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1. POLICY STATEMENT(S)

Research at Unitec will be undertaken in accordance with this policy and other relevant generally accepted ethical standards and processes. The Unitec Research Ethics Committee (UREC) shall be responsible for ensuring that all staff and Student research that involves humans as participants complies with this policy and those standards and processes.

Please Note: This policy should be read in conjunction with the two guideline documents [Research Ethics Guidelines](#) and [Guidelines for Applications for Ethical Approval](#).

2. DEFINITIONS AND INTERPRETATIONS

2.1. 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 the Unitec Research Ethics Committee.

2.2. 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.

3. PROCEDURES

3.1. 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.

3.2. 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.

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) clinical trials using human participants i.e. trials requiring completion of Statutory Declaration B (consult www.hrc.govt.nz);
- d) any research using patients, facilities, information, funds or staff of a District Health Board, or patients or health care information from an organisation providing health services;
- e) research involving human remains;
- f) 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.

3.3. UREC Terms of Reference

3.3.1. 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.

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

3.3.2. 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.

At least one half of the total membership should be external, i.e. not currently a Student or employee of Unitec.

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.

3.3.3. Term 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.

3.3.4. Officers

3.3.4.1. Chairperson

UREC shall be chaired by an external member, ideally with no affiliation to Unitec. The chairperson shall be elected annually by the members of UREC by a majority decision. 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. These shall be noted in the Annual Report as is required by the HRC.

3.3.5. 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.

3.3.6. 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) Injury Prevention, Rehabilitation and 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;
 - 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.

3.3.7. 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 faculties or departments 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 [Research Ethics Guidelines](#) and [Guidelines for Applications for Ethical Approval](#).

3.3.8. Complaints and Appeals

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 Development. In such cases the Executive Dean 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, and none shall be members of UREC.

3.3.9. 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
 - ii) Creativity, innovation and courage
 - iii) Relevance and responsiveness
 - iv) Care, tolerance and respect
 - v) Fairness and justice

REFERENCE DOCUMENTS

- [1] [Research Ethics Guidelines](#)
- [2] [Applications for Ethical Approval Guidelines](#)
- [3] [Conduct of Research and Consultancy Policy](#)

DOCUMENT DETAILS

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