

Sunway Medical Centre Independent Research Ethics Committee (SREC)

RESEARCH CLOSURE REPORT FORM

(The Research Project Closure Report should be submitted to SREC within 90 days of study closure. In the case of premature suspension or termination, SREC should be notified within 15 days with reasons for the suspension or termination and a summary of results.)

Title of Research Project			
Protocol No.			
Principal Investigator			
Sponsor			
Initial SREC Approval No.			
Commencement Date of Research (Date of First Subject Enrolment)		Closure Date of Research (date when study is officially closed)	
Total Number of Subjects actually enrolled		Targeted Number of Subjects to be enrolled	
Total Number of Subjects enrolled and withdrawn from start to end of this research (<i>provide details in Table 1</i>)		Total Number of Serious and/or Adverse Events reported from start to end of this research (<i>provide details in Table 2</i>)	
Is this study closure according to plan or is it a premature study closure?			
If premature termination, please state reason(s)			
What are the findings in this research project to date? (<i>to be commented by investigator only</i>)			

The above-stated research project has been carried out according to the SREC-approved research protocol and the requirements of Sunway Medical Centre Independent Research Ethics Committee have been followed. All subjects enrolled have signed and received copies of the informed consent forms and written subject information (if applicable) approved by SREC for this project.

Principal Investigator

Date

TABLE 1

Number of subjects enrolled and withdrawn from this research from

_____ to _____
(commencement date of trial) (closure date of trial)
(dd/mm/yy)

No.	Subject Initials	Date subject withdrawn	Reason for withdrawal	Was study drug restarted again?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) (closure 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 46150 Petaling Jaya, Selangor.
Tel: 03-7491 1256 Fax: 7491 1255