Wellington Institute of Technology

Te Whare Wānanga o te Awakairangi

BUSINESS POLICY MANUAL

Manual Section:	**Research**
Policy Number and Title:	**9.2 Human Ethics Policy**
Approved by:	Academic Board and EMT
Date of Approval:	
Effective from:	
New Policy or Replacement:	Replaces Policy QMS 11.5
Manager Responsible for the Policy:	Director Strategy and Performance

Purpose of the Policy

The purpose of this policy is to ensure legal requirements and ethical standards are adhered to, human rights and rights to privacy are protected, and ethical practices in research, professional practice, teaching and administration are promoted when working with human subjects. It prescribes the principles of ethical practice and the procedures for gaining ethical approval for proposals involving human participants.

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1.0 Introduction

Ethics and ethical principles extend to all spheres of human activity. They apply to our dealings with each other, with animals and the environment. They should govern our interactions not only in conducting research but also in teaching, commerce, employment and politics. Ethics serve to identify good, desirable or acceptable conduct and provide reasons for those conclusions.

This policy identifies the ethical principles and values, which should govern research, scholarship and professional practice involving humans. Throughout this policy the term "involving" is used to mean not only those who are the principal focus of the activity but also those on whom the activity impacts.

This policy should be read in conjunction with BPM 9.1 Innovation and Research Policy which requires all research activities to be fully documented, peer reviewed and approved prior to their implementation.

1.1 Definitions

Administration
Administration includes any administrative activity undertaken by any employee of WelTec while in the course of their employment.

Clinical trial
A clinical trial is defined very broadly as "any research on human subjects conducted to gain new knowledge into mental and physical health and disease". Any procedure involving human participation for the purpose of acquiring new health knowledge is included in the definition. A clinical trial does not include any research based on the analysis of secondary sources of health information.

Conflict of interest
A person has a conflict of interest when they are in a position of trust which requires them to exercise judgment on behalf of others (people, institutions, etc.) and also has interests or obligations of the sort that might interfere with the exercise of that judgment, and which they are morally required to either avoid or openly acknowledge. (The lesser requirement of open acknowledgment is usually adopted when it seems too burdensome to require that the person in a position of trust to divest themselves of the interest that conflicts with their position of responsibility. For example, some journals require that authors disclose any substantial financial interests that might have biased their research assessment. Requiring investigators to divest themselves of investments that they may have made on the basis of their scientific judgment would be too burdensome, and might even suppress publication.)

Participant
A participant is any person:

- whose views, beliefs, behaviour, actions, condition, state of health or other characteristics the researcher proposes to study; or
- whose personal information the researcher proposes to collect or use; or

- who participates in a teaching, practical session or administrative activity that requires ethical clearance including subjects, clients, informants, students, staff, patients and deceased persons; or
- who is the subject of a creative work including painting sculpture, digital media depiction or audio recording.

Personal information
Personal information means any information about an individual who may be identifiable from the data once it has been recorded in some lasting and usable format, or from any completed research. It includes visual and/or audio representations of the person in the form of pictures, sculptures, photos, video recordings, audio recordings and our digital media depictions.

Professional practice
In this policy professional practice covers those activities that enable staff and students to practise their craft on human subjects or using human tissue, in order to:
- develop their skills and competencies;
- maintain their professional practice; or
- instruct students in the course of teaching.

Research
Research in this policy means any intellectually controlled investigation or creative work which leads to advances in knowledge or professional practice involving human participants or human tissue conducted by any student or employee of WelTec while in the course of their study or employment with the Institute. It includes:
- research projects conducted by staff;
- student research projects that are part of course requirements;
- surveys or questionnaires undertaken by the Institute administration or student services concerning organisational practices;
- research projects undertaken by an outside agency conducted within the precincts of the Institute; or
- research projects conducted by an outside agency at the request or under the auspices of the Institution.

It does not include the analysis of data collected elsewhere.

Teaching
Teaching includes any teaching activity undertaken by any employee of the WelTec while in the course of employment with the Institution.

Vulnerable participants
Vulnerable participants are those with diminished autonomy and include children, minors, prisoners, mentally infirm or unconscious persons and deceased persons and their next of kin,

2.0 Links

This Policy links to:
- 9.1 Innovation and Research Policy
- 9.3 Animal Ethics Policy

- 9.4 Internal Funding of Research
- Academic Quality Standard 11 – Research,
- Annual Programme Reports
- Health Research Council (HRC) Act 1990,
- Human Tissue Act 1964,
- Accident Rehabilitation and Compensation Insurance Act 1992,
- Privacy Act 1993,
- Human Rights Act 1993.

3.0 Policy principles and guidelines

3.1 Ethical Principles

Any research or professional practice activity (including teaching) must be evaluated to ensure that it complies with the ethical principles outlined below.

Respect for the inherent dignity and the rights of persons

Individuals should be respected, treated as autonomous agents and people with diminished autonomy are entitled to protection. Respect is embodied in the practice of gaining informed consent for any procedure/practice involving the person and the commitment not to use the person only as a means to an end. Activities involving participants with diminished autonomy are at particular risk and require people to take special care.

Respect for privacy and confidentiality

Participants' personal information and privacy must be protected at all stages of a research project/activity unless the participant has given a prior written consent for disclosure. Researchers/professional practitioners must conform to the requirements of the Privacy Act 1993 and any applicable code of practice that the Privacy Commissioner has issued under the Act (such as the Health Information Privacy Code 1994). In particular, researchers/professional practitioners should:

- note that it is preferable to collect personal information directly from the individual concerned;
- take steps to ensure that participants know that the researcher/professional practitioner is collecting information, why he or she is collecting it, who will receive the information, and what consequences there are, if any, of not supplying the information;
- ensure participants know of their rights of access to and correction of personal information;
- ensure that they collect only that personal information which is relevant, accurate, up to date, complete, and not misleading;
- keep personal information secure and for only as long as is required, but, if it constitutes original data for the purposes of a research project, for at least five years;
- use personal information only for the purpose for which they acquired it, unless they obtain the authorisation of the individuals concerned.

Personal information, for the purposes of this policy, also includes photographs, voice recordings and visual records, recordings and representations of the person involved.

Beneficence

Ethical practice carries with it obligations to carry out activities involving human subjects in a manner that maximises possible benefits and minimises possible harm. (The obligation to do no harm is referred to as non-maleficence.) Harm, in this context, extends beyond physical harm to a wide range of psychological or emotional distress, discomfort, exposure to illegal acts such as pornography or drug use, and economic or social disadvantage. Researchers and professional practitioners exercise beneficence in assessing the risks of harm and potential benefits to participants, in being sensitive to the rights and interests of people involved in their activities and in reflecting on the social, moral and cultural implications of their work.

Informed consent
Participation of humans in research projects, creative work or professional practice activities must be voluntary and obtained through informed consent. Consent must be obtained without duress, undue influence, or disproportionate financial inducements. Consent in writing is mandatory, except in minimally intrusive research (eg questionnaires eliciting non-personal information).

Where the participant can understand his or her interests, the researcher, teacher or administrator must seek the individual's informed consent. Where a participant is not competent to give consent, the researcher, teacher or administrator must seek proxy consent from a person legally representing the person's interests. In any activity involving children, the researcher, teacher or administrator must obtain the consent of the child's legal guardian. Where either the child or the legal guardian declines consent, the child is not able participate in the project/activity. The person's decision not to participate has priority over any other valid proxy consent (e.g., by legal guardians or representatives).

Social Justice
Questions of social justice arise when the people likely to receive the benefits of research/professional activity are not the same as those who bear its burdens. In an educational institution, researchers/professional practitioners should recognise the potential for injustice where some groups are regularly selected as research subjects because of convenience and without regard to the frequency of research with those populations or to whom the benefits of the research flow. Questions of justice can also arise in relation to the use of public funds for research.

Avoidance of unnecessary deception
Deception of participants in projects/activities is justified only where the impact of the deception on the participant is minimal, the potential knowledge to be gained is significant, and no less deceptive means are reasonably available. Wherever possible, projects or exercises involving a measure of deception:

- must incorporate an appropriate debriefing of the participants at the end of the project/activity.
- must provide the participants with an explanation of the goals and procedures of the project/activity from the researcher/professional practitioner.
- must ensure that staff are available to provide appropriate support if required after participants have taken part in the project/activity should any stress, harm or other concerns arise.

Conflict of interest
Generally, researchers/professional practitioners must avoid any project that puts them in a position where their activities as a researcher, clinician, teacher or administrator might come in conflict with their interests as a professional or private individual, for example, research involving students the teach or staff they work with. Applicants must explain to the Ethics Committee the nature of any potential conflict, and what actions if any they propose to take to minimise, avoid or resolve the conflict.

Cultural and social sensitivity
Researchers, teachers and administrators must ensure that their actions are appropriately sensitive to participants' cultural, moral and social frameworks including age, gender, religion and social class. Researchers must discuss any issues relating to Māori cultural and ethical values by consultation with the whānau, hapū or iwi concerned and the Chief Executive Officer or her or his nominee.

3.2 Policy Guidelines

Ethical approval
Proposals for any research, teaching or administrative activity at WelTec which:

- involves individuals or groups as the subject of experimentation, creative work or study;
- involves human tissue or samples; or
- otherwise concerns individuals' personal information, rights and freedoms

must have ethical approval. An approved Research Proposal Approval form is attached as Appendix 3.

All projects will be assessed as either high or low risk by the researcher/practitioner and approval will be acquired using approved processes.

A Self Assessment form to assist researchers determining whether their project is high or low risk is attached as Appendix 2.

An activity classified as high risk must be approved by either:

- WelTec's Human Ethics Committee; or
- The Ethics Committee of another institution; or
- An Ethics Committee approved by the Health Research Council; or
- The Director General of Health.

Where approval has been obtained from a source outside of WelTec, a copy of the approval given by that other committee must be given to WelTec's Human Ethics Committee and approval confirmed before the project/session commences.

An activity classified as low risk may be approved by:

- A Senior Manager/Executive Dean; or
- A Faculty Research Committee; or
- WelTec's Human Ethics Committee.

Where there is any doubt as to whether the project is high risk or low risk, it will be treated as a high risk project and be considered by the WelTec Human Ethics Committee.

Any applicant may refer any proposal assessed as low risk to the WelTec Human Ethics Committee for its consideration and approval. If an applicant is unsure whether their application is classified as high or low risk they should submit the application to the WelTec Ethics Committee for consideration and approval.

In determining whether the proposed activity is ethical, regardless of whether it is low risk or high risk, an assessment should be made as to whether:

- the proposed methodology is robust, intellectually and/or academically sound and the proposal has merit;
- there is a process in place to enable participants to give their informed consent free from any form of coercion;
- the proposal adequately protects participants' rights of privacy and confidentiality;
- the procedures used ensure the risk of harm to participants is minimised;
- there are steps in place to ensure vulnerable participants are especially cared for;
- the limits of and justification for any deception or potentially illegal activity proposed is stated;
- appropriately qualified supervision will take place and where appropriate, describes how it will occur;
- any steps taken to avoid or deal with any real or potential conflict of interest are adequate;
- the process for respecting different cultures, values, worldviews and beliefs of participants are adequate; and
- the activity give adequate effect to the principles of the Treaty of Waitangi.

Proposals that are turned down by a Senior Manager/Executive Dean may be resubmitted to the WelTec Human Ethics Committee for approval.

Every Faculty/Business Unit that considers proposals under this policy must report its decisions, as soon as they have been made, to the Director Strategy and Performance or his or her nominee.

WelTec Human Ethics Committee

WelTec will maintain a Human Ethics Committee as a subcommittee of its Academic Board. The terms of reference and membership of this committee is attached as Appendix 4.

High risk activities

Any research, creative work, teaching or administration proposal that involves any of the activities listed below is classed as high risk and requires Ethics Committee approval:

- Any project using personal depictions/representations, or collecting personal information or any information about an individual who may be identifiable from the data/depiction once it has been recorded in some lasting and usable format, or from any completed research/creative work;
- Any project involving the taking or handling of any form of tissue or fluid sample from humans or cadavers;

- Any project that has the potential to cause any form of physical or psychological stress;
- Any situation which might place the safety of participants or researchers at any risk;
- Any project involving the administration or restriction of food, fluid or a drug to a participant; ·
- Any project with a potential conflict between the applicant's activities as a researcher, teacher, professional practitioner or administrator and their interests or role as a professional, tutor or private individual; ·
- Any project that involves the participation of minors or other vulnerable individuals;
- Any project that includes any form of deception or potentially illegal activity, which might threaten an individual's emotional, physical or psychological well-being.

Low risk activities

If a proposal does not involve high risk activities, it is classified as low risk and may be approved by a Faculty Research Committee or Senior Manager/Executive using the principles set out in this document.

Processes that Faculties/Business Units establish for this purpose must ensure that only persons with an appropriate degree of independence and expertise evaluate proposals.

Approval of teaching activities that have ethical considerations

Before the first offering of any teaching, research, creative work or professional practice activity involving human subjects that is routinely undertaken as part of a course of instruction, ethical approval must be obtained as appropriate.

A further approval is required every three years from the date the activity first received approval or if the procedures change from those originally approved.

In cases where a taught course requires each of the students to undertake a research project/ activity of a particular generic type which involves human participants, the School/Faculty may submit to the WelTec Human Ethics Committee a single proposal seeking ethical approval for the generic project/activity.

Once approved, such generic projects/activities are regarded as repeated teaching activities and the approval is for three years providing no substantive change is made to the protocol in the interim.

Individual student examples of the generic project may be considered and approved at School level by a Head of School during the three-year period, providing they fall clearly within the parameters of the generic approval and are reported to the Committee using the standard Reporting Sheet.

Exempt proposals

Proposals involving existing publicly available documents or data (for example, analysis of archival records which are publicly available) do not require approval under this policy, unless they are classified as high or low risk.

Staff undertaking degrees at other institutions
Staff, under this policy, must ensure they get ethical approval, when required, for all research, creative work, teaching or administration undertaken as part of their course of study when enrolled at another tertiary institution if there is any possibility of attributing work completed to WelTec. Under most circumstances this attribution will be able to be made.

If ethical approval is obtained from another tertiary institution, a copy of any decision must be sent to the WelTec Human Ethics Committee before the research, creative work, teaching or administration exercise begins.

Ethical approval must be obtained from WelTec for all activities conducted that use WelTec staff or students or their information.

Remuneration
Reimbursement for participants' out-of pocket expenses, time, and any discomfort or inconvenience is permissible, only to the extent that this constitutes recompense.

The following types of remuneration are not permitted:

- Remuneration, which might operate to induce participation of persons whose circumstances disqualify them from participation in the research.
- Remuneration, which, in the circumstances, discriminates improperly between participants and non-participants.
- Remuneration, which discriminates improperly between different participants or different classes of participants. ("Improper" in these circumstances means discrimination on irrelevant grounds such as a remuneration unrelated to the contribution made through participation. Giving participants preferential access to programmes, treatment, or resources would constitute improper discrimination as would discrimination on any of the prohibited grounds set out in the Human Rights Act 1993.)

Where a participant withdraws from a project after it has begun, he or she may receive a payment proportional to his or her participation. A participant who withdraws from a research project, teaching or administrative activity must in no way suffer any disadvantage consequent on withdrawal.

Compensation for injury or harm
Any proposal, which might expose participants to risk of physical or mental harm, requires adequate provision for compensating participants in the event that harm occurs. In order for participants to give informed consent to participate, they must be aware of the arrangements that have been made to compensate them in the event of injury.

WelTec's Human Ethics Committee will not approve any proposed activity where the applicant proposes compensation arrangements, which in total are less than those that the Accident Rehabilitation and Compensation Insurance Corporation would provide if the injury occurred in circumstances not related to teaching or research.

Where a proposal qualifies as a clinical trial which is excluded from the coverage of the Accident Rehabilitation and Compensation Insurance Act 1992 (that is, where the trial is conducted principally for the benefit of the manufacturer or distributor of the medicine or item to which the trial relates), the applicant must:

- detail for which events and at what level the manufacturer of the medicine or item sponsoring the trial will provide compensation to any participant in the event of the participant suffering harm in the course of, or as a result of, participation in the trial;
- identify what other liability, if any, the Institute might face as a result of a participant suffering harm in the course of, or as a result of, participation in the trial;
- provide a clear statement in the Information Sheet and in the Consent Form explaining that the participant is not covered by ACC, and explain what level of compensation the sponsor will provide and for which events, what level of compensation the Institute will provide and for which events, and which risks the participant must carry personally, in order that a participant knows exactly under which circumstances and with what risk he or she might participate in the trial.

WelTec's Human Ethics Committee will only give final approval for clinical trials to be conducted principally for the benefit of a manufacturer or distributor of a medicine or item after the Chief Executive Officer or her or his nominee has agreed that the proposed compensation to be made available to participants in the event of harm is satisfactory.

Where the proposal is a clinical trial but is not excluded from the coverage of the Accident Rehabilitation and Compensation Insurance Act 1992 (because it is not conducted principally for the benefit of a manufacturer or distributor of a medicine or item), the applicant must:

- identify what liability, if any, the Institute might face as a result of a participant suffering harm in the course of, or as a result of, participation in the trial;
- provide a clear statement in the Information Sheet and in the Consent Form explaining the limited extent of ACC cover,
- explain what level of compensation the Institute will provide and for which events, and which risks the participant must carry personally, in order that a participant knows exactly under which circumstances and with what risk he or she might participate in the trial.

Allegations of Ethical Misconduct in research, teaching or administration

Allegations of Ethical Misconduct may be applied to any form of research, creative work, teaching or administration conducted under the auspices of WelTec. All allegations should be addressed to the Chief Executive Officer in writing.

Annual reporting

All ethical approvals given at a Faculty level must be reported to the Human Ethics Committee at least annually and a report of all ethical approvals must be provided to the Academic Board annually. A form to be used for this purpose is attached as Appendix 5.

4.0 Application

This policy applies to all staff and students of WelTec involved in research or professional practice activities involving the use of human subjects.

5.0 Statement of Responsibility

- All staff of the Institute are responsible for complying with this policy.
- Academic staff are responsible for supervising students engaged in activities with human ethics implications
- Senior Managers/Executive Deans are responsible for considering and approving proposal applications not requiring approval of the Institute's Human Ethics Committee.
- The Chief Executive is responsible for considering complaints and/or allegations of Ethical Misconduct.
- The Chief Executive is responsible for agreeing proposals for compensation as they arise.

To assure compliance with these principles and policies, WelTec's Human Ethics Committee will:

- require all Senior Managers/Executive Deans to complete and return an annual survey of proposals requiring ethical approval;
- require details of any Faculty procedures, including Faculty Research committees, for the consideration of proposals involving ethical matters;
- ensure that the memorandum which accompanies the request for the annual survey contains a summary of this policy so that Senior Managers/Executive Deans will be reminded of current procedures on an annual basis;
- audit Faculty/Business Unit ethics procedures; and
- audit projects for compliance with this policy and the terms of the approval given by the Ethics Committee or the Business Unit/Faculty ethics process.

6.0 Evaluation

Internal Audit/Quality Assurance will audit Compliance against this policy as part of their annual audit plan.

7.0 Review

This policy will be reviewed from time to time as legislation or organisation direction dictates.

8.0 Appendices

Appendix 1 – Procedures
Appendix 2 – Self-assessment Checklist for Ethical Approval

Appendix 3 – Application for Ethics Committee Approval for Research, Teaching or Administration Activity
Appendix 4 – Terms of Reference for the Ethics Committee
Appendix 5 – Annual Reporting Form

Appendix 1 – Procedures

Assessing proposals

Before commencing any research, teaching or professional practice activity involving human participants, the person responsible for undertaking or overseeing the activity should complete the proposal form in Appendix 2 and the self-assessment checklist attached as Appendix 1 to determine whether:

- Ethical approval is required
- Ethical approval should be sought from the ~~Head of School/~~Senior Manager/Executive Dean of their work area; or
- Ethical approval from the WelTec Human Ethics Committee is required.

If the activity requires approval from the ~~Head of School/~~Senior Manager/Executive Dean, the applicant should submit the application form contained in Appendix 2 to the ~~Head of School/~~Senior Manager/Executive Dean for approval.

If the activity requires approval of the WelTec Human Ethics Committee, the applicant should complete the application form contained in Appendix 3 and submit it to the ~~Academic Director~~Director Strategy and Performance or his/her nominee.

Informed consent

The method used to gain informed consent must be included in any proposal. The information provided to gain the consent of the participant must: ·

- be adequate and appropriate, using language that prospective participants can understand.
- describe any attendant discomforts or material risk.
- explain the purpose of the research, teaching or administrative exercise and include a description of any benefits that the researcher expects.
- disclose all financial implications for participants including payment of expenses or fees, and explain all compensation or indemnity arrangements.
- include an offer to answer any questions and the name, Institute phone number, e-mail and fax addresses (as applicable) of the person from whom further information can be obtained during the course of the research, and a summary of the results when the project is complete. ·
- include an offer of assistance in case of distress, and provide contact details.

There must be a statement to the effect that: potential participants who decline to participate will suffer no adverse effect; participants are free to withdraw their consent and discontinue participation in the research, teaching or administrative activity at any time without disadvantage.

Ethical Approval by ~~Heads of School/~~Senior Managers/Executive Dean

A ~~Head of School,~~ Senior Manager//Executive Dean may either assess the proposal themselves, using the application form as a guide, against the ethical principles outlined in this policy, or establish a Faculty/Business Unit Ethics Committee to undertake this task.

If a Faculty/Business Unit Ethics Committee is established, terms of reference and a mode of operation must be developed. Care must be taken at all times to prevent potential or real conflicts of interest.

Faculty/Business Unit Ethics Committees must assess or have assessed the methodology of the proposal under consideration either directly or through obtaining knowledge elsewhere.

Where a Senior Manager/~~Head of School is~~Executive Dean is unable to adjudicate on a proposal, they may refer it to the WelTec Human Ethics Committee.

If an application is rejected by the ~~Head of School~~Senior Manager/Executive Dean or Faculty/Business Unit Ethics Committee, the applicant may apply to the WelTec Human Ethics Committee for approval using the form attached as Appendix 3.

For studies that carry no risk to participants and do not involve a significant intrusion on privacy, the provisions of these paragraphs may be relaxed.

Ethical Approval by Human Ethics Committee

The WelTec Human Ethics Committee meets monthly or as required to consider applications for ethical approval. Applications will only be considered if they are submitted on the approved application form and contain all the required information.

The WelTec Human Ethics Committee will interpret the signature of a ~~Head of School or a~~ Senior Manager/Executive Dean on the application form as an assurance that the methodology is sound. Where the ~~Head of School or~~ Senior Manager/Executive Dean is an applicant, this duty falls on an appropriate staff member designated by the Chief Executive Officer. The Ethics Committee may, however, seek independent verification of methodology or scientific validity.

Compliance with other standards

Research proposals must incorporate, where appropriate, the spirit of the Treaty of Waitangi. This means that all parties involved in the research project must respect the principles of partnership and sharing implicit in the Treaty.

Research proposals must also conform to any other relevant professional codes relating to research. Where there is any inconsistency between the Institute policy and a professional code, the researcher must advise the Committee of the inconsistency, and the Committee shall determine what is to apply.

Records and annual reporting of activities

School Research Coordinators should keep the signed-off application forms for all proposals put forward for ethical approval.

For proposals approved at ~~School-~~Faculty level, the ~~Head of School/~~Senior Manager/Executive Dean will forward the signed-off proposal (whether approved or declined) to the School Research Coordinator.

For proposals approved by the Human Ethics Committee, the ~~Academic~~ Director Strategy and Performance or his/her nominee will forward a copy of the Committee's decision to the School Research Coordinator who will maintain the School's records.

In February each year, the ~~Head of School/~~Exectve Dean/Senior Manager will prepare and submit a report, as part of the Annual ~~Academic~~ Self Assessment Report, to the Academic Board outlining the number of ethical proposals considered at School /Faculty and Institute level for the previous year. A report template to assist this reporting is attached as Appendix 5.

Appendix 2 – Self assessment checklist for Ethical Approval

Name of Project	
Name of person(s) undertaking project	
~~**Head of School/**~~ **Senior Manager/Executive Dean**	
Type of project[1]	

Criteria	Description	Proposal meets this criteria Y, N, N/A
Research or teaching merit	Does the proposal demonstrate the activity is well designed? Poor design and inadequate safeguards have implications for the safety of participants.	
Human tissue*	Does the activity involve taking any form of tissue or fluid sample from humans or cadavers	
Informed consent	Is there a process in place to obtain informed consent from participants?	
Confidentiality and privacy*	Are there adequate steps in place to protect the privacy and confidentiality of participants?	
Vulnerable participants*	Does the activity involve vulnerable participants? If yes, is there a process in place to either gain informed consent from their caregiver or and/or to protect their rights?	
Minimisation of harm*	Does the proposal have adequate processes in place to minimise potential harm, including physical or psychological stress to participants?	
Administration or restriction of food, fluid or drug*	Does the project involve administrating or restricting food, fluid or a drug to a participant? If so are adequate safeguards in place?	
Appropriately qualified supervision	Appropriately qualified personnel must supervise research, teaching or administration involving human participants.	
Deception*	Does the activity involve any form of deception? If yes, is this deception justifiable in the project design? Are there mechanisms in place to manage any unintended consequences of this deception?	
Conflict of interest*	Is there any real or potential conflict of interest between any person undertaking this activity?	
Social and cultural sensitivity	Are there mechanisms in place to recognise social and cultural difference in relation to the activity being undertaken?	

*** Proposals containing activities marked (*) must be referred to the WelTec Human Ethics Committee for approval**

[1] Is this a teaching activity, a research project, a professional practice activity or some other type of activity
~~* Activities marked (*) must be referred to the WelTec Human Ethics Committee for approval~~

Appendix 3 – Application for Approval of a Research Project or Teaching Activity Requiring Ethical Approval by WelTec's Ethics Committee

APPLICATION FOR APPROVAL OF A RESEARCH, PROJECT OR TEACHING ACTIVITY REQUIRING ETHICAL APPROVAL

Issued by: Academic Board
Date of issue:

Notes: 1. If you have already filled in a similar 'Application for Approval of Research Project' form for another tertiary institution **please attach it to this form**. There is no need to duplicate the information onto this form if it is included in the attached form.

Before preparing an application, please familiarise yourself with the Institute's Human Ethics Policy and (if applicable) specific codes relating to research in your discipline.

The Treaty of Waitangi section (section 2) must be completed in full. It is not sufficient to say that the Treaty will be complied with. Details of consultation with Māori must be given and the responses obtained as applications often have serious human ethical issues.

The sections of the application form should be lengthened or shortened to suit the information entered. It is helpful if applicants use a font different to the default font on the electronic application form as this helps to distinguish the applicant's entries from the standard headings and guideline notes which appear throughout the application form.

Please use language, which is, as far as possible, free from jargon and is comprehensible to lay-people.

Please ensure your Consent Form and Information Sheet have been carefully proof-read, the institution as a whole is likely to be judged by them.

Please send the completed application to the ~~Academic Director~~Director Strategy and Performance or his/her nominee.

Proposed research teaching or administration for:	
Project title:	
Research, Teaching or Administration:	
School:	
Supervisor (if known and applicable):	
Proposed starting date:	
Proposed completion date:	
Proposed source of funding if applicable:	
Comment on independence of the research teaching or administration if relevant:	
Is the research teaching or administration consistent with the Treaty of Waitangi? (See Section 2	☐ **YES** ☐ **NO**
Is this application for a repeated teaching exercise?	☐ **YES** ☐ **NO**

SECTION 1 – GENERAL

(a) Objectives of the project (briefly outline)
(b) Method of data collection (attach interview or survey questions or tests to be presented to subject)

(c) Benefits and scientific value of the project
(d) Characteristics of the subjects (participants)
(e) Method of recruitment (give details of any inducements offered)

(f) Payments that are to be made/expenses to be reimbursed to subjects
(g) Other assistance that is to be given to subjects (e.g. meals, transport)
(h) How informed consent is to be obtained (include a copy of any consent form and information sheet that is to be used. They should be separate documents). Refer to your Ethics Committee Guidelines.

(i) How issues of confidentiality are to be dealt with if the research is to be conducted on an anonymous basis. Refer to your Ethics Committee Guidelines.
(j) Procedure for the storage of access to and destruction of data, both during and at the conclusion of the research. Refer to your Ethics Committee Guidelines.
(k) Feedback procedures

(l) Reporting and publication of results
(m) Qualifications this research, teaching or administration may contribute to (if any)

(n) Potential Problems: Explain whether there will be harm or discomfort to participants, medical or legal problems, or problems of community relations or controversy, or whether any conflicts of interest might arise. Researchers also have an obligation to be available after participants have participated in the project, should any stress, harm, or related concerns arise. Participants normally should have the opportunity to obtain information relating to the outcome of the project if they wish.

SECTION 2 – TREATY OF WAITANGI

Indicate how the research proposal is consistent with the Treaty of Waitangi.

Note: *It is recommended you use the relevant section of your **Ethics Committee Guidelines** as a guide to the type of information the Ethics Committee is seeking.*

Printed Name and Signature of Researcher:	
Date:	

Signature of ~~Head of School /~~Senior Manager /Executive Dean **Approving Research:**	
Date:	

Signature of Chairperson of Ethics Committee:	
Date:	

Approved/Declined subject to the following conditions:

Please check:
Applicant - that the application is in the name of an Institute staff member and not, for example, a student researcher.

Font - that a font has been used which is different to that used for the information and guidance already provided in the template by the Human Ethics Committee
Signatures - that the appropriate signatures are in sections 19 and 20.

Data storage and disposal - that in section (j) you state clearly the details of the secure storage of the data (normally within a Institute School) and who will be responsible for the eventual disposal of the data (which must normally be kept for at least 5 years. An appropriate member of the Institute staff should normally be responsible for the eventual disposal of data - not a student researcher.) If the data is to be stored other than within a Institute School a detailed justification for this is given.

Questionnaires - that any questionnaire to be used in the project is attached to the application

Information Sheet / Consent Form - that these are attached and that the language and style used is appropriate to the age and knowledge of the likely readers; detailed justification for this is included in the main application); both forms conclude (in anticipation of approval) with the statement “This project has been reviewed and approved by the Ethics Committee of the Wellington Institute of Technology”; and that they have been carefully proof-read;

Stapled as one document - that all components of each copy of the application are stapled together with one staple. Thee copies should be sent to the current chair of the Ethics Committee and a copy to your Head of School and the ~~Academic~~ Director Strategy and Perfromance.

Appendix 4 – Terms of Reference for the WelTec Human Ethics Committee

1. Purpose

The primary objective of the Committee is to ensure all research within the Institution or under the auspices of the Institution, which involves human participants or the use of personal information is carried out in accordance with the institution's ethics policy.

3. Objectives and Scope

The objective of the Committee is to:

- Consider, and where appropriate approve, research proposals forwarded to the Committee in accordance with the applicable ethics/research policy of the institution from which the research proposal emanates;
- Recognise or note approvals granted by other properly accredited ethics committees;
- Consider any ethical issues relating to the involvement of human participants in research or teaching referred to it by any member of the Institution;
- Ensure that research is carried out in accordance with the principles of the Treaty of Waitangi and other recognised professional guidelines/codes of practice relating to research.
- When requested by the Institution, make recommendations on ethical practices and policy issues;
- Report annually to the **Chief Executives and Academic Board** of the Institution.
- Provision of ethical advice on other teaching and administration activities referred to the Committee.

4. Membership

The Committee shall comprise six members. In choosing Committee members, the Institution may take into account the following factors:

- gender balance;
- a diversity of knowledge and experience in ethics, law, health sciences, research design and tikanga Maori;
- personal qualities.

The following categories of members are appointed for two (2) year terms:

- An independent chairperson jointly appointed by the Chief Executive. If the Chairperson is absent at a meeting, the Committee members present may elect one of its members to chair that meeting.
- An Academic Board representative.
- Two independent members appointed by the Chief Executive.
- Two Maori representatives appointed by the Chief.
- One Executive Dean

An Executive Secretary to the Committee appointed by the Chief Executive, after consultation with the Chairperson of the Committee, for a renewable one (1) year term to carry out the following functions:

- Receive and collate research proposals and other documentation to be considered by the Committee.
- Prepare agendas and give notice of Committee meetings to members.
- Take minutes of Committee meetings and communicate to researchers and individuals the Committee's decisions or recommendations on their proposal or issue.
- Provide administrative services to the Committee including paying fees, travel and incidental expenses, arranging venues and refreshments, maintaining Committee records, preparing reports and all other incidental matters.

A membership of the Committee may end or be terminated in the following circumstances:

- On expiry of the member's term of office unless renewed in writing for a further two (2) year term by the body/person who has the authority to make the appointment.
- By the member resigning in writing and communicating this to the Executive Secretary.
- If the member is a institution representative and he/she has left the employment of the institution.
- If a member fails to attend three consecutive meetings without offering their prior apology.
- For cause, by the Chief Executive, if in their opinion the member:
    1. Has become medically or mentally incapacitated and unable to perform his/her duties properly for three (3) consecutive meetings.
    2. Fails to disclose a conflict of interest and fails to withdraw from the meeting at which the matter giving rise to the conflict of interest is being considered.
    3. Is convicted of any offence involving dishonesty or any other serious offence, which could bring the Committee into disrepute.
    4. Is declared bankrupt.

The Executive Secretary shall advise a member if their term of office has expired or has been terminated.

Where a member's term has expired or been terminated, they may be replaced by the same process used to appoint them.

5. Meetings

The Committee will meet monthly (if required) at dates and venues to be advised by the Executive Secretary from time to time.

The Executive Secretary, after consultation with the Chairperson, will be responsible for calling meetings as required and may call additional meetings if needed.

A quorum for the purposes of considering proposals shall be four (4) members of whom at least two (2) must be Institution representatives and two (2) independent members.

In limited circumstances, a fast track process for research proposals requiring urgent approval may be used (see paragraph 7).

6. Powers and Procedures of the Committee

Approval

- No research or activity set out in a proposal referred to the Committee under paragraph 1 of these Terms of Reference and in accordance with the ethics policy of the Institution may begin until the Committee approves the proposal and notifies the applicant in writing.
- If another recognised and accredited Ethics Committee has approved the proposal, the Committee may, at its discretion, recognise the approval without separately considering the application. However, the applicant must provide the Committee with a copy of the proposal and a copy of its approval from the other Ethics Committee.

Method of Application

- The Committee will consider proposals at its scheduled meetings.
- Applications for approval must be fully and correctly presented on the Committee's standard application form.
- The Committee will treat the signature of the relevant Head of School as an assurance that the proposal is soundly based.

7. Decisions

The Committee may seek expert advice as it requires on any proposal.

The Committee may approve only those proposals which comply with the general ethical principles and policy criteria.

Where a proposal does not comply with the general ethical principles and policy criteria, the Committee may:

- Provisionally approve a proposal subject to changes made to the Committee's satisfaction. The Committee will give reasons to the applicant for the changes it requires. The Committee may delegate the responsibility to give final approval on behalf of the Committee to the chairperson after the researcher has made the required amendments.
- Decline a proposal. If it does this, the Committee will give reasons to the researcher.
- There are no appeals from the decisions of the Committee but the Committee is always prepared to re-examine a decision in light of further material being presented to it.

Where a Committee member has a proposal before the Committee or has a conflict of interest whereby his/her impartiality could be questioned, then they must withdraw from the Committee whilst that proposal or matter is being considered.

A researcher may request fast track consideration of a proposal where he or she can give valid reasons in writing for the need for urgency, and the commencement of the research project would be unnecessarily delayed if it had to wait until the next scheduled meeting.

At the discretion of the Chairperson, the Committee may consider proposals using the following “fast track” process.

Proposals will be posted, faxed or emailed to Committee members.

Members will be asked to consider the proposal and either approve (provisionally or otherwise) or decline the proposal.

A proposal using the “fast track” process must be approved in writing by a minimum of four (4) Committee members.

Any member may object to the “fast track” process being used, in which case the proposal will be referred to the next scheduled meeting for consideration.

The Executive Secretary will report the result of the use of the “fast track” process at its next scheduled meeting and will also keep details of all occasions on which this process is used and include this in the Committee’s annual report to the Chief Executive and Academic Board.

If a material change is made to a proposal, the researcher(s), or the human participants, the applicant must seek further approval from the Committee. Applicants are responsible for informing the Committee if any of these changes occur.

Appendix 5 – Annual Reporting Form

To be Submitted to Academic Board as part of the Annual Academic Report.

School Name	
Senior Manager	
Reporting year	
Number of Research Proposals considered at a School level	
Number of Teaching/Professional practice Proposals considered at a School level	
Number of Research Proposals approved at a School level	
Number of Teaching /Professional practice Proposals approved at a School level	
Number of Research Proposals declined at a School level	
Number of Teaching/Professional practice Proposals declined at a School level	
Number of Research Proposals referred to WelTec Human Ethics Committee	
Number of Research Proposals approved by the WelTec Human Ethics Committee	
Number of Research Proposals declined by WelTec Human Ethics Committee	
Number of Teaching/Professional practice Proposals referred to WelTec Human Ethics Committee	
Number of Teaching/Professional practice Proposals approved by the WelTec Human Ethics Committee	
Number of Teaching/Professional practice Proposals declined by WelTec Human Ethics Committee	
Issues arising	
Comments	
Signature of School Research Coordinator	
Signature of Head of School/Senior Manager	