



Research Ethics Policy

Table of Contents

1. PURPOSE.....	2
2. SCOPE.....	2
3. POLICY STATEMENT.....	2
3.1. ANIMAL ETHICS.....	2
4. PROCESS.....	2
4.1. CONTEXT AND POLICY ENVIRONMENT.....	2
4.2. SCOPE.....	2
5. DEFINITIONS.....	3
5.1. INTERPRETATION.....	4
6. TERMS OF REFERENCE.....	4
6.1. UREC TERMS OF REFERENCE.....	4
6.1.1. GENERAL POWERS.....	4
6.1.2. APPOINTMENTS, COMPOSITION AND SKILLS OF MEMBERS.....	4
6.1.3. TERMS OF OFFICE.....	5
6.1.4. OFFICERS.....	5
6.1.4.1. CHAIRPERSON AND DEPUTY CHAIRPERSON.....	5
6.1.5. MEETINGS.....	6
6.1.6. DETERMINANTS OF RESEARCH ETHICS.....	6
6.1.7. DECISION MAKING PROCESS.....	6
6.2. COMPLAINTS AND APPEALS.....	7
6.2.1. COMPLAINTS CONCERNING THE ASSESSMENT OF AN APPLICATION.....	7
6.2.2. APPEALING A DECISION OF UREC.....	7
6.2.2.1. GROUNDS FOR APPEAL.....	7
6.2.3. COMPLAINTS REGARDING THE ETHICAL CONDUCT OF RESEARCH.....	8
6.3. OTHER MATTERS.....	9

1. PURPOSE

Any research involving human or animal participants, animal or human materials, personal information, or involving clinical trials, or combinations of such studies, requires ethical approval. This requirement is governed by several Acts of Parliament, including the New Zealand Public Health and Disability Act 2000, The Health Research Council Act 1990 and the Animal Welfare Act 1999 (for a full list of relevant Acts, please see the accompanying guidelines). The Unitec Research Ethics Committee is an approved ethics committee of the Health Research Council Ethics Committee (HRCEC) and able to undertake independent assessment on behalf of the HRCEC.

2. SCOPE

All staff, students and contractors conducting research at Unitec are governed by this policy.

3. POLICY STATEMENT

Research at Unitec will be undertaken in accordance with this policy and other relevant generally accepted ethical standards and processes. All staff and **Unitec Research Associates** have the responsibility to ensure that all research that they or their students undertake, that involves humans as participants, complies with this policy and those standards and processes meet ethical requirements.

The Unitec Research Ethics Committee (UREC) shall be responsible for reviewing individual staff and Student research applications (as submitted to the committee) that involves humans as participants to ensure these comply with this policy and those standards and processes.

Please Note: This policy should be read in conjunction with the Human Research Ethics **Guidelines**.

Commented [AL1]: At the moment the policy does not explicitly indicate that Research Associates of Unitec may make use of the Unitec Research Ethics Committee. UREC suggests that this be added.

Commented [AL2]: Full stop added

3.1. Animal Ethics

The use of animals for research, testing, or teaching is governed by the Animal Welfare Act 1999. No research, testing or teaching involving animals is to occur at Unitec without prior approval of an approved Animal Ethics Committee. Unitec does not have a formal code of ethical conduct regarding the use of Animals in research, testing or teaching and therefore has entered into a formal arrangement with an approved Animal Ethics Committee as required by the Animal Welfare Act 1999. Activity of this nature must comply with the policies and procedures of this committee.

4. PROCESS

4.1. Context and Policy Environment

Unitec recognises the need for studies in which humans participate in research. Unitec is also aware of its responsibility for ensuring that the privacy, safety, health, social sensitivities and welfare of such participants are adequately protected. In addition, researchers need to ensure that research is conducted in an environment safe for the researcher(s) as well as participants. Where there is a conflict between this Policy and Procedures and any legislation or regulations currently in force, the legislation or regulations shall prevail.

4.2. Scope

While all research at Unitec shall uphold high ethical standards, the following do not require specific approval from UREC:

- a) research that does not involve human participants or animal subjects and is not foreseen to adversely affect human participants 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) one-off interviews with public figures, e.g. politicians, prominent authors;
- f) seeking a professional or authoritative opinion, except where this is part of a study of the profession or area of expertise;
- g) where certain student research projects are covered by an approved Research Component of a Teaching Programme (Form C) and where harm minimisation criteria are not exceeded.

4.2.1. Furthermore, UREC is not able to appraise the following types of research projects:

- a) research involving or affecting animals;
- b) research using genetic modification (see below);
- c) interventional studies using human participants (exceptions to this are outlined in the Standard Operating Procedures for Health and Disability Ethics Committees)
- d) research involving human remains;
- e) any clinical study requiring the approval of the Standing Committee on Therapeutic Trials, the Gene Technology Advisory Committee or the Environmental Risk Management Authority.

For each of the above types of research projects, application must be made, using the appropriate forms, to an accredited animal or regional Health and Disability Ethics Committee, details of which can be obtained from the UREC Secretary.

Where there is any doubt regarding the need for ethical approval it is the responsibility of the researcher and/or the research supervisor to consult with UREC in the first instance. UREC is not authorised to approve certain types of research projects, such as those noted above and in such cases researchers will require approval from another ethics approval body.

Commented [AL3]: Section reformatted from "h" to "4.2.1", lettering then reformatted to reflect this change.

5. DEFINITIONS

In this policy, unless the context otherwise requires, the following definitions shall apply:

Academic Board	means the Academic Board of Unitec, established under the Academic Statute;
Academic Statute	means Unitec's Academic Statute;
HRC	means the Health Research Council of New Zealand established under the Health Research Council Act 1990;
Student	means a person enrolled for one or more courses at Unitec;
Unitec	means Unitec Institute of Technology

UREC	means Unitec Research Ethics Committee
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5.1. Interpretation

In this policy:

- a) Clause headings and other headings are for ease of reference only and will be ignored in construing this policy;
- b) Any reference to any gender includes all genders and a reference to the singular includes the plural and vice versa;
- c) Any reference to a statute or regulation will be construed as a reference to that statute or regulation as amended or re-enacted from time to time.
- d) Except where defined in this policy or where it is inconsistent with the context, terms used shall bear the meaning set out in the Education Act 1989.

6. TERMS OF REFERENCE

6.1. UREC Terms of Reference

6.1.1. General Powers

UREC has been established under the Academic Statute.

UREC's powers and functions, as set out in the Academic Statute, are to:

- a) Recommend to the Academic Board policy and processes for ensuring that Unitec's research complies with ethical standards and international best practice;
- b) Approve research projects by staff and students with respect to ensuring compliance with ethical standards and international best practice;
- c) Approve protocols for ensuring that research complies with ethical standards;
- d) Provide advice and guidance with regard to ethical standards related to research to anyone undertaking research at Unitec; and
- e) Provide an avenue for handling complaints or queries made in relation to the ethics of research at Unitec.

Membership and practice of UREC shall be in accordance with the National Standards for Ethics Committees and the HRC's Guidelines on Ethics in Health Research and shall be approved by Council.

The committee shall also include student membership where possible.

UREC is responsible to Council through the Academic Board and shall have the power to report directly to Council.

6.1.2. Appointments, Composition and Skills of Members

UREC shall have no fewer than seven members.

All appointments shall be at the discretion of UREC under guidance of the Chair and made by a majority decision of UREC.

Vacancies for external membership will normally be advertised by public advertisement in appropriate media. Vacancies for internal members (usually Unitec employees) shall be openly advertised in appropriate internal media.

The composition of the UREC is to be in accordance with the HRC and National Guidelines. The Chair and UREC shall ensure that at least two members of the Committee shall be Maori and these may be external or internal members.

Membership is not transferable and cannot be delegated or exercised by proxy.

The range of skills and expertise of members of UREC will ideally include:

- a) Awareness of Maori issues and understanding of Maori tikanga, including knowledge of the Treaty of Waitangi;
- b) Knowledge of the experiences and perspectives of people with disabilities; c) Legal knowledge;
- d) Professional expertise in healthcare and patient advocacy;
- e) Awareness of gender health perspectives;
- f) Knowledge of both qualitative and quantitative research methods;
- g) Knowledge of health and disability service delivery;
- h) Knowledge of ethical theory;
- i) Healthcare consumer and/or research participant perspectives;
- j) An understanding of rural health issues (if the area of geographical responsibility is predominantly rural); and
- k) An understanding of relevant scientific/medical knowledge and cultural perspectives.

6.1.3. Terms of Office

Each member shall be appointed for a three-year term and may be eligible to serve a second consecutive term of three years to provide continuity and full use of increased experience and expertise. No member, including the Chairperson, shall serve on UREC for more than six successive years. A former member will not usually be considered for reappointment until at least three years after his or her retirement from UREC.

Staggered retiring dates for committee members should be utilised where possible to allow a degree of continuity and these shall be monitored by the Chairperson.

Unless a member vacates his or her office, every appointed member of UREC shall continue in office until his or her term of membership expires.

If a member retires from UREC within his or her three year term, UREC shall review the range of skills and expertise available from the remaining members to determine whether the vacancy needs to be filled.

6.1.4. Officers

6.1.4.1. Chairperson and Deputy Chairperson

The chairperson shall be elected annually by the members of UREC by a majority decision. It is recommended that the chair of the ethics committee be an external member. A deputy chairperson may also be elected, using the same procedure. If a chairperson is elected who has affiliations to Unitec, the committee shall establish procedures for dealing with any actual or perceived conflicts of interest that may arise, and in this instance the deputy chair shall be an external member of UREC. These shall be noted in the Annual Report as is required by the HRC.

6.1.5. Meetings

UREC will meet at least nine times per year.

A quorum will be half of the total membership and must require the presence of at least two external and two internal members. Where a quorum is not met any decisions made by the committee will be ratified as soon as possible via a e-meeting of the committee.

Commented [AL4]: Deleted repetition.

6.1.6. Determinants of Research Ethics

- 1) Unitec research practice must not infringe New Zealand laws, regulations and treaties, including:
 - i. Te Tiriti O Waitangi / the Treaty of Waitangi
 - ii. Human Rights Act 1993
 - iii. New Zealand Bill of Rights Act 1990
 - iv. Mental Health (Compulsory Assessment and Treatment) Act 1992
 - v. Protection of Personal and Property Rights Act 1988
 - vi. Accident Compensation Act 2001
 - vii. Privacy Act 1993
 - viii. Codes of practice of the Health & Disability Commissioner (Code of Health and Disability Services Consumers' Rights, 1996), the Privacy Commissioner (Health Information Privacy Code, 1994) and the Race Relations Commissioner.
- 2) UREC's practices will adhere to the Ministry of Health's Operational Standard for Ethics Committees, the HRC's Guidelines on Ethics in Health Research and the DHB Research Medicine industry guidelines.
- 3) UREC will emphasise eight guiding ethical principles governing research activities using humans. These are:
 - i. informed and voluntary consent;
 - ii. respect for rights and confidentiality and preservation of anonymity and the protection of identity;
 - iii. minimisation of harm;
 - iv. cultural and social sensitivity;
 - v. limitation of deception;
 - vi. respect for intellectual and cultural property ownership;
 - vii. avoidance of conflict of interest;
 - viii. research design adequacy

Commented [AL5]: Added "and the protection of identity" in order to reflect the difference between 'anonymous' and 'confidential' data collection.

6.1.7. Decision Making Process

UREC shall make decisions by consensus where possible. The Chairperson shall ensure that members of the committee are free to participate fully in discussion and debate.

Internal members should not regard themselves as representatives of particular Networks/Practice Pathways of Unitec but rather as representing the interests of Unitec as a whole and participating in a joint decision-making process.

In the interests of being better informed, members may wish to consult on ethical issues with sources outside the committee, for example, applicants, individuals, groups, iwi and hapu, and this should be supported and encouraged. However, the confidentiality of the protocol and details of the issue under appraisal must be protected. Where there is insufficient expertise on the committee to assess an application properly or address an issue raised, UREC may seek

additional expert advice. Such experts may be invited to attend a relevant meeting but cannot take part in the decision-making process for any application.

At the Chairperson's discretion, in exceptional circumstances, applications for ethical approval under urgency may be granted conditional approval by a sub-committee of no fewer than three members nominated by the chairperson.

This conditional approval requires a unanimous decision of the sub-committee and must be ratified by UREC.

UREC shall develop operational procedures for the processing of applications and promulgate these as required. These procedures are documented in the Human Research Ethics Guidelines.

6.2. Complaints and Appeals

6.2.1. Complaints concerning the assessment of an application

Complaints regarding the assessment of an application for ethical approval and/or the procedures and/or the decision-making process used by UREC in reaching a particular decision will be investigated using the following procedures:

The complaint must first be submitted in writing to the UREC Secretary.

- 1) UREC will deliberate on the complaint. As part of its deliberation UREC may liaise with national or regional health bodies and with the Health Research Council (HRC) Ethics Committee regarding any part of the complaint.
- 2) UREC will provide a written response to the complainant detailing out how the complaint was investigated and the result of their consideration of the complaint.
- 3) UREC will provide the complainant a reasonable opportunity to respond in writing and to attend a committee meeting for further discussion.
- 4) If the complainant responds in writing or attends a committee meeting, UREC will provide a final decision in relation to the complaint in writing to the complainant.

6.2.2. Appealing a decision of UREC

An appeal of a decision of UREC can be submitted if a final decision (application has been withdrawn or declined by the committee) has been provided by UREC. Appeals of a decision of UREC shall be submitted to the Chair of Academic Board and will be conducted according to the following procedure:

6.2.2.1. Grounds for Appeal

That there has been a material irregularity in the assessment of the application or in the procedures adopted by the committee, or there is substantive disagreement in regards to a decision of UREC.

Procedures

- 1) An application for appeal shall be made in writing, summarising the relevant facts and setting out the grounds for appeal, no later than 90 days after the final decision of UREC has been made.
- 2) Within 10 days the Chair, Academic Board or their nominee, shall determine whether the appellant has established grounds for an appeal.
- 3) The Chair, Academic Board or their nominee, shall advise by written notice to the Chair of UREC that an application for an appeal has been received and include a copy of the Appellant's application for appeal. The Chair of UREC or delegate shall provide a written

response relating to the Appellant's application to appeal, and shall provide a copy of all relevant documents, including a copy of any committee minutes or files notes relating to the decision. A copy of this written response will be provided to the Appellant.

- 4) An Appeal Committee shall be established, and shall be provided with the appeal documentation and the UREC response. The Appeals Committee shall consist of the Chair, Academic Board or their nominee, three senior academic staff and at least one member of a HRC accredited institutional ethics committee from another institution, and none shall be current members of UREC.
- 5) The appeal hearing shall be held at a time convenient to all parties, including the Appellant. The committee Convenor shall advise the Appellant of his/her right to appear at the hearing, to be accompanied by whanau or a support person, to appoint an advocate to speak on his/her behalf, to request an interpreter, and the right to request a Maori representative on the Appeals Committee.
- 6) The appeal hearing shall be an open consultative event with both parties to the appeal in attendance for each other's explanations. The hearing shall follow meeting rules as follows:
 - i. All comments and questions are addressed or asked through the Convenor; The Appellant and/or advocate is invited to present his/her case, followed by an opportunity for members of the Appeal Committee to ask any questions
 - ii. The Chair of UREC or his/her delegate is invited to explain and clarify the decision made and then speak to matters raised in the appeal, followed by an opportunity for members of the Appeal Committee to ask any relevant questions'
 - iii. Either party may ask questions and the Convenor may also invite either party to present any additional information relevant to the hearing;
 - iv. All parties apart from the Appeal Committee are then requested to leave the meeting;
 - v. The Appeal Committee considers all the evidence presented and makes a decision.

Appeal Outcome

The Appeal Committee shall either:

- 1) Reject the appeal, or
- 2) Uphold the appeal and require UREC to reconsider their decision. The Appeal Committee shall provide UREC with a detailed response and targeted advice on matters that require attention in considering the application.

6.2.3. Complaints Regarding the Ethical Conduct of Research

Complaints may be made to UREC that research is not being conducted according to protocol approved by UREC. These will be investigated according to the following procedure: The complaint must be made in writing to the UREC Secretary. This complaint will be treated as confidential to the committee unless requested otherwise by the complainant.

At the discretion of the UREC chairperson, UREC will set up a subcommittee to investigate the complaint. This committee will include the ~~Dean~~ **Director** of Research, and at least one internal and one external member of UREC.

The chairperson or subcommittee will normally contact the researcher about the complaint. While the complaint is being investigated, UREC may request that the research be put on hold. UREC may seek advice from, or refer complaints to, other bodies as might be deemed appropriate.

A written response will be provided to the complainant and the researcher detailing the committee's findings.

Commented [AL6]: Changed to reflect change in title.

The researcher will be given the opportunity to provide a written response to the committee's findings.

Outcomes

UREC shall either:

- 1) Uphold the complaint and withdraw ethical approval for the research. All research must stop, and any data collected as a result of this research must be discarded and not used in future research or publications. Research may only commence again once a new application for ethical approval has been submitted and approved, or
- 2) Uphold the complaint and issue a warning to the researcher. A request for variation to the application is to be submitted to UREC if required.
- 3) Uphold the complaint and provide advice to the researcher on how to avoid ethical difficulties in their future research.
- 4) Find the complaint is unfounded with no evidence of misconduct identified in the investigation.
- 5) In all cases where any form of misconduct has been identified, appropriate parties at Unitec will be notified for follow up according to the relevant Unitec policies.

6.3. Other Matters

- 1) All new members of UREC shall receive an orientation to the committee and both initial and ongoing access to training relevant to their participation.
- 2) ~~This policy will be implemented in a way that honours the Unitec values:~~
 - i. ~~Integrity, honesty and accountability~~ **Kaitiakitanga (Gaurdianship)**
 - ii. ~~Creativity, innovation and courage~~ **Mahi Kotahitanga (Co-operation)**
 - iii. ~~Relevance and responsiveness~~ **Whakaritenga (Legitimacy)**
 - iv. ~~Care, tolerance and respect~~ **Rangatiratanga (Authority and Responsibility)**
 - v. ~~Fairness and justice~~ **Ngākau Māhaki (Respect)**

REFERENCE DOCUMENTS

- [1] [RESEARCH ETHICS GUIDELINES](#) [2] [APPLICATIONS FOR ETHICAL APPROVAL GUIDELINES](#)
 [3] [CONDUCT OF RESEARCH AND CONSULTANCY POLICY](#)

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AMENDMENT HISTORY

Version	Issue Date	Reason for Revision	Approved by
2	29/04/2010	Total Review	Academic Board
3	13/02/2014	Minor Review – Complaints and Animal Ethics	
4	30/10/2014	Removal of section 6.1.2, Paragraph 5 – change required to better align REC membership with HRC requirements.	Academic Board
4.1	02/05/2015	Updated to reflect new roles, positions and committee structures	Academic Board