Sunway Medical Centre Independent Research Ethics Committee (SREC)

SERIOUS ADVERSE EVENT REPORT FORM

(Serious Adverse Event Report Form (All Serious Adverse Events (SAEs) and Adverse Drug Reactions (ADR)) that are both serious and unexpected occurring in the Sunway Medical Centre are to be reported to SREC within one working day from first knowledge by the investigator or his research team using this form. SAEs reported outside Sunway Medical Centre (eg. Those received via CIOMS reports in Multicentre Studies) are to be notified to SREC within one month of its receipt by the Investigator or his/her research team. Such reports need to be submitted with an accompanying letter only.)

Title of Research Project						
Protocol No.						
Principal Investigator						
Sponsor						
Type of SAE Report *(tick one)*	□	New / initial	□	Follow – up		
Subject Initials			Age		Sex	
Date of SAE Onset			Date of SAE resolution			
Date when SAE was *first* informed to Investigator or Research Team						
Description of SAE						
Tick Appropriate Outcome	□	Resulted in death				
	□	Is life threatening				
	□	Requires inpatient hospitalization or prolongation of existing hospitalization				
	□	Results in persistent or significant disability/incapacity				
	□	Is congenital anomaly/birth defect				

INFORMATION ON SUSPECTED DRUG				
Name of Drug(s)		**Dose**		
Route of Administration		**Indication**		
Treatment Dates	From (start date)		To (end date/ongoing)	
Concomitant Drug(s)	Name			
	Route of Administration			
	Dose			
Do you consider this SAE to have causal relationship to the suspected drug? *(tick appropriate answer)*	□	Definite		
	□	Probable		
	□	Possible		
	□	Unlikely		
	□	Not related		
	□	Insufficient information		
What were the measures taken?	□	Suspected drug discontinued		
	□	Dose reduced		
	□	Drug treatment for the SAE		
	□	No drug treatment given for the SAE		
	□	Discontinuation of concomitant drug(s)		
	□	Non-drug treatment (specify)		
Does this SAE significantly alter the risk-benefit analysis to the research subjects in this research project? *(to be commented by investigator only)*				
Name of Reporter			Date	
Signature of Reporter				

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