



INSTITUT JANTUNG NEGARA  
National Heart Institute

## IJN Research Ethics Committee

### NOTIFICATION OF PROTOCOL DEVIATIONS/VIOLATIONS FORM

*The IJNREC Chairman can suspend or terminate studies at his discretion when issues of non-compliance appear to place subjects at risk. All significant protocol deviations and non-compliance must be reported promptly to the IJNREC.*

#### **Details of Research Project**

|                             |  |
|-----------------------------|--|
| Project Registration Number |  |
| Project Title/Study Project |  |
| Sponsor                     |  |
| Investigator                |  |

#### **Please respond below questions.**

**Minor protocol deviation** (*nonsystematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*)

**Major protocol deviation / protocol violation** (*persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk*)

Describe the protocol deviation/violation/non-compliance (include date of occurrence):

Explain the reason for the deviation/violation :

Indicate the Treatment/Outcome of the event :

Was subject safely compromised?



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Was a SAE reported as a result of this event?

Did this deviation/violation have a serious impact on the conduct of the study or the outcome of the research?

Describe the steps taken to resolve this particular occurrence.

Describe the prevention steps to prevent similar occurrence in the future.

Signature :

Date :

*(DD/MMM/YYYY)*

Investigator :

#### ***FOR OFFICE USE ONLY***

Date Received :

Name :

Signed :



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Report reviewed; no further action required at this time

Report reviewed; the following required from Investigator :

Report reviewed; recommend further action to Investigator :

Reply to Investigator; Date : \_\_\_\_\_ (*dd/mmm/yyyy*)