

Sunway Medical Centre Independent Research Ethics Committee (SREC)

RESEARCH PROGRESS REPORT FORM

(The First Report should be submitted one year 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 Enrolled	_____ to _____ (commencement date of trial : dd/mm/yy)	No:
Number of Subjects Enrolled and Subsequently Withdrawn (provide details in Table 1)	_____ to _____ (commencement date of trial : dd/mm/yy)	No:
Number of Serious and/or Adverse Events Reported (provide details in Table 2)	_____ to _____ (commencement date of trial : dd/mm/yy)	No:

Has any new information or new findings changed the risk versus benefit to subjects significantly since this research project was first approved by SREC?

Yes No

If yes, please describe.

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Number of subjects enrolled and withdrawn from this research from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 : 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No.	Subject Initials	Date subject withdrawn	Reason for withdrawal	Was study drug restarted again?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 : 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