THOMSON HOSPITAL
KOTA DAMANSARA

SERIOUS ADVERSE EVENT (SAE) REPORTING FORM

No.	Particular	Description				
1.	Study Title					
2.	Reference No/NMRR ID					
3.	Principal Investigator / Sub-Investigator's Name					
4.	Name of Sponsor (if applicable)					
5.	Subject Initials		Age		Sex	
6.	Date of SAE onset		Date of SAE resolution			
7.	Date when SAE was first informed to Investigator /Research Team					
8.	Location of SAE occurrence (e.g., at study site or elsewhere)					
9.	Was this SAE expected?	☐ Yes ☐ No				
10.	Relevant Medical History					
11.	Brief description of the nature of the SAE					
12.	Outcome of SAE	☐ Resulted in Death – Date: _____ ☐ Life-threatening ☐ Hospitalization – initial or prolonged _____ ☐ Disability / incapacity ☐ Congenital anomaly/ Birth defect ☐ Requires intervention to prevent permanent impairment ☐ Other: _____				
13.	Intervention type	☐ Medication or Nutritional Supplement Specify: _____ ☐ Device Specify: _____ ☐ Surgery Specify: _____ ☐ Behavioral/ Lifestyle modifications Specify: _____				
14.	Relationship of SAE to intervention	☐ Unrelated (clearly not related to the intervention) ☐ Possible (may be related to intervention) ☐ Definite (clearly related to intervention)				

15.	Was study intervention discontinued due to event?	☐ Yes. If yes, date of last dose/intervention: (_____) ☐ No		
16.	What medication/steps were taken to treat the SAE?	□ Drug permanently discontinued □ Dose Reduced □ Drug treatment given for SAE □ Discontinuation of concomitant drug □ Non- Drug Treatment (specify): _____		
17.	List any relevant tests, laboratory data, history, including preexisting medical conditions			
18.	Is there any ethical concern or other matter to be highlighted to THKD REC?			
19.	Type of report	☐ Initial ☐ Follow-up ☐ Final		
20.	Name of Person Reporting			
21.	Signature of person reporting		Date	

Please send the completed SAE Reporting Form with supporting documents to:
THKD REC Secretariat, c/o THKD Clinical Research Centre,
No. 11, Jalan Teknologi, Taman Sains Selangor 1, PJU 5,
Kota Damansara, 47810, Petaling Jaya, Selangor
Tel: +603-6148 7078/ Fax: +603-6287 1212
Email: crc.thkd@tmclife.com