



How to submit research project to Institut Jantung Negara Ethics Committee (IJNEC)?

Applicant

- A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application for review of the ethics of proposed research.

Application Procedure

- An application for IJNEC review in respect of proposed research must be made in writing and signed by a qualified researcher responsible for the conduct of the study. All properly submitted and valid applications shall be reviewed in a timely fashion and in accordance with the review procedures described in this SOP. A valid application is one which has been submitted by an appropriated investigator, is complete, with all the necessary documents attached and is signed and dated.
- The application should include the following information and materials:
 - I. Application material should be submitted to the Chair, IJNEC (15 copies)
 - II. The application material must include an application letter and other accompanying/supporting materials:
 - III. The completed application, signed by the Investigator, should be submitted in hard copy to the IJNEC Secretary.
 - IV. Signed applications and accompanying documentation must reach the IJNEC no later than two weeks before the next scheduled IJNEC review meeting.
 - V. All applications will be acknowledged in writing within 7 working days of receipt, including the communication of the incompleteness of an application where this applies.
 - VI. All applications will receive notification in writing of the decision of the IJNEC following review no later than 90 working days after acknowledgement of receipt of a valid application.
 - VII. The letter of notification will, where applicable, outline the application procedure of amendments to the protocol, the recruitment material, the potential research participant information or the informed consent form.
 - VIII. Where the IJNEC requires supplementary information or changes to documents from the applicant, the timeframe for this will be outlined in the letter of notification.
 - IX. No revisions may be made, prior to the IJNEC meeting, to an application that has been accepted for review and assigned a reference number. Where an applicant considers it necessary to revise the application form or supporting documents prior to review, the application should be withdrawn.

Application Materials

- The following documents are mandatory for submitting for ethical review
 - I. IJNEC Application Form (dated and signed)
 - II. Research protocol
 - III. Participant information sheet
 - IV. Participant consent form
 - V. Investigator(s) curriculum vitae (updated, signed and dated)
 - VI. Evidence of insurance or indemnity (if applicable)

- Other types of supportive documents may include, whenever necessary;
 - I. A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation ('flowchart') of the protocol
 - II. A description of the ethical considerations involved in the research
 - III. Case report forms, diary cards or questionnaires intended for research participants, advertisements, where applicable
 - IV. An adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on a study product (where one is being used) together with a summary of clinical experience with the study product to date (e.g. recent investigators' brochure, published data etc)
 - V. A written participant information sheet and informed consent form in translated version whenever necessary
 - VI. Confirmation that external funding for the project costs has been granted subject to ethical approval (letter of offer or equivalent)
 - VII. All documents must bear version numbers and dates