



INSTITUT JANTUNG NEGARA
National Heart Institute

IJN Research Ethics Committee SAE REPORTING FORM

All incidents must be reported on this form within 7 working days of the investigator's becoming aware of the incident. All SAE(s) must be notified to IJNREC within 24 hours. Fatal and life-threatening events must be reported within 48 hours of notification.

Details of Research Project

Project Registration Number	
Project Title/Study Project	
Sponsor	
Investigator	

Adverse Event Information

Event Date : _____ (DD/MMM/YYYY)

Subject Initials : _____ Gender : Male Female Age : _____ yrs

Adverse Event Term(s) :

Brief Description of the Event (provide summary) :

- Unexpected** (i.e., not listed as an anticipated risk in the IJNREC-approved consent form)

Category of the serious adverse event :

- Death – date [_____] (DD/MMM/YYYY)
- Life-threatening
- Required hospital admission or prolongation of hospitalization
- Persistent disability or significant incapacity
- Congenital anomaly/birth defect/cancer
- Required intervention to prevent permanent impairment
- Expected** (i.e., listed as an anticipated risk in the IJNREC-approved consent form but the frequency or severity is greater than expected)



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Assessment of Event's Relationship to study medication(s)/device :

Definitely Related Possibly Related Unrelated

Treatment given for Adverse Event :

Outcome of Event :

Recovered Recovering Not recovering Death

Provide the following information of Local Serious Adverse Events:

Number of subject enrolled locally : _____ subject(s)

Are there prior reports of similar events? Yes No

If yes, how many, and did they result in a change in the Informed Consent Form or the Protocol?

I have reviewed all the information included in this report and confirm it is accurate based on review of all available information concerning the reported event(s).

Signature : _____ Date : _____
(DD/MMM/YYYY)

Investigator : _____

FOR OFFICE USE ONLY

Date of Received : _____

Received by : _____

Signature : _____



IJN Research Ethics Committee
SAE REPORTING FORM

REVIEW BY SECRETARY, IJNREC

- Further review is NOT required by IJNREC
- Further review is required by the IJNREC

COMMENTS :

Signature : _____ Date : _____
(dd/mmm/yyyy)

FURTHER REVIEW OF SAE BY CHAIRMAN, IJNREC

Final Decision by IJNREC following further review :

- Approved for continuation
- Approved conditional on changes
- Suspended pending further review

Signature : _____ Date : _____
(dd/mmm/yyyy)