



# Applications for Ethical Approval

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## 1. PURPOSE

Approval by Unitec Research & Ethics Committee (UREC) will be required before any research activities that involve the participation of humans as subjects, directly or indirectly, are initiated by the staff member or student researcher. To check whether approval is required, please consult these Guidelines. This will enable the researcher to decide whether full application to UREC or another ethics committee, e.g. the Health and Disability Commissioner, is required. Where ethical approval is required, research cannot commence until such approval has been given in writing.

These guidelines are not a substitute for reading, interpreting and implementing the intent of Unitec's [Research Ethics Policy](#). People using these Guidelines should refer in the first instance to the policy itself, and in the case of conflict, the policy shall prevail.

## 2. GUIDELINES

### 2.1. Individual Application for Ethics Approval for a Research Project

#### 2.1.1. [Form A](#)

This is for research which *does not meet* all criteria for harm minimisation. Staff researchers are personally responsible for obtaining approval. For student research, research supervisors must co-sign the application and ensure that:

- the application is submitted to UREC;
- students understand the principles and procedures set out by UREC;
- the project is appropriately supervised;
- the project is of an acceptable standard for the discipline concerned.

#### 2.1.2. [Form B](#)

This is for research which *does meet* all criteria for harm minimisation (consult Guidelines). Staff researchers are personally responsible for obtaining approval. For student research, research supervisors must co-sign the application and ensure that:

- the application is submitted to UREC;
- students understand the principles and procedures set out by UREC;
- the project is appropriately supervised;
- the project is of an acceptable standard for the discipline concerned.

### 2.1.3. **Form C - Application for Ethical Approval for a Research Component of a Teaching Programme**

This application is to enable UREC to delegate authority to the applicants to approve non-contentious research (i.e. normally submitted under Form B) within a teaching programme. Approval for Research Components of a Teaching Programme can be for a maximum of three years. Teaching programmes cover:

- student research projects;
- courses that have a significant component of research;
- research laboratories;
- or class research exercises.

## 2.2. **Submission of Application**

The appropriate form should be completed and sent to:

UREC Secretary

Research Office and Postgraduate Centre

Unitec New Zealand

Private Bag 92025

Auckland

Phone: 815 4321 extension 6162

Email: [ethics@unitec.ac.nz](mailto:ethics@unitec.ac.nz)

Completed applications must be received by the UREC Secretary at least 10 working days prior to the next meeting in order to be processed at that meeting.

The applicant must send all completed forms plus attachments (i.e. survey instruments, information and consent forms) electronically to the UREC Secretary or the research supervisor as appropriate. The signed declaration page (cover page of the application form) and any supporting information not able to be supplied electronically (such as letters of support) should be sent as hard copy by normal mail to the UREC Secretary.

The applicant is responsible for ensuring that the research supervisor and/or Head of Department receive the application form and all relevant attachments in the form they prefer. These people must personally sign the declaration page after which the staff applicant or supervisor as appropriate, is responsible for ensuring the signed copy is sent to the UREC Secretary.

Reading of the application cannot commence until all documentation is received. The principal reader may discuss the application with the applicant and /or supervisor as appropriate.

### **2.2.1. Retrospective approval**

Retrospective approval will not be given for any research already commenced.

## **2.3. Exceptions from Approval Requirements**

- 1) While ethical considerations must still be upheld, the following do not require specific approval from UREC:
  - a) research that does not involve human or animal subjects and is not foreseen to adversely affect human or animal subjects;
  - b) evaluations conducted within Unitec for quality assurance purposes;
  - c) research involving existing, publicly available documents or data (e.g. analysis of archival records, which are publicly available);
  - d) preliminary interaction or discussion where the exact research aims have not yet been formulated;
  - e) research in which a single investigator is the subject of his or her own research, and where no hazardous outcomes are foreseen;
  - f) one-off interviews with public figures, e.g. politicians, prominent authors;
  - g) seeking a professional or authoritative opinion, except where this is part of a study of the profession or area of expertise;
  - h) where harm minimisation criteria are not exceeded, and where certain student research projects are covered by an approved Research Component of a Teaching Programme ([Form C](#)).
- 2) Under certain circumstances, UREC cannot approve some research projects. This includes projects using animals. Other examples of research projects that UREC cannot approve are given in the Guidelines for Institutional Ethics Committees to Refer Research Studies to a Health and Disability Ethics Committee (consult [www.hrc.govt.nz](http://www.hrc.govt.nz)). In such cases, application must be made to a Health and Disability Ethics Committee using their (or the national) application form.
- 3) UREC may from time to time redefine these exempt and modified categories or determine new ones.

## **2.4. The Declaration and Indemnity**

- 1) All applicants are required to sign a declaration guaranteeing the accuracy of the information that is provided, and that the ethical conduct of the research as approved by the Ethics Committee will meet the requirements of these Policies and Procedures.
- 2) Any significant departure from the project approved, particularly around issues of consent, confidentiality, sensitivity and potential harm to participants, must be notified to the committee and approval sought before proceeding with the changes.
- 3) Provided the research is properly conducted within the limits of the approval, the researcher is indemnified against such accident and misadventure that may occur.

## **2.5. Complaints Procedures**

Complaints regarding an application and / or the decision-making process used by UREC in reaching a particular decision will be investigated using the following procedure:

- The complaint must be made to the UREC Secretary in writing.
- UREC will deliberate on the complaint. As part of its deliberation UREC may liaise with national or regional health bodies on services and treatment and with the Health Research Council (HRC) Ethics Committee on research and innovative treatment issues.
- UREC will give a written explanation about how the original decision in question was reached.
- UREC will give the complainant a reasonable opportunity to respond in writing and to attend the next committee meeting for further discussion.
- If the complainant responds in writing or attends a committee meeting, UREC will provide a decision in writing to the complainant.

Complaints that research is not being conducted according to the protocol approved by UREC will be investigated using the following procedure:

- The complaint must be made to the UREC Secretary in writing.
- At the discretion of the UREC chairperson, UREC will set up a subcommittee to investigate the complaint.
- The chairperson or subcommittee will normally contact the researcher about the complaint. Anonymity will be maintained if requested by the complainant.
- While the complaint is being investigated, UREC may request that the research be put on hold.
- UREC will communicate the final decision to all parties in writing.

UREC may seek advice from, or refer complaints to, other bodies as might be deemed appropriate.

Complainants may appeal a decision of UREC to the Executive Dean, Academic. In such cases the Executive Dean, Academic shall convene an appeal committee to adjudicate the appeal. The appeal committee shall consist of senior academic staff and at least one member of a HRC accredited institutional ethics committee.

## **2.6. Withdrawal of Approval by UREC**

Where UREC has determined that research is not being conducted according to the protocol approved, UREC can withdraw approval for the research.

## **2.7. Liability and Insurance**

- 1) Both staff and students of Unitec are covered for personal liability as researchers under the insurance policies held by Unitec, providing research is carried out according to the protocols approved by UREC.
- 2) In cases when clinical trials are being conducted by Unitec staff or students (for a definition and information on clinical trials, Unitec adheres to the HRC Guidelines on Ethics in Health Research regarding compensation for research participants (see sections 3.5 and 5.6 of the HRC Guidelines on Ethics in Health Research (consult [www.hrc.govt.nz](http://www.hrc.govt.nz))). Such compensation may apply (but is not solely restricted) to Accident Compensation Corporation and Insurance Corporation Cover.

## **REFERENCE DOCUMENTS**

- [1] [Application for Ethical Approval – Form A](#)
- [2] [Application for Ethical Approval – Form B](#)
- [3] [Application for Ethical Approval – Form C](#)
- [4] [Research Ethics Policy](#)
- [5] Guidelines on Ethics in Health Research (consult [www.hrc.govt.nz](http://www.hrc.govt.nz))
- [6] Guidelines for Institutional Ethics Committees to Refer Research Studies to a Health and Disability Ethics Committee (consult [www.hrc.govt.nz](http://www.hrc.govt.nz))

## DOCUMENT DETAILS

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