

Principles and Procedures: Human Ethics in Research

Category:	Research	Policy Number:	AB9 - 3/96 (B)
Title:	Human Ethics in Research	Date approved:	6 August 1996
Prepared by:	Research and Development Manager	Date of Last Revision:	August 2010
Authorised by:	Academic Board	Date for review:	August 2011

Section A – Principles and Procedures

1.0 General Ethical Principles for Guiding Research

The human rights that require protection in research include the right to self-determination; informed consent; confidentiality; anonymity; beneficence; non-maleficence; fair treatment; truthfulness and integrity; justice; retention of data; debriefing; validation of research; ownership of data and have harmful effects addressed.

Self-determination

This principle upholds the freedom of each person to make autonomous decisions. Refusal to participate in research must not result in adverse consequences for potential research participants.

Informed Consent

Consent is voluntary and informed if the intended participant understands the benefits of the research, agrees without coercion to participate and has been provided with an explanation in terms the participant understands, including:

- the nature and purpose of the activities
- potential harmful consequences of taking part in the research
- participants' rights include the right to:
 - decline to participate,
 - withdraw from the research at any time without penalty of any sort,
 - privacy and confidentiality,
 - negotiate the amendment and review of contributions and their ownership,
 - be offered an opportunity to debrief if necessary during or on conclusion of participation,
 - receive feedback about the outcome of the activity in an appropriate form.

Confidentiality

Research information should be handled in a way, which protects the confidentiality of the participants and ensures the safe custody of the data. Care must be taken to protect the legitimate privacy of individuals, communities and institutions.

Anonymity

The findings should be conveyed in such a way that the participants cannot be identified as individuals, unless agreement to the contrary has been obtained from the participants. Participants must be informed of the potential harmful effects to others of disclosure of the participants' identity.

Beneficence and non-Maleficance

In planning specific research procedures and conducting both pilot and mainstream research, the researcher must ensure that the risk of cultural, social, physical, psychological, emotional and spiritual harm to participants is kept to an absolute minimum by:

- a detailed explanation of the specific risks for any given research procedure.
- due consideration of alternative procedures to ensure optimal benefit.
- determining whether monitoring and support procedures may be necessary both during and after the activities.

Fair treatment

Subject to the maintenance of confidentiality in respect of individuals, all participants should be fully informed about projects in which they are involved. Also, in conducting the research, the researcher must at all times respect the rights, wishes, beliefs, consent and freedom of the individual participant.

The principle of fair treatment also allows for volunteers to be compensated for the inconvenience and time spent, although such payment should not be so large as to be an inducement to participate.

Truthfulness and Integrity

Honesty in all dealings including issues such as conflict of interest, bias, plagiarism, hidden agendas, making and keeping commitments and generally being completely scrupulous in all research activities.

Justice

The ethical obligation to treat each person in accordance with what is equitable, moral and proper, and to give each person what is due to him or her. It also refers to the equitable distribution of both the burdens and the benefits of participation in the research.

Debriefing and Disclosure

Any data collection tool which uses less than full disclosure of the intention of the study prior to its use, places an obligation on the researcher to clarify fully the nature of the study and remove any misconceptions that may have arisen. The researcher has a responsibility to ensure there are no lasting negative consequences for the participant.

When communicating research findings, material should be presented in ways that are easily understood by participants.

Addressing Negative Consequences

Where procedures might result in undesirable consequences, the researcher has the responsibility to anticipate where possible and rectify any negative consequences that occur.

Retention of Data

The protection of confidentiality of participants and to ensure that credibility of the research data can be verified. Data may include transcripts of interviews, artefacts, documents and/or electronically stored data/information/records.

Participant reimbursement and compensation

Participants in research conducted under the auspices of WINTEC may be considered for reimbursement or compensation for actual expenses, provided they are reasonable.

2.0 Procedures

2.1 Procedures for Ethical Scrutiny

(see Appendix 1, Waikato Institute of Technology (Wintec) Human Ethics approval process)

2.1.1 The major role of the Human Ethics Research Committee (HERC) is to ensure that ethical standards for research undertaken at the Institute are met.

2.1.2 The Human Ethics in Research (HER) Policy requires all proposals be submitted to the HERC via the Research office for initial scrutiny.

2.1.3 The Research and Development Manager will distinguish between proposals with a human focus (eg research on human participants, health information, or human tissues) or human related focus (eg projects involving cultural artefacts). Human focus proposals will be scrutinised by the HERC. Human related proposals will be scrutinised and confirmed by the HERC Chairperson, in conjunction with the Research and Development Manager who will notify HERC of any decisions.

2.1.4 All proposals received by the Research and Development Manager will be circulated to all members of the HERC.

2.1.5 The Human Ethics Research (HER) policy requires that prior to submission of a research proposal researchers formally consider ethics, research processes and appropriate ethical and professional codes. Such consideration should take place in dialogue with colleagues, mentors and/or research supervisors with recognised experience in research processes and the subject content field.

2.1.6 Colleagues, mentors and/or research supervisors will be named in the research proposal.

2.1.7 The HERC will scrutinise proposals and discuss ethical issues in an open and informed manner having regard for the different research perspectives.

Conclusions by the Committee will denote whether each proposal is:

- approved,
- provisionally approved,
- approval deferred, or
- declined outright.

2.1.8 *Research approved by the Human Ethics in Research Committee.* Researcher/s will be notified formally of the HERC decision. Approved research places an obligation on researcher/s to fulfil their stated obligations whilst undertaking the research. Reference to fulfilment or changes to the obligations should be made by the researcher in the interim and final reports.

2.1.9 *Research provisionally approved*

Researcher/s will be notified formally of the HERC decision. Research can proceed subject to recommended revisions of the proposal or satisfactory answers being received.

2.1.10 *Approval Deferred*

Research must not proceed until the issues raised by the Committee have been addressed and resubmitted to the full satisfaction of the Committee. The Committee will give a full description of the outstanding issues to the researcher. Only after full approval has been given and appropriate resourcing has been secured can the research proceed.

2.1.11 *Declined Outright*

Researcher/s will be notified formally of the HERC decision. Research, which has been declined outright, must not proceed or be linked in any way with the Institute. The notification will include a right of appeal to Council or a second opinion can be sought from the University of Waikato Ethics committee. The Committee will give full justification for declining this research.

2.1.12 Proposals requiring ethics assessments of a clinical nature or which include implications for human physical health must be forwarded by the Research and Development Manager to the Northern Y Regional Ethics Committee or, where appropriate, another regionally based ethics committee if the research is being conducted outside the Waikato region. In such a case, the *National Application Form for Ethical Approval* must be completed; the Research and Development Manager should be contacted for this form and the *Guidelines for Completing the National Application Form for Ethical Approval*

2.2 Procedures for Ensuring the Confidentiality of Data

- 2.2.1 Confidential information must be stored in a safe place under secure conditions at all times. This procedure protects the confidentiality of the subjects and ensures the safe custody of the data. Care must be taken to protect the legitimate privacy of institutions, communities and ethnic groups.
- 2.2.2 Researchers should be aware that there is an ethical dimension to the formulation and publication of results. The researcher must remain sensitive to the possibility the research findings may be used out of context. Researchers where possible should always be wary of being cited out of context and try and ascertain the reasons for any individual or organisations wishing to do so.
- 2.2.3 Appropriate arrangements are needed to protect the physical security, collection, use, disclosure, storage and destruction of health information (refer Health Information Privacy Code 1994 and Privacy Act 1993. Privacy Commissioner Te Mana Matapono Matatapu: available at Research Connections). www.privacy.org.nz

2.3 Procedures for Appealing the Decisions of the Ethics Committee

- 2.3.1 *Complaint*
Complaints about the administration or decisions of the Human Ethics in Research Committee can be made to the Committee Chairperson or the Research Office. It is suggested that complaint be the first avenue of challenge in all cases, as many issues will be able to be resolved through this process.
- 2.3.2 *Second Opinion*
A second opinion may be requested at any stage of the application. The Wintec Human Ethics in Research Committee has an agreement with the University of Waikato Ethics Committee, whereby they will review any applications which require a second opinion. The UOW ethics committee would reconsider the application and deliver its opinion to the HERC. The HERC is then required to either agree with the UOW Ethics committee or explain why not. The final decision remains with the HERC.

3. Wintec Human Ethics in Research Committee (HERC)

3.1 Membership

The Ministry of Health (Manawa Hauora) Operational Standard for Ethics Committees, paragraph 176 states “the minimum number of members of a committee should be 10, including an external chairperson...”

- 3.1.1 HERC is a committee of the Wintec Council.
- 3.1.2 The Wintec Council will appoint the membership.
- 3.1.3 The Chair of the HERC will be an external member and be appointed by the Council for a period of three years.

A quorum of the HERC will be five members including the Chairperson or designated deputy and one external member.

The Research and Development Manager will be a member of the Committee.

3.1.4 Delegation of authority from the Chairperson

3.1.4.1 The Chair can delegate the responsibilities of the Chair as required.

3.1.4.2 Prior to any absence, the Chair will nominate a member of the Human Ethics in Research Committee (preferably an external member) to take responsibility for the Chairmanship while they are away.

- 3.1.5 Council will appoint membership from the staff of Wintec for a three (3) year term. At least two of these staff will have relevant research expertise.

Staff members can be re-appointed for no more than two (2) consecutive terms. A stand-down period of three years will apply

- 3.1.6 External Membership (non-staff members appointed by the Council) will consist of three external members who do not have affiliation with the organisation, and at least one of whom is Maori .

These external members will hold significant positions in the local community and may be experienced in research methodologies and ethical evaluation. External members (3) will be appointed for a three (3) year term. In establishing the Committee, terms will be staggered in order to ensure continuity.

External members can be re-appointed for no more than two (2) consecutive terms.

- Three external representatives (one who is Maori) and (one to be the Chair)
- Three staff members (internal members) representing research active schools.
- Two members who have Iwi affiliations
- Two additional staff members (internal) with research expertise
- Research and Development Manager

- Executive Officer (non-voting)

3.1 Terms of Reference

- 3.2.1 The Committee will receive research proposals referred to it for consideration.
- 3.2.2 The Committee will make written recommendations to the researcher(s). The Committee may offer appropriate advice to the researcher/s involved (see section 1.9 – 1.11). A member of the committee will be nominated to communicate directly with the researcher should any clarification be required.
- 3.2.3 The Executive Officer is responsible for convening the HERC and reporting on its activities to the Council, Faculty Research Sub-Committees and Research Committee as appropriate.
- 3.2.4 The members of the Committee will treat information submitted in the proposals in confidence. Standard Local Body Act protocols will apply to the disclosure of these minutes. (Local Government Official Information Act and the Official Information Act)
- 3.2.5 Members of the Committee will be required to declare any conflicts of interest.
- 3.2.6 The HERC will keep minutes of its meetings recording its review of ethical issues in research proposals.
- 3.2.7 A bi-annual training scheme for the Membership of the Human Ethics in Research Committee will be arranged and this will include:
- essential elements of ethical review
 - the Treaty of Waitangi and its application to ethical review
 - awareness of Maori culture, tikanga and health and research approaches
 - procedures and protocols for health research and innovative practice
 - overview of the health and disability sector and the research sector
 - consensus decision-making and group processes
 - the types of expert advice that may be needed
 - introduction to the principles of the Privacy Act 1993 and the Health Information Privacy Code 1994
 - individuals' rights under the Code of Health and Disability Services Consumers Rights 1996
 - awareness of the needs of specific cultural groups in each geographical area
(Refer Ministry of Health Operational Standard for Ethics Committees, March 2002.)

4.0 HERC Sub-committee

A Human Ethics in Research Sub-committee will be established in the following circumstances:

4.1 Student applications:

If there is a significant number of student applications the time to consider the applications may be extended. For practical purposes and to expedite the decision making process, a HERC sub-committee may be established

4.2 Applications approved with conditions:

HERC may approve an application with conditions. In these circumstances, the HERC sub-committee will follow-up with the applicant when:

- there is a query or queries relating to an application
- clarification is required on a certain aspect of the application, or
- additional information is required

Upon receipt of a satisfactory response or the requested information, the HERC Sub-committee will confirm the approval.

4.3 All applications and decisions made by the HERC sub-committee will be tabled as agenda items at the next formal Human Ethics Committee meeting for full Committee, and formal acceptance and noting.

4.4 The HERC Chair will nominate representatives on the sub-committee from the formal Committee. A minimum of three Committee members are required, one being the Chair.

5.0 Compliance Standards

5.1 All relevant human ethical issues are identified and thoroughly dealt with.

5.2 Any unresolved ethical issues are identified.

5.3 An informed colleague/mentor is identified for each researcher as part of the collegiality of the Institute's Research culture.

5.5 HERC will provide an annual report on its activities to the Council by March of each year.

6.0 Systems for Reporting

- 6.1 *Applications for Internal Research Funding.* All internal applications requiring ethical approval will be considered by the HERC.
- 6.2 *Applications for External Research Funding.* All external applications requiring ethical approval will be considered by HERC.
- 6.3 *Protocols for Maori Research.* All Researchers involved with Maori need to be reviewed via the policy on Protocols/Principles for conducting Research in a Maori Context (AB9-7/00).
- 6.4 *Applications for the Research Fund for Teaching (Non-Degree) and Corporate Staff.* The Research Manager will forward proposals to the HERC as appropriate.

Section B – Associated Information

1.0 Definitions

Ethics provide the guidelines and principles that uphold moral values. Researchers and reviewers of research have an ethical responsibility to recognise and protect the dignity, welfare, interests, and fundamental human rights of individuals and groups involved in or affected by the process and/or products of research. This ethical responsibility includes meeting the obligations embedded in the Treaty of Waitangi and the conduct of research via the Protocols/Principles for Conducting Research in a Maori Context (AB9-7/00)

Artefacts are defined for the purposes of this policy as effects such as photographs, cultural heirlooms and iwi taonga, oral and written records belonging to various whanau and hapu, human tissue by-products, as well as places considered sacred for cultural or religious purposes.

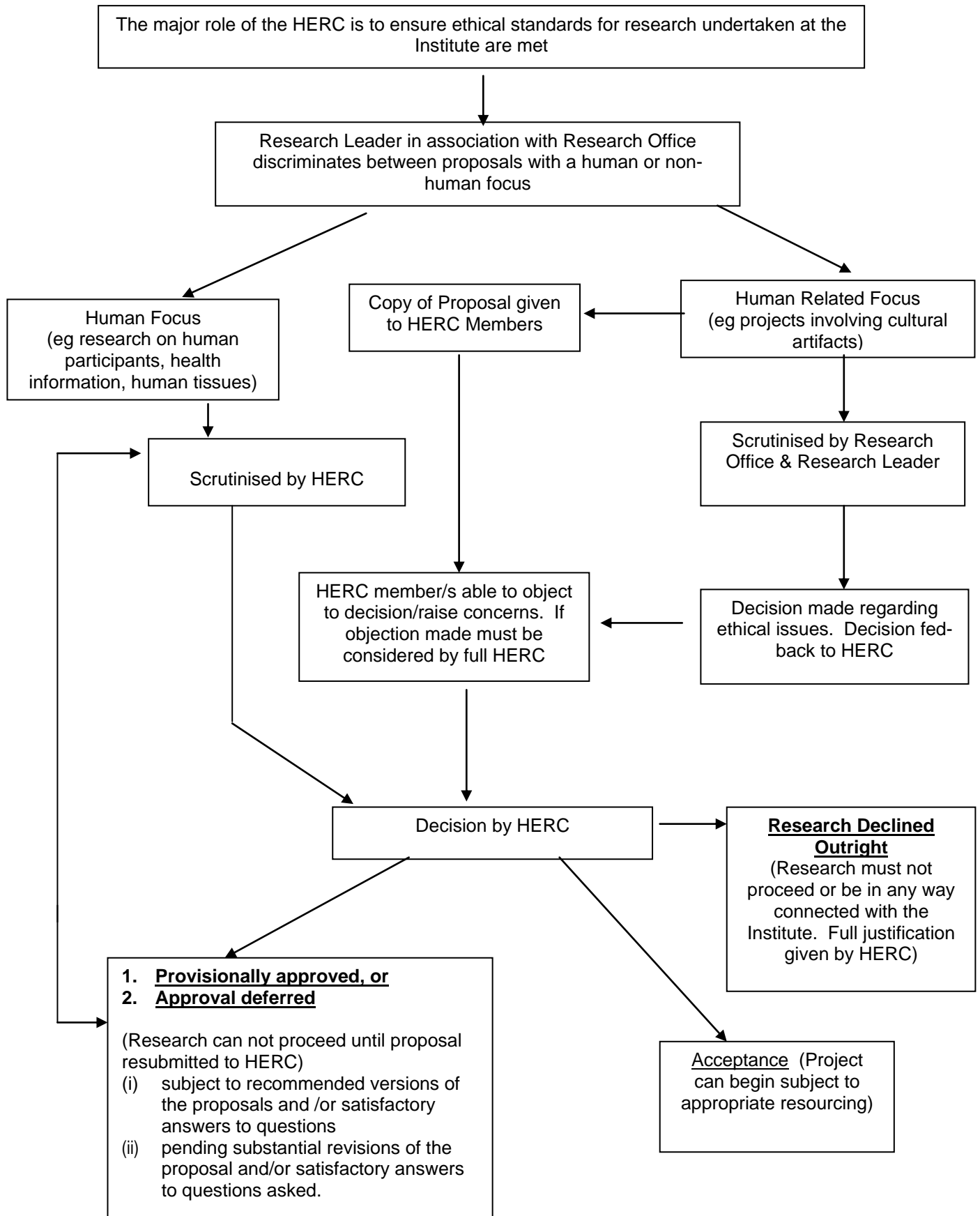
Researchers are, for the purposes of this policy, defined as all staff and students conducting research under the auspices of the Institute.

2.0 References

- 2.1 Intellectual Property considerations include ownership issues for data and research products and lawful access to data sets. Procedures and guidelines for intellectual property issues are dealt with in the Intellectual Property Policy and Procedures (EX-G-100).
- 2.2 All research must adhere to the procedures and policies embedded in the Treaty of Waitangi, please refer to the “Protocols/Principles for Conducting Research in a Maori Context (AB9-7/00)”.
- 2.3 All research requests involving staff and students at the Institute will be governed by the policy entitled “Conducting Research Involving the Institute’s staff and/or students (AB9-5/00)”.
- 2.4 All research involving the manipulation of animals will be conducted under the auspices of the Animal Welfare Act 1999, and the Animal Ethics in Research Policy (AB9-6/98).
- 2.5 All external research applications requiring approval shall adhere to the consolidated Research Policy.

Section C - Process

Appendix 1: Flowchart of Approval Process for Human Ethics in Research Policy



Appendix 2:

Ethics Checklist for Researchers

- Wintec HER Policy has been read?
- The human ethical implications have been identified?
- The ethical considerations and the need for confidentiality have been discussed with an informed colleague/mentor?
- The issues surrounding anonymity have been examined?
- Assistance has been sought in clarifying ethical issues which are unclear?
- A draft questionnaire or other instrument has been included with the research proposal?
- Has a clear English statement been produced describing the research for participants?
- The ways of dealing with the ethical implications of the research are appropriate?

The application form and examples of information sheets and consent forms are held on the Research Office Website under [Human Ethics](#).

Please forward one signed copy and one electronic copy of your completed application to the Research Office, W Block, e-mail research@wintec.ac.nz.

Refer Part A (Policy)