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## Human Ethics Policy

### Research Policy Group

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#### 1 Purpose

Whether they are teachers or students, all members of the University whose teaching or research involves human subjects or human tissue or otherwise affects people's privacy, rights and freedoms, should always consider whether their work requires ethical approval. The University has a code of ethical conduct for the use of human subjects in research, to protect the rights of individuals and groups who are the subject of research, experiments set up for teaching purposes, and other similar activities conducted under the auspices of the University. It also provides a degree of protection for the researcher or teacher. This policy sets out the procedures that must be followed by staff and students when conducting research involving human subjects.

The University has a Human Ethics Committee, with a membership approved by the University Council, whose chief function is to review, approve and monitor any research proposal involving human subjects. This policy should be read in conjunction with the Human Ethics Committee Guidelines, a copy of which is attached as Appendix A.

#### 2 Organisational Scope

This is a University-wide policy and applies to all staff and students conducting research on human subjects during the course of their study or employment with the University. The policy also applies to research conducted under the auspices of [VicLink](#) to any research conducted within the precincts of the University, and to research conducted by an outside agency at the request or under the auspices of the University.

#### 3 Definitions

For purposes of this policy, unless otherwise stated, the following definitions shall apply:

Head:	Any head of a school, or group, or any manager of a University administrative unit, or the head's or manager's nominee.
HEC:	The University Human Ethics Committee
HEC Approval:	Approval granted by the Human Ethics Committee to proceed with research involving human subjects
HRC:	Health Research Council
Human Subject:	Any human participant, client, informant, or any person or group subjected to experimental procedures, whether those individuals or that group is involved knowingly or otherwise (also referred to as 'subject')

Personal Information:	Information about an identifiable individual
Publicly Available Information:	Information that is public or is available to the public, if not actually released, or is discoverable under the <a href="#">Official Information Act 1982</a> or other statute by persons other than the subject themselves or their guardians
CREC:	Central Regional Ethics Committee
Research:	Any research involving human subjects or human tissue conducted (a) by a student or employee of the Victoria University of Wellington while in the course of their study or employment with the University, including research projects carried out by students as part of course requirements and surveys or questionnaires undertaken by the University administration or student services concerning purely organisational practices; (b) within the precincts of the University; (c) under the auspices of <a href="#">VicLink</a> ; (d) by an outside agency at the request or under the auspices of the University
Sensitive Information:	Private personal information that is not publicly available (e.g. personal income, sexual practices, drug taking, illegal activities), and commercial information supplied in confidence
Teaching:	Any teaching activity undertaken by any employee of Victoria University of Wellington while in the course of employment with the University
Teaching Activity:	Any teaching activity which requires the participation of students as subjects in teaching exercises, laboratory exercises, training sessions, or student projects, but does not include teaching activities such as those which require students to answer questions in class or written assignments as part of their University studies
UTDC	University Teaching Development Centre

## 4 Policy Content and Guidelines

### 4.1 Research and Teaching Activities Involving Human Subjects

- (a) Participation of a human subject in any research project, course work project, or teaching activity or laboratory class must be voluntary and obtained through informed consent. Non-participation must not result in any penalty to the student. (Sample consent forms are given in Appendix C).
- (b) Inconvenience and discomfort to subjects must be balanced against the benefit to the subject and/or society, and the importance of the knowledge to be gained.
- (c) The information provided to gain the consent of the subject must be adequate and appropriate.
- (d) Research or teaching activities involving human subjects or human tissue must be supervised by appropriately qualified personnel, who have responsibility for ensuring that all procedures relating to ethical standards are complied with. It is the

responsibility of the supervisor to ensure that any person who is involved in the activity and is not employed by the University will conform to ethical standards.

- (e) The identity of subjects is to be protected at all stages of a research project unless prior written consent has been obtained from the subject for it to be disclosed.
- (f) Where a project involves a measure of deception, any departure from the standard of completely informed consent must be acceptable when measured against possible benefit to the subject and the importance of the knowledge to be gained as a result of the research project or teaching activity. Wherever possible, projects involving a measure of deception should incorporate an appropriate "de-briefing" of the participants after the project has been completed. Applications involving deception should in the first instance be submitted to the HEC but subsequent applications of the same kind may be handled by an approved ethics committee (refer section 4.13(b)).
- (g) Informed consent should usually be in writing and signed and, where relevant, include the statement regarding insurance cover set out in section 4.2 below. However, in some situations written informed consent may be inappropriate, e.g. for cultural reasons or where the person wishes to avoid self-incrimination. Where this is so, the application for ethical approval must detail the reasons for departing from the usual procedures with respect to consent.
- (h) All research projects or teaching activities which involve human subjects or human tissue must be reviewed by, and receive the approval of, the HEC prior to initiation. The Committee may give approval for up to three years at its discretion. The Committee may also require progress reports or a final report on the project and, with respect to research being funded by the Health Research Council, the Committee will require progress reports at least annually.
- (i) Applicants are responsible for informing the Committee if their project changes significantly during the period for which approval has been given. In such cases the Committee will determine if a new application for approval is necessary or if any changes to the conditions of approval are required.

#### **4.2 Insurance Cover**

The University retains insurance cover against claims relating to harm, loss or damage suffered by participants in research projects as a result of any negligent act, error or omission by or on behalf of the University. Where relevant, (e.g. for research involving human tissue), these words must be incorporated into consent forms. Where a person suffers personal injury as a result of medical error or medical mishap during a clinical trial in the University, the injury will be considered for coverage under the accident compensation scheme, if the trial has had HEC approval.

#### **4.3 Research and Teaching Activities Which Require Ethical Approval**

- (a) With the exception of those activities listed in section 4.4(b), no research or teaching activity involving human subjects, human tissue or otherwise affecting people's privacy, rights and freedoms may proceed without approval under this policy. Where appropriate, it is the responsibility of course organisers and principal researchers or research supervisors to gain HEC approval and to ensure that required ethical standards are maintained. Students are expected to make their own applications for ethical approval after consultation with their academic supervisors.
- (b) Approval is required for research and teaching activities which involve access to personal identifying information not already publicly available. Where access to

personal information located outside the University has been granted by the holding agency, an application for ethical approval is still necessary.

- (c) Approval is required for research and other activities involving questionnaires and surveys conducted within and outside the University (exceptions are noted in sections 4.4(b) and 4.7).
- (d) The principles and procedures presented here apply specifically to research and teaching activities with adult human subjects and human tissue. In general, the same principles apply where children or other dependent people are the participants, but their use as subjects presents a special case and as such demands additional ethical considerations. Researchers who involve children or other special groups in their work should seek the advice of the HEC in relation to these additional considerations and procedures.
- (e) Independent bodies associated with the University (e.g. some hostels) may make an application to the HEC, which may in its discretion give ethical advice to the applicant.

#### **4.4 Research and Teaching Activities Which Do Not Require Ethical Approval**

- (a) From the start of any research that involves human subjects, it is always important for researchers to consider whether ethical approval is required. The following should be read in that light.
- (b) Ethical approval is not required for:
  - (i) Exploratory research consisting solely of preliminary interaction or discussion where the exact research aims have not yet been formulated. If a researcher later wishes to use data collected at an exploratory stage, retrospective consent should be obtained;
  - (ii) Research in which the investigator is the subject of their own research, and where no physically or emotionally hazardous procedure is involved;
  - (iii) Some interviews which merely seek non-sensitive factual information as set out in section 4.8(a);
  - (iv) Research involving existing publicly available documents or information (for example, analysis of public archival records).
- (c) Research involving oral or written questionnaires may fulfil the criteria set out in section 4.7. In such cases a single application should be made to the head or manager who has the responsibility to ensure that the research undertaken observes the ethical principles set out.

#### **4.5 Procedures Regarding General Applications**

- (a) Persons initiating research (principal investigators or research supervisors), or conducting teaching activities (course organisers), involving human subjects or human tissue are responsible for obtaining HEC approval and for complying with the requirements set forth in this policy. These persons are responsible for ensuring that HEC approval has been obtained for research projects that are initiated from school resources.
- (b) In all cases, applicants, whether staff or students, must discuss the ethical implications of their research or teaching activity with the head of their school or other person to whom responsibility has been delegated in the school, including supervisors in the case of student projects, before seeking HEC approval.

- (c) Research projects submitted to outside granting agencies or to any source of internal University research funds should, wherever possible, receive HEC approval before the application for funding is made. Where this is not possible, the application for HEC approval should be concurrent with the application for funding. The following procedures apply where ethical approval is sought in conjunction with an application for funding from any contestable University research funds.
- (i) In cases where the methodology is not sufficiently far advanced for approval in principle to be obtained from the HEC, a small seeding grant for preparatory work can still be made on the condition that HEC approval is obtained before any field work (including piloting of research instruments) takes place.
  - (ii) In all other cases where funding is required for the development of survey instruments, prior approval should still be sought from the HEC before applying for funding. In such cases approval may be given in principle by the HEC on the basis that the research instruments must receive subsequent approval before field work commences.
- (d) Members of the University intending to conduct research or a teaching activity which requires ethical approval must complete and submit an application to the Secretary of the Committee after discussion as set out in section 4.5(b). Applications should be written in plain language and must follow the appropriate HEC form, copies of which have been circulated to all schools and groups. Additional copies may be obtained from <http://www2.vuw.ac.nz/home/research/overview.html#hec>. Applications on the appropriate HEC form must be accompanied, as appropriate, by a copy of both an information sheet and a separate consent form for participants, as well as any questionnaire or interview schedule to be used in the research or teaching. Information letters and consent forms must be on University letterhead and include the name and contact details of the supervisor, in the case of student research. Further information on information sheets and consent forms, and examples, can be found in Appendix C.
- (e) All applications for ethical approval, whether staff or student research, must be signed off by the Head of School (or person with delegated authority), before being submitted to the HEC.
- (f) Student research projects at undergraduate and postgraduate level are subject to HEC approval in the same way as are staff research projects.
- (g) Applications must be approved before data collection or other activity involving human participants is initiated. The HEC will not normally consider giving retrospective approval (see section 4.4(b)(i)).

#### **4.6 Procedures Regarding Applications Involving Services and Facilities under the Jurisdiction of a Health Funding Organisation**

- (a) All research that is funded by the Health Research Council or involves any clinical trial conducted by a registered health professional or involves funding by or access to the data of any organisation which requires ethical approval by a committee accredited by the Health Research Council or the Director General of Health, must be forwarded to CREC in the area where the research is to be conducted. This is necessary because:
- (i) The Human Ethics Committee is not accredited to approve this type of research;
  - (ii) For legal reasons (the effect of the [Injury Prevention, Rehabilitation and Compensation Act 2001](#));

- (iii) To ensure that University procedures meet the requirements of funding agencies and agencies granting access to data.
- (b) Applications involving services facilities, patients or patient data related to a health agency must obtain school approval in principle in the first instance before being referred to the CREC in the area where the research will be conducted.
- (c) Applications requiring approval from a CREC must be sent to the Secretary of the HEC in the first instance, who will take responsibility for ensuring that the applications are forwarded to the relevant CREC. These applications must be submitted on the relevant REC application form (which differs from the HEC application form). The applicant is also responsible for ensuring that the Secretary of the HEC is provided with sufficient copies to meet the REC requirements.
- (d) Advice of the decisions of the CREC and equivalent ethics committees in other areas relating to applications from University staff must be communicated by the applicant to the secretary of the University's HEC.

#### **4.7 Procedures Regarding Research Involving Written Questionnaires Only**

- (a) Research in which the subject's participation is restricted to the completion of a written questionnaire in a manner not requiring disclosure of the subject's identity, and which meets the criteria for questionnaires in section 4.7(b), may be approved in writing by the Head of the School. A copy of that approval must be sent to the Secretary of the HEC.
- (b) The questionnaire must:
  - (i) Be totally anonymous (responses should be returned anonymously and there should be no coding or other means of identifying respondents from the response);
  - (ii) Not contain questions on sensitive topics (e.g. sexual practices, drug taking, illegal activities);
  - (iii) Be designed to meet the research goals set;
  - (iv) In the case of student projects, be subject to appropriate supervision;
  - (v) Normally state the purpose of the questionnaire, the use to which the results will be put, the disposal of the questionnaire forms, and the fact that the questionnaire is anonymous.
- (c) Questionnaires concerning operational practices (e.g. library usage), may be approved under the same conditions as in sections 4.7(a) and (b), with necessary modifications.
- (d) Any other research involving questionnaires should be submitted to the HEC for approval in the standard way.

#### **4.8 Procedures Regarding Interviews**

- (a) Ethics approval is always required where the interviewee's name will be used as the source of data or of a quotation. Interviews where the interviewee's name will be kept confidential also require approval. The only exceptions are:
  - (i) Where the object of the interview is merely to seek non-sensitive factual information (e.g. requests for statistical information or information about services from public agencies);
  - (ii) Informal discussions with colleagues, family and friends.

- (b) Where the information is to be attributed or used in a formal sense, ethics approval must be obtained.
- (c) Where ethical approval is required, the applicant should normally obtain written informed consent from the interviewee. This requirement is for the protection of both the interviewer and the interviewee. Exceptions may be justified where, for example, the interviewee does not wish to be identified even in a consent form, where it would be inappropriate to obtain written consent, or where there are cultural or religious reasons for not obtaining written consent (see section 4.1(g)). Where written informed consent is not to be obtained, the interviewee must still receive a written information sheet explaining the research, the nature of the interview, the proposed use of the material, who will have access to it and whether or not it will be anonymous. All exceptions to the written consent requirement must be fully explained in the ethics application.

*Note 1: It is good practice to give the interviewee the opportunity to check any write-up of the data which relies on what the interviewee has said. The interviewee can thus make corrections. A separate release form is useful in some situations.*

*Note 2: Where the interviewee is a public figure (e.g. a politician), written consent would, usually, still be sought. Experience suggests that some politicians may refuse to sign a consent form. In these circumstances the researcher may decide not to hold the interview. On the other hand, the interview might be crucial to the research and provide important data. If the researcher decides to proceed with the interview without written consent, there is a risk that the interviewee may subsequently deny what was said and could even take further action. It is advisable therefore for the researcher to seek permission to tape the interview, to ask the interviewee subsequently to approve the proposed quotations to be used by the researcher and, in the absence of such approval, to consider carefully whether the data can be used. In any case where such an interview takes place without written consent, the ethics committee should be informed as soon as possible that the approved procedures could not be followed.*

- (d) All interviews, whether or not the subject of an application for ethical approval, must comply with the [Privacy Act 1993](#). Note that the University is an “agency” and that all personally identifiable information collected or held by the University staff is subject to the principles.
- (e) Where interviews are conducted either in the classroom or in the wider community, and where they are part of general student course work involving a group of students who are asked to do essentially the same task and provided there is appropriate supervision, a single application should be made to the head of the school who has the responsibility to ensure that the interviews observe the ethical principles set out, and who must, for record purposes, forward a copy of the application to the HEC Secretary once it has been approved by the head.
- (f) Postgraduate research should be the subject of an individual application by the student concerned.

#### **4.9 Procedures Regarding Teaching Activities Involving Human Subjects**

- (a) HEC approval must be obtained for any teaching activity in which students or human tissue are used as subjects for experiments in teaching situations.
- (b) HEC approval must be obtained for undergraduate projects or teaching exercises involving any of the following with human participants, either in the classroom or the wider community (except for anonymous questionnaires meeting the criteria outlined in section 4.7):
  - (i) Oral or written questionnaires;

- (ii) Observation of interviews;
- (iii) Interventional projects.

*Note: "Interventional projects" include obvious physical invasions such as taking blood samples or giving electric shocks, and include any projects in which the experimenter intervenes to influence the behaviour of individual subjects through manipulation of the social, psychological, or physical environment.*

- (c) Provisions governing the involvement of students or community members as participants/subjects in any teaching activity are set out in Appendix B.
- (d) Approval for teaching activities involving human subjects or human tissue will normally be given for three years. If within this period there is any change in the procedure or activity, a new application must be made by the head of the school concerned.

#### **4.10 Evaluation Exercises Undertaken by the UTDC**

- (a) A summative student evaluation of teaching must comply, where applicable, with the [Code of Practice issued by the University Teaching Development Centre \(UTDC\)](#) and with the rules governing confidentiality of information in the Notes for student evaluation of teaching and courses issued annually by the [UTDC](#).
- (b) Summative and formative student evaluations being administered by the [UTDC](#) may be approved by the Director of the [UTDC](#).
- (c) HEC approval must be obtained for all other summative evaluations.
- (d) HEC approval must be obtained for other formative evaluations which:
  - (i) Request the names of students completing the evaluation;
  - (ii) Request information about anyone other than the person conducting the evaluation;
  - (iii) Request any other information of a private or sensitive nature.

#### **4.11 Payments to Subjects of Research and Teaching Activities**

Generally, there should be no payment to subjects, and any proposal for such payment (other than recovery of expenses) requires the permission of the Human Ethics Committee.

*Note 1: Granting approval for payment to subjects is not normally delegated to an ethics committee approved under section 4.13(b), or to a head or manager.*

*Note 2: Subject to section 4.11(a), given the diversity of research undertaken the policy of the Human Ethics Committee regarding payments to subjects shall be flexible and sensitive.*

*Note 3: Adequate provision for the recovery of expenses (of researcher/teacher and of subject) should be a routine feature of research or teaching activities.*

*Note 4: Where appropriate, a clear statement of the cash payments (and other material or economic advantages) which are available, and any conditions which apply, should be a standard feature of the information provided to prospective participants as part of the informed consent process.*

#### **4.12 Storage, Security and Destruction of Data**

- (a) All projects which involve the collection of personal information must comply with all New Zealand legislation on privacy ([Privacy Act 1993](#)).
- (b) Personal information must be handled in a way which protects the confidentiality of the subjects and ensures the safe custody of data.

- (c) Researchers, supervisors and teachers must ensure that personal information is protected by reasonable security safeguards against loss, unauthorised access, use, modification or disclosure and other misuse. Where a project involves the collection of personal information, the application to the HEC must set out clearly who is entitled to have access to that information and under what conditions, and whether personal information will be used in the writing up or other means of completion of the project.
- (d) Research information collected for one purpose shall not be used, without the written consent of any person who is the subject of that information, for another purpose unless it is in the public arena or is available in a non-identifying manner which follows an HEC – approved delinking process (where appropriate).
- (e) The written information sheet and consent forms presented to the subject must clearly indicate what will happen to collected data when the research has been completed (e.g. how and where it will be stored, and for how long).
- (f) Personal information should not be kept for longer than is necessary to complete the particular project and to allow for academic examination, challenge or peer review. Where it is proposed to keep such information for a longer period, this must be justified in the application for ethical approval. Some professional associations require data to be kept secure for a minimum of five years to enable later substantiation of research findings. It is important that any confidential or sensitive material be kept in a secure and locked environment before it is destroyed and that subjects be told how personal material will be stored and for how long.

*Note: Documents and information held by staff are potentially discoverable under the [Official Information Act 1982](#). Documents and information held by students are not. Information collected by students for their research should thus be available to supervisors and others if needed for academic verification and review but should not be retained by staff.*

#### **4.13 The Functions of Schools and Groups in the Ethics Consideration Procedure and Delegation of Responsibility**

- (a) All schools and groups must have in place procedures for considering ethical issues relating to research projects and teaching activities, before these are referred to the HEC. The formal responsibility for this rests directly or ultimately with the head, although the head may delegate responsibility for checking that projects are completed within an approved time or that documents are destroyed as agreed with participants when ethics approval was originally given.
- (b) Where the level of cases is sufficiently high, a faculty, school, or group may be given permission by the HEC to establish its own ethics committee. The policies, procedures and guidelines of such ethics committees must conform to this policy and must be approved by the HEC. Such committees must include at least three staff members from the faculty, school or group and one member of the HEC in their membership. Where such approval has been given, the HEC may delegate the review and approval of projects to the approved ethics committee.
- (c) An ethics committee acting under delegated authority must advise the secretary of the HEC within seven days of every project receiving ethical approval and forward a copy of the application to which that approval relates. Any case which raises novel or particularly difficult ethical issues must be referred to the HEC for a decision. The representative of the HEC on the approved ethics committee has particular responsibility for ensuring that cases involving such issues are forwarded to the HEC for approval.

- (d) An applicant who is dissatisfied with the decision of an approved ethics committee may appeal in writing to the HEC for a second opinion (see section 4.14).

*Note: Schools and groups may develop their own additional guidelines which are specific to the research and teaching of those schools and groups. Where it is appropriate, the adoption of ethical guidelines developed by relevant professional organisations is encouraged.*

#### 4.14 Appeals

- (a) Where an applicant is dissatisfied with the decision of a Head of a committee approved under section 4.13(b) the applicant may appeal to the HEC Standing Committee. A decision of the Standing Committee may be appealed to the full HEC.
- (b) An appeal under section 4.14(a) may also be lodged by any other person, including research participants, researchers, supervisors, or members of the public.
- (c) Any person or body dissatisfied with a decision of the HEC may seek a second opinion directly from the Health Research Council (HRC) Ethics Committee as described in the HRC Accreditation Guidelines and the National Standard for Ethics Committees. Following receipt of this independent advice from the HRC Ethics Committee, the VUW HEC then makes a final decision.
- (d) The HEC itself may also seek a second opinion from the HRC Ethics Committee.

*Note: Complainants will be kept informed about the progress of their complaint and will be informed in writing about the outcome.*

#### 4.15 Sanctions

Where University employees fail to obtain ethical approval when such approval is required or where they act contrary to the decision of a body authorised to consider applications for ethical approval, the matter may amount to misconduct and be dealt with under the University's [Conduct Policy](#). Where a student has engaged in an unethical activity, the matter should be dealt with by the student's examiner or supervisor, and where necessary, referred to the head of the school. In serious cases, the misconduct provisions of the University's [Student Conduct Statute](#) or the [Assessment Statute](#) may be used.

## 5 Legislative Compliance

The University is required to manage its policy documentation within a legislative framework. The legislation directing this policy is the:

[Health Research Council Act 1990](#)

[Injury Prevention, Rehabilitation and Compensation Act 2001](#)

[Official Information Act 1982](#)

[Privacy Act 1993](#)

## 6 References

[Assessment Statute](#)

[Conduct Policy](#)

[Student Conduct Statute](#)

[University Teaching Development Centre](#)

[VicLink](#)

## 7 Appendices

[Appendix A: Human Ethics Committee Guidelines](#)

[Appendix B: The Involvement of Human Subjects in Teaching Activities](#)

[Appendix C: Sample Consent Forms and Information Sheets](#)

[Appendix D: Human Ethics Committee Application Form](#)

## 8 Approval Agency

Vice Chancellor

## 9 Approval Dates

This policy was originally approved on: 8 October 2003

This version was approved on: 8 October 2003

This version was amended on: 13 July 2007

This version takes effect from: 13 July 2007

This policy will be reviewed by: 13 July 2009

## 10 Policy Sponsor

Deputy Vice Chancellor (Research)

## 11 Contact Person

The following person may be approached on a routine basis in relation to this policy:

Allison Kirkman

Convener, VUW Human Ethics Committee

Ext 5676