<ul style="list-style-type: none"> ● No ● Yes (explain changes in attached narrative) 	
<ul style="list-style-type: none"> ● Others (Specify) 			
Impaired participants		Have any participating investigators been added or deleted since last review?	
<ul style="list-style-type: none"> ● None ● Physically 			



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<ul style="list-style-type: none"> Cognitively 		<ul style="list-style-type: none"> Both 		<ul style="list-style-type: none"> No 		<ul style="list-style-type: none"> Yes (Identify all changes in the attached narrative) 	
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?			
<ul style="list-style-type: none"> No Yes (explain changes in attached narrative) 				<ul style="list-style-type: none"> 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?			
<ul style="list-style-type: none"> None 				<ul style="list-style-type: none"> No 		<ul style="list-style-type: none"> Yes (append a statement of disclosure) 	
<ul style="list-style-type: none"> Delete 							
<ul style="list-style-type: none"> Add 				<ul style="list-style-type: none"> No 		<ul style="list-style-type: none"> 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)							
Decision Points				Recommendation			
<ul style="list-style-type: none"> Renew Approval Recommend Further Action Request Additional Information Site Visit 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			
<ul style="list-style-type: none"> Renew Approval Recommend Further Action Request Additional Information Site Visit 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							