INSTITUT JANTUNG NEGARA
National Heart Institute

Reporting events to Institut Jantung Negara Ethics Committee (IJNEC)?

Reporting requirements

- On-going research should be subject to continuing monitoring. The Committee should indicate the quorum requirements, the reporting procedure and the communication procedure for on-going monitoring, which may vary from the requirements and procedures for the initial decision on the application. The frequency of such monitoring should reflect the degree of risk to participants/volunteers in the research project. As a minimum, the IJNEC will require an annual report from the Principal Investigator, but the committee can agree more frequent reporting at the time of approval of the application.

Adverse Events

- As a condition of approval of the research proposal the IJNEC will require investigators to immediately report any serious or unexpected adverse events on participants/volunteers or unforeseen events that might affect the benefits/risks ratio of the proposal.

- A serious adverse event (SAE) is defined as any occurrence that:

    I. Results in death
    II. Is life threatening
    III. Requires in-patient hospitalisation or prolongation of existing hospitalisation (in the case of a clinical trial)
    IV. Results in persistent or significant disability/incapacity.
    V. Congenital abnormality

- An unexpected event is an adverse reaction, the nature and severity of which is not consistent with relevant information available at the time of original approval.

- Investigators may take urgent safety measures to eliminate immediate jeopardy to the research participants/volunteers prior to approval by the IJNEC. However, investigators should provide the Committee with a written report of any action taken at the earliest opportunity. The Committee will review the new material and decide whether there are sufficient grounds for changing its initial decision to grant approval to the proposal.

- IJNEC shall require, as a condition of approval of each project, that researchers report SAE and other Adverse Event to the IJNEC according to the following procedure:

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Serious Adverse Events (SAEs) (submitted on the Single or Periodic SAE form)

I. All internal SAEs must be notified to the IJNEC within 24 hours after the investigator first learns of their occurrence. A detailed, written report must be submitted within seven (7) working days (using Single SAE form)

II. External SAEs must be reported in a prompt manner (within 24 hours after the investigator first learns of their occurrence) A detailed, written report must be submitted within fifteen (15) working days if the information impacts the continued ethical acceptability of the trial (using Single SAE form)

III. All other external SAEs need only be submitted if they are suspected or unexpected (SUSAR) and may be submitted as a periodic listing. A periodic listing of SUSARs must be submitted at least six monthly (using Periodic SAE form)

- Any other event that occurs as part of a research such as deviation from or violation of the protocol which affects patient safety, requires a change in the inform consent and protocol, must be submitted in letter format to the IJNEC.

- Notifications of SAEs are submitted by the PI (or delegate) to the IJNEC on a SAE form which includes:

I. Advice from the PI as to whether, in his/her opinion, the adverse event was related to the protocol
II. Advice from the PI as to whether, in his/her opinion, the adverse event necessitates an amendment to the protocol and/or Consent Form
III. Advice from the PI as to whether the event has been notified to the “Independent Safety and Data Monitoring Board” (if applicable)