Sunway Medical Research Ethics Committee (SREC)

RESEARCH PROGRESS REPORT FORM

(The First Report should be submitted within **30 days** before the annual anniversary from the date of issue of the SREC decision notification form for full approval and thereafter annually until the research ends. SREC may require more frequent progress reports for studies with higher risk to the subjects.)

Title of Research Project			
Protocol No.			
Principal Investigator			
Sponsor			
Initial SREC Approval No.			
Official Commencement Date			
of Research			
Official Scheduled Date of			
Research Closure/End			
Total Number of Subjects	to		
Enrolled	(commencement date of trial : dd/mm/yy)	No:	
Number of Subjects Enrolled	to		
and Subsequently Withdrawn		No:	
(provide details in Table 1)	(commencement date of trial : dd/mm/yy)		
Number of Serious and/or	to		
Adverse Events Reported		No:	
(provide details in Table 2)	(commencement date of trial : dd/mm/yy)		
Has any new information or new findings changed the risk versus benefit to subjects significantly since this research project was first approved by SREC? No			

If yes, please describe.		
The above-stated research project has been ca	rried out according to the	SREC-approved research proto
and the requirements of Sunway Medical Ce		
followed. All subjects enrolled have signed and		ormed consent forms and writi
subject information (if applicable) approved by	y SREC for this project.	
Principal Investigation		
Principal Investigator:	Date:	

TABLE 1

Number of subjects enrolled and withdrawn from this research from to

(commencement date of trial:	dd/mm/yy)
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No.	Subject Initials	Date subject withdrawn	Reason for withdrawal	Was study drug restarted again?
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

TABLE 2 Summary of Serious and/or Unexpected Adverse Events reported in this research from to

(commencement date of trial: dd/mm/yy)

No.	Subject Initials	Serious and/or unexpected adverse event (If diagnosis is not available, please state the sign or symptom)	Date of SAE onset	Date reported to SREC (dd/mm/yy)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Please return the completed form with supporting documents to: SREC Secretariat, c/o SunMed Clinical Research Centre, Sunway Medical Centre, No. 5 Jalan Lagoon Selatan, Bandar Sunway 47500 Petaling Jaya, Selangor

Tel: 03-8601 1079 Fax: 8601 1069