Otago Polytechnic

Guidelines on Ethical Practices in Research

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Purpose

Educational establishments in New Zealand highly prize academic freedom as guaranteed in the Education Act 1989.

Otago Polytechnic recognises that freedom to engage in research is a necessary precursor to good educational practice. Educational freedom, however, attracts certain responsibilities under the Act, one of which is an assurance that educational institutions conduct research to the highest ethical standards. In this sense, the activities of educational institutions can expect to be subjected to public scrutiny. Under scrutiny, it must be possible to demonstrate highest ethical standards.

Otago Polytechnic is aware of its responsibility for ensuring that the privacy, safety, health, social sensitivities and welfare of research participants, staff and students are adequately protected. To this end a Research Ethics Committee has been established to review and approve the adequacy of protection for all human participants in research projects. The purpose of the Research Ethics Committee is to:

- Provide assurance of safety to participants that their rights have been considered and respected, including establishing informed consent, confidentiality and the storage and use of data.
- Advise and protect researchers regarding their rights and duties.
- Protect those who may be affected by research results or outcomes.
- Ensure methodologies are appropriate and representative, for example so that participant's time is not wasted.

It is the policy of the Institution that all staff or student projects which involve human participants must receive the approval of the Otago Polytechnic Research Ethics Committee prior to commencement.

This guideline has the purpose of setting out and promoting best ethical practices in research and has the intention of meeting the requirements of the Education Act 1989. It sets out the principles and procedures to be used for the determination of whether research proposals, using human participants, satisfy ethical standards.

All staff and other persons affiliated with Otago Polytechnic, engaged in research, are obliged to consider the need for ethical approval of their work in accordance within these guidelines. Academic Board has responsibility to approve such work through its Standing Research Ethics Committee. Research Ethics Committee may delegate some responsibilities to Heads of School/ Programmes/Service area Managers or their designated depute.

Applications will only be accepted on the current template available on the Otago Polytechnic website.

Research Proposals Which Require Approval by the Research Ethics Committee

Researchers should assess the ethical status of their work with colleagues and inform their Head of School/Programmes/Service Area Manager or their delegated depute of their project.

The following proposals require approval from the Committee:

- 1. All research projects to be conducted by staff or students at or under the auspices of Otago Polytechnic which are to include:
 - Human participants classifiable as Category A. This includes research
 conducted by researchers who are external to the institution if intended to involve
 Otago Polytechnic staff or students. Human participation includes individuals or
 groups as the subject of experimentation, or study involving human tissue or
 samples, or otherwise using individuals' personal information, rights and
 freedoms.
 - The Research Ethics Committee is not qualified to approve any research on animals, as approval for such research is the responsibility of the University of Otago Animal Ethics Committee
- 2. Any research project that fell into the preceding categories which has been continuing for three years or longer since it obtained approval from an Ethics Committee.
- 3. Any research proposal which is planning changes to the project which raises (further) ethical issues.
- 4. When joint research is being undertaken between two or more institutions, then ethics approval must be obtained from all institutions before commencing the project.

Exempt from application are proposals which have already gained approval by another Ethics Committee provided that the committee is appropriately accredited for the purpose of the project (e.g. an Ethics Committee accredited by the Health Research Council for health-related research). In this case the researcher should complete only section 1, and submit to the Otago Polytechnic Research Ethics Committee with the approval obtained providing the Committee with relevant proposals and approvals.

Also exempt are proposals involving existing publicly available documents or data, unless they otherwise fall within Category A.

Research involving patients or stored health information should go straight to the Health and Disability Ethics Committees.

Key Information for New Researchers

Developing an ethics application is an integral part of the design of any research project that will require ethical approval. (See above.) If this is your first time you are encouraged to make contact with an ethics support person or mentor to help you with your planning and application. You may find some of the following resources helpful:

Sample Document JMcDrury JYarwood.pdf

Sample Document CMcConnell.pdf

These practices are more likely to make your application go through smoothly. This is standard for experienced researchers.

Category A Proposals

(require approval by the Otago Polytechnic Research Ethics Committee)

This category includes any research proposal involving:

- · personal information which is identifiable
- the taking or handling of any form of tissue or fluid sample from humans or cadavers
- any form of physical or psychological stress
- situations which might place the safety of participants or researchers at risk
- the administration or restriction of food, fluid or a drug to a participant
- a potential conflict between the applicant's activities as a researcher, clinician or teacher and their interests as a professional or private individual
- the participation of minors or other vulnerable individuals (including students; clients; patients)
- any form of deception or inducement

Category B Proposals

(require approval by the Head of School/Programmes/Service Area Manager or their designated depute)

This category includes any staff research which falls outside the jurisdiction of the Research Ethics Committee as defined by the criteria for Category A, where areas have their own internal ethical processes, which have been approved by the Otago Polytechnic Ethics Committee, but which still warrant ethical considerations (for example access to staff and/or students for teaching qualification).

This category also includes all student research which would otherwise fall into Category A where Schools/Programmes /Service Areas have their own internal ethical approval process

Every Head of School/Programmes/Service Area Manager or their designated depute must provide an annual report on their decisions on Category B proposals to the Otago Polytechnic Research Ethics Committee and these systems will be audited.

The Research Ethics Committee will review School/Programmes/Service Area structures and processes for approval of Category B proposals.

Generic Proposals Under Category A

In cases where a paper requires each of the students to undertake a project of a particular generic type which involves human participants, and which falls within the criteria of Category A, the School/Programmes/Service Area may submit to the Research Ethics Committee a single proposal seeking ethical approval for the generic project. Such approval is again valid for three years or until changes are made, whichever occurs earlier.

Principles Governing Ethical Approval

The Research Ethics Committee will base their consideration of research proposals on the following principles.

Research Merit

Based on the potential for harm to participants, the Research Ethics Committee must be satisfied that the ethical considerations are congruent with the proposed methodology of the stated research proposal.

In assessing a proposal, the Committee will be assisted by:

- The Head of School/Programmes/Service Area Manager or their designated depute's comments (Heads of School/Programmes/Service Area Managers or their designated deputes have a responsibility for consideration of merit when they sign the Application Form that is submitted with the proposal).
- Qualifications of the applicant or supervisor (appropriately qualified personnel must supervise research involving human participants).

When necessary, the Research Ethics Committee may seek further advice on a methodology.

Researchers must demonstrate intent to publish or otherwise distribute the findings of their research. This includes making available to participants a comprehensible summary of their findings.

Informed Consent

Human participation in any research project must be voluntary and based on understanding of adequate and appropriate information about what such participation will involve. Participants in research activities must give their written consent. The researcher must demonstrate how they will obtain consent. It should be made explicit to participants if their data cannot be withdrawn, for example after data collection or analysis/collation.

The information provided to gain consent of the participant must:

- Adequately describe the nature and purpose of the research.
- Use language that the prospective participants can understand and where necessary provide an interpreter.
- Identify potential risks associated with the research project such as pain, stress, moral or cultural offence, embarrassment, fatigue, psychological distress and identify how such risks will be managed.
- Explain financial or other costs, including reimbursement, compensation or indemnity arrangements¹.
- Include how the researcher or their supervisor can be contacted to answer questions both prior to consenting and during the course of the research.
- Include how the research results will be made available to the participant.
- Consent must be given voluntarily. This means that there must be no duress, undue influence², or disproportionate inducements³. Researchers whose proposed

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¹ Researchers involved in clinical trials must consider the need for compensation or indemnity arrangements in light of the Accident Rehabilitation and Compensation Insurance Act 1992.

² Involvement in research must not unfairly discriminate against those who choose not to participate.

participants are in any sort of dependent relationship with them (for example: their students; clients; patients) need to be particularly careful about the possibilities of implicit coercion.

- Consent must be in writing except for minimally intrusive research (for example questionnaires that elicit non-personal information) or where the researcher can justify their decision to the Research Ethics Committee's satisfaction. In gaining written consent, the form must contain the following:
 - There will be no adverse effects should you decline to participate in this research.
 - You are free to withdraw your consent and discontinue participation in the research activity at any time without disadvantage and without having to provide reasons for withdrawal.
 - A clear statement must provide information on the latest point at which data can be withdrawn.
 - In projects using an anonymous questionnaire where written consent is not required, a statement should be included to the effect that completion of the questionnaire implies consent.

Vulnerable Participants

Informed consent processes may need to take account of vulnerable participants. Those considered to be vulnerable include children, prisoners, and people with a mental illness, altered state of consciousness or intellectual disability. Where the vulnerable participant is not competent to give consent, proxy consent must be sought from a person legally representing the person's interests. Where the vulnerable participant can understand his or her interests, the researcher must seek the individual's informed consent. In the case of children, consent must come from both the child's legal guardian and the child where appropriate. The vulnerable person's decision not to participate has priority over any other valid proxy consent.

Privacy and Confidentiality

The researcher is responsible for all information collected during the project and must identify the steps that they will take to ensure the privacy of participants. This includes:

- If you are recruiting participants through another organisation you will need to
 demonstrate that the privacy of participants has been secured and that you have
 clear processes and written permission from that organisation to approach their
 staff/members/colleagues/students. Provide a hard copy of the permission with your
 application.
- Storage of data (including data stored on a computer) should be password protected.
- Data stored on removable media, like floppy disk, CD and DVD, should be locked away.
- Data should not be stored on a networked computer unless it is encrypted.
- The use of codes and passwords for identification (where applicable).

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³ Remuneration of participants for their expenses, time and discomfort is acceptable but must not be excessive. It must not discriminate between participants and non-participants or classes of participants. Withdrawal from a project would entitle the participant to partial remuneration proportional to their involvement thus far.

- The destruction of data at the end of the project⁴.
- Preservation either of participant's anonymity or confidentiality (except in situations
 where it has been agreed that the participant will be identifiable) in reporting of results
 and other publications from the research.
- Demonstration of the steps they will take to ensure that others (for example research assistants) understand their responsibility to ensure the privacy of participants.
- Dissemination of the results of the research.

In accordance with principle 2 of the Privacy Act, all information must be collected from the participant unless the specific exceptions outlined in the Act apply.

The Privacy Act 1993 and applicable codes of practice which have subsequently been issued by the Privacy Commissioner (for example Health Information Privacy Code 1994) must be adhered to.

Minimisation of Harm

The researcher or teacher must identify how inconvenience and discomfort to the participant have been balanced against benefits (both present and future) to the participant or to society, and the importance of the knowledge to be gained.

Any conflict of interest between the researcher and potential participants must be made clear at the outset. Staff should not involve students as participants in their own research if they are currently or likely to be teaching or assessing them. Where this is not possible, the guidance of the Research Ethics Committee should be sought early in planning the project.

Limitation of Deception

Deception of participants is not congruent with the principle of informed consent. For this reason, the Research Ethics Committee will only consider, for approval, research projects where the impact of the deception is minimal and the potential knowledge to be gained is significant with no other less deceptive means available.

Participants must be debriefed as soon as possible, including full information about the reasons for the deception and the true purpose of the project. Participants must be able to withdraw their data and participation at this stage. Researchers must identify how they will provide support to participants following the project should any stress, harm or other concern arise.

Cultural and Social Considerations

Researchers must consider the cultural and/or social implications of their projects. Appropriate guidance relating to Māori cultural and ethical values will need to be sought by the researcher and evidence of the involvement in and support of the project should be included with the proposal.

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⁴ Researchers need to identify the time frame over which the data will be kept. For research projects it is acceptable that original data should be stored for at least five years from completion of the research.

What To Do

Check that you are working off the current website document.

Complete Section 1.

Download and save the current website document and complete and print out. Discuss your application with your School/Programmes/Service Area ethics support person. Give to Head of School/Programmes/Service Area Manager or their designated depute to sign and retain a copy for the School/Programmes/Service Area records.

Then forward in hard copy to the Research Ethics Committee Administrator, Directorate Reception, Level 3, F Block, Forth Street Campus.

Complete Section 2.

Email this to the Research Ethics Committee Administrator at EthicsAdmin@tekotago.ac.nz (keep a copy for your records).

Note: If you are required to seek approval from more than this Research Ethics Committee then we advise you to start early as dialogue may be required when there is a joint application. (Also see joint research note page 2)

Helpful Information

Sample Headings to Structure a Participant Information Form

Project title

General introduction

What is the aim of the project?

How will potential participants be identified and accessed?

What type of participants are being sought?

What will my participation involve?

Should you agree to take part in this project you will be asked to ...

How will confidentiality and/or anonymity be protected?

What data or information will be collected and how will it be used?

Results of this project may be published but any data included will in no way be linked to any specific participant without prior consent.

You may request a copy of the results of the project and it will be available at

Data Storage

The data collected will be securely stored in such a way that only those mentioned above will have access to it. The data will be password protected, stored in a locked cupboard, stored in a locked room. At the end of the project any personal information will be destroyed for any raw data on which the results are based. This will be retained in secure storage for a period of five years, after which it will be destroyed (in line with what is stated on the consent form).

Can participants change their minds and withdraw from the project?

You can decline to participate without any disadvantage to yourself of any kind. If you choose to participate, you can stop participating in the project at any time, without having to give any reasons. You can also withdraw any information that has already been supplied until the stage agreed on the consent form.

You can refuse to answer any particular question, and ask for the *recorder/camera /audio/video* to be turned off at any stage.

What if participants have any questions?

If you have any questions about the project, either now or in the future, please feel free to contact either:

or:

Any additional information given or conditions agreed to will be noted on the consent form.

Sample Consent Form

(Design your own and include only what is relevant to your study.)

Project Title

I have read the information sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:

- my participation in the project is entirely voluntary and I am free to refuse to answer any particular question
- I am free to stop participating at any time
- I can choose to withdraw information provided without giving reasons and without any disadvantage
- I cannot withdraw any information I have supplied after the data is analysed / March 24th / participant identifying information is removed.
- I am aware I cannot withdraw my information once the focus group is complete / questionnaire has been returned
- my data will be destroyed / returned to me / returned to my representative at the
 conclusion of the project but any raw data on which the results of the project depend
 will be retained in secure storage for five years after which it will be destroyed. If it is to
 be kept longer than five years my permission will be sought.
- I will receive if
- the results of the project may be published (you may also want to state "or used at a presentation in an academic conference") but my anonymity / confidentiality will be preserved
- I will receive a copy of the research findings

Additional information given or conditions agreed to				
I agree to take part in this project under	the conditions set out in the Information Sheet.			
	(signature of participant)			
	(date)			
	(signature of researcher)			

This project has been reviewed and approved by the Otago Polytechnic Research Ethics Committee

Research Ethics Committee

Functions

Researchers must have written approval from the Research Ethics Committee before commencing activities as required by Otago Polytechnic Policy on Ethical Practices in Research and Teaching.

- Ensure that all teaching and research within the Polytechnic, or under the auspices of the Polytechnic, which involves human participants or the use of personal information is carried out in accordance with the Polytechnic's policies on ethics.
- Withdraw approval for any research project that does not comply with guidelines, and notify the project leader and the Academic Board in writing.
- Consider any matter of ethical concern relating to the involvement of human participants in research or teaching which any student or member of staff of the Polytechnic raises with the Committee.
- Ensure that research or teaching proposals are carried out in accordance with the principles of the Treaty of Waitangi, with the currently applicable National Standard for Ethics Committees, and other relevant professional codes relating to research.
- Foster awareness of those procedures and of ethical principles in general within the Polytechnic.
- Enable accreditation of the Committee under the currently applicable National Standard for Ethics Committees
- Recommend and review policy and procedures and advise the Academic Board on issues relating to research, ethics in research.
- Report to Academic Board

Membership

Membership of the Research Ethics Committee will comprise:

- Chief Executive (or her/his nominee)
- Four Heads of School (or their nominees), at least one of which must be from each Faculty
- Member representing local iwi to be nominated by Ngai Tahu. (This may be subject to change on the advice of Ngai Tahu)
- Student representative nominated by the Students Association
- A member of an Ethics Committee from another institution
- Two persons not involved in research on human or animal subjects, and who are not members of the academic staff
- A registered medical practitioner, if invasive techniques are to be used with human volunteers
- The Committee has the authority to co-opt other expertise as necessary.

Academic Board will appoint members.

The Board will invite expressions of interest from appropriately qualified people according to vacancies.

In making these appointments, Academic Board should consider:

- Committee expertise in ethics and law
- Gender balance
- Range of research conventions in different disciplines

Chair

The Chair will be appointed by Academic Board

Documents for Further Reference

This list is not definitive. Other documents may also provide helpful information.

Appropriate occupational group codes

Copyright Act 1994

Harassment Policy

Health and Disability Commission Act 1994

Health and Safety in Employment Act 1992

Human Rights Act 1993

Injury Prevention, Rehabilitation, and Compensation Act 2001

Patents Act 1953

Privacy Act 1993

Student Regulations

Treaty of Waitangi Act 1975

You may also like to visit:

Health Research Council:

http://www.hrc.govt.nz/root/Ethics/Ethics%20Overview/Ethics_Issues.html

New Zealand Health and Disability Ethics Committees: http://www.newhealth.govt.nz/ethicscommittees/application.htm

Health and Disability Commissioner http://www.hdc.org.nz/

Human Rights Commission http://www.hrc.co.nz/home/default.php

Health and Safety http://www.osh.dol.govt.nz/law/hse.shtml

Acknowledgement

Massey University Web Site - Human Ethics Committee (MUHEC)

http://humanethics.massey.ac.nz/committee information.htm

Category B Accreditation Process

Introduction

The Otago Polytechnic Research Ethics guidelines require all research being undertaken by staff or students at or under the auspices of Otago Polytechnic to be considered for ethical approval. Research involving human participants will normally come to the Committee for approval (Category A). However, selected research (Category B approvals) may be granted by those Schools/Departments/Units which have demonstrated to the Research Ethics Committee that they have an acceptable process for considering Category B applications, and recording the decisions made. This paper outlines the requirements and the process by which Schools/Programmes/Service Areas can become approved to give ethical approval to Category B research to be undertaken in their area.

Category A approvals

(The following extracts are from the Research Ethics guidelines available from Polybase.) Applications are required for any research which includes:

- 1. Human participants classifiable as Category A. This includes research conducted by researchers who are external to the institution if intended to involve Otago Polytechnic staff or students. Human participation includes individuals or groups as the subject of experimentation, or study involving human tissue or samples, or otherwise using individuals' personal information, rights and freedoms. (The Research Ethics Committee is not qualified to approve any research on animals, as approval for such research is the responsibility of the University of Otago Animal Ethics Committee)
- 2. Any research project that fell into the preceding categories which has been continuing for three years or longer since it obtained approval from an Ethics Committee.
- 3. Any research proposal which is planning changes to the project which raises (further) ethical issues.
- 4. When joint research is being undertaken between two or more institutions, then ethics approval must be obtained from all institutions before commencing the project.

Research Ethics Committee approval is required for all research involving:

- Personal information which is identifiable
- The taking or handling of any form of tissue or fluid sample from humans or cadavers
- Any form of physical or psychological stress
- Situations which might place the safety of participants or researchers at risk
- The administration or restriction of food, fluid or a drug to a participant
- A potential conflict between the applicant's activities as a researcher, clinician or teacher and their interests as a professional or private individual
- The participation of minors or other vulnerable individuals (including students; clients; patients)
- Any form of deception or non disclosure

Any such research requires an application to an Ethics Committee.

Category B approvals

Other research (including nonhuman research or research that does not involve personal information) is called Category B research. Category B approvals may be granted by those Schools/Programmes/Service Areas which have demonstrated to the Research Ethics Committee that they have an acceptable process for considering Category B applications, and recording the decisions made. The procedures and processes must be sustainable and auditable.

Once a School/Programmes/Service Area has developed their process and procedures they should be presented to Research Ethics committee which will then "accredit" the School/Programmes/Service Area to manage Category B approvals. The procedure and process can be presented to the Research Ethics Committee by way of a memo with a short summary of each component and any sample forms, flowcharts or documents. It is not expected this will be more than 1-1.5 pages in length.

The School/Programmes/Service Area's documented process will outline:

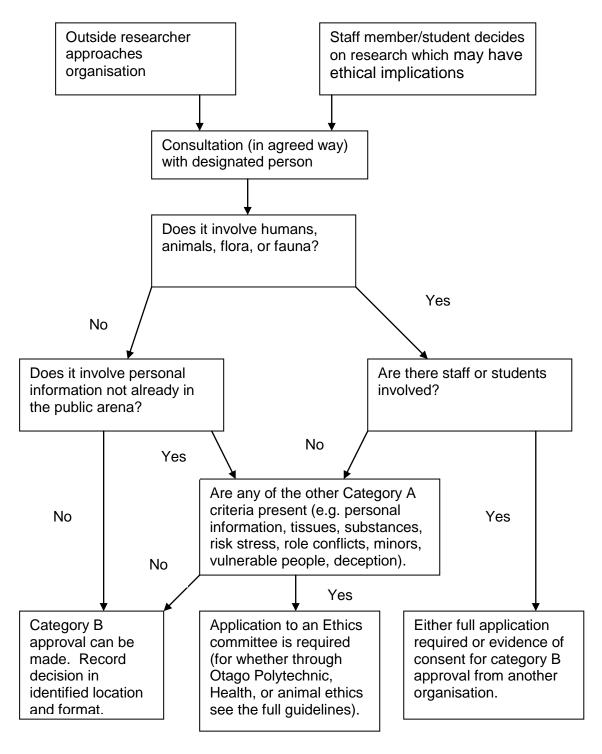
- 1. The role and name of the person in the School/Programmes/Service Area who will identify whether the research project/request falls outside the Category A requirements, and records the event/application/approval for audit.
- 2. A mechanism to ensure this role continues over time, with staff changes.
- 3. A clear outline of steps that staff within that School/Programmes/Service Area needs to follow to have the decision made, with the format to be used locally.
- 4. The format for such records, which must capture sufficient information to enable the Research Ethics Committee to ensure that no Category A research has been approved at School/Programmes/Service Area level.
- 5. The storage location that will enable an Annual Report to be made to Research Ethics Committee, and audit to occur.

In outlining these key components, Research Ethics Committee do not intend that any research to be approved by School/Programmes/Service Area requires a full research proposal solely for identifying the nature of any ethics approval needed. Our expectation is that there will be sufficient information to ensure that Category A research has been excluded. This may include, for example, one paragraph by email or a maximum of one page forwarded to the designated authoriser.

One example of research that may be so approved is an anonymous survey that requests no personal information, collected from non vulnerable people with whom there is no immediate power relationship. A research proposal (for example) involving textiles, adaptations to machinery or a meta analysis would not normally require ethics approval (depending on the involvement of participating humans!) although they may need other considerations of a permission or commercial access nature. A questionnaire approved by another organisation seeking only anonymous information from staff is probably also Category B.

Heads of School/Programmes/Service Areas should consult with any relevant Academic Leaders, and if such accreditation is required, prepare the short summary outlined above, and forward it to the Research Ethics Committee for approval. Applications coming to Research Ethics Committee falling outside Category A will be returned to School/Programmes/Service Areas with a request for such a process to be developed. Research Ethics Committee will monitor research reports, grant applications and staff changes to identify School/Programmes/Service Areas which may need to develop their Category B processes. We expect to review each School/Programmes/Service Areas' process after their first year and then on a three yearly basis.

Outline of Otago Polytechnic Category A or B Decision Making Process



Research Ethics Committee is available to help colleagues determine the required process for specific applications. Also note:

- Research Ethics Committee is happy to provide exemplars for approved School/ Programmes/Service Areas and to discuss these processes with Heads planning such an application.
- These processes have been described to cover ethical research: they do not address the ethical aspects of teaching, nor necessarily teaching ethics or teaching research.

Where lecturers are intending students to carry out small data collection activities that involve the public in disclosing personal information, it is appropriate that a generic (multiple years) application is made. Class exercises of data collection of personal information or characteristics should include a clear statement of how consent will be obtained, the anonymity of data collected, and the appropriateness of this personal information to be collected without a full Research Ethics Committee application.

- The Educational Development Centre in association with the Research Ethics Committee offers training for both emerging researchers and those who mentor them.
- Research Ethics Committee is happy to provide consultations on how an introduction to ethics may be taught in all research methods papers.

Implementation Process

Heads of School/Programmes/Service Areas will be contacted by members of the Research Ethics Committee to outline the above process and to discuss specific needs of each area. Sample accreditation applications will be added to the intranet as each approved school/area agrees that their processes may be shared with others.