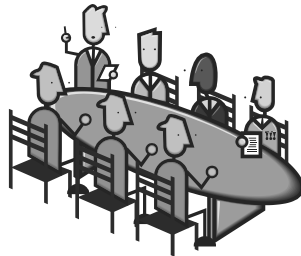




## ETHICS COMMITTEE APPROVAL



Research for  
Better Health  
Outcomes

The Ethics Committee (EC) should safeguard the rights, safety and well-being of all trial patients.

Special attention should be paid to trials that may include particularly vulnerable patients.

The ethics surrounding clinical trials is an integral theme of the Declaration of Helsinki. This document, which was first issued in 1964 and is updated periodically, emphasises that within clinical trials participating subjects should freely give informed consent and that their safety should be the paramount consideration.

## Investigator Responsibilities

To ensure that written approval of both the protocol and informed consent form has been obtained from the EC before the onset of the trial.

To be aware of when you should contact the EC during the course of the trial, and the appropriate reporting procedure.

To inform the EC of safety issues according to the local regulations at each site and when the trial has concluded.

## THE NZ HEALTH AND DISABILITY ETHICS COMMITTEES (EC)

The EC is an independent body with no member having a vested interest in the trial. It is composed of both specialists and lay people (12 members) and its primary function is to ensure the safety of all trial patients. The committee will evaluate all documentation to satisfy themselves of:

- (1) the scientific value of the trial;
- (2) the qualifications of the investigator;
- (3) the relative risks and benefits to which the patients are likely to be exposed; and
- (4) the information given to the patients and procedures for obtaining consent.

Before initiating a trial, the investigator must have obtained written and dated approval from the EC and also obtained relevant internal review pertinent to the appropriate DHB.

### BEFORE THE STUDY

- Ensure that you know which documents you are expected to submit to the EC. Check the NZ Health and Disabilities Ethics Committee web site for the most up to date information (<http://www.ethicscommittees.health.govt.nz/>). The committee will, in general, require:
  - ☑ A covering letter detailing the documents submitted;
  - ☑ All the information available on the proposed project e.g. if an investigational product; all toxicity data and trial results to date;
  - ☑ The trial protocol, including full details of the trial objectives, how patient recruitment (e.g. advertisements) and randomisation will proceed, how informed consent will be obtained and how patient confidentiality will be safeguarded;
  - ☑ The informed consent form together with any updates;
  - ☑ An up-to-date curriculum vitae of the investigator;
  - ☑ Information on the provision of compensation or treatment in the event of harm or disability being caused to a patient as a result of participation in the trial if relevant)
  - ☑ Approval letter from the relevant Maori group.
  - ☑ A signed Locality Assessment form from the General Manager
- Ensure that any changes required by the EC are implemented. These may include amendments to the protocol or the informed consent form, or the addition of further safeguards into the trial.

### Tips

- Find out when the EC meets and their typical response time. These factors could have a significant impact on the planned timetable of the trial.
- Determine at the start the number of copies of documents the committee requires. This will save delays incurred as a result of incomplete submission.

**Tips continued:**

- Don't write in first person e.g. Rather than writing 'We expect'; document "The expectation is"
- Don't document the fact that this project was marked highly for a qualification as the EC aren't interested in those facts

**DURING THE STUDY**

- Ensure that written approval has been obtained before the first patient is recruited into the trial.
- Ensure that all documentation relating to the deliberations of the EC is kept in the trial file.
- Provide periodic reports throughout the trial to the EC, as required.
- Ensure that you notify the EC when:
  - An amendment of the protocol is deemed necessary;
  - A serious and unexpected adverse drug reaction occurs (however, reporting should always be done according to each site's local regulations)
  - Re-evaluation of the ethical aspects of the trial is required, e.g. an interim analysis may indicate a significant benefit or detriment in one of the treatment arms.
- Ensure that approval is received, according to each site's local regulations, for any protocol amendments before they are implemented.

**Tips**

- Contact the EC to find out what protocol changes require approval. Approval will be mandatory for such amendments as the addition of further laboratory tests; however, purely administrative changes may not need to be submitted.

**AFTER THE STUDY**

- Inform the EC upon completion of the trial.
- Ensure that what you report, and the method of reporting, conform to the requirements of the EC.