



Unitec Human Research Ethics Guidelines

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1. PURPOSE

Unitec recognises the need for studies in which human participants may serve as research participants. Unitec is also aware of its responsibility for ensuring that the privacy, safety, health, social sensitivities and welfare of such participants are adequately protected. In addition, researchers need to ensure that research is conducted in an environment safe for the researcher(s) as well as the participants.

Unitec Research Ethics Committee (UREC) provides guidelines to support and advise staff and students wishing to undertake research in which humans may be used as participants.

It is Unitec policy that all staff or student research projects which involve human participants must receive the approval of the UREC before they start.

These guidelines are not a substitute for reading, interpreting and implementing the intent of Unitec's Research Ethics Policy. People using these Guidelines should refer in the first instance to the policy itself, and in the case of conflict, the policy shall prevail.

2. APPLICATION AND SCOPE

These guidelines and associated policy apply to all staff and students at Unitec undertaking research in which humans may be used as participants.

3. GUIDELINES

3.1. Ethical Principles Governing Research and Teaching Activities

UREC emphasises eight guiding ethical principles governing research and teaching activities using humans. These are:

- 1) Informed and voluntary consent.
- 2) Respect for rights and confidentiality and preservation of anonymity.
- 3) Minimisation of harm.
- 4) Cultural and social sensitivity.
- 5) Limitation of deception.
- 6) Respect for intellectual and cultural property ownership.
- 7) Avoidance of conflict of interest.
- 8) Research design adequacy.

3.2. Application procedures and forms

Approval by UREC will be required before any research activities that involve the participation of humans as participants, directly or indirectly, are initiated by the staff member or student researcher. Researchers should check what form of approval may be required using these guidelines. This will enable the researcher to decide whether full application to UREC or another ethics committee, e.g. the Health and Disability Ethics Committee, is required. Where ethical approval is required, research cannot begin until such approval has been received in writing.

3.3. Individual Application for Ethics Approval for a Research Project

Form A

This is for research which *does not meet* all criteria for harm minimisation. Staff researchers are personally responsible for obtaining approval. For student research, research supervisors must co-sign the application and ensure that:

- 1) the application is submitted to UREC;
- 2) students understand the principles and procedures set out by UREC;
- 3) the project is appropriately supervised;
- 4) the project is of an acceptable standard for the discipline concerned.

Form B

This is for research which does meet all criteria for harm minimisation (consult Guidelines). Staff researchers are personally responsible for obtaining approval. For student research, research supervisors must co-sign the application and ensure that:

- 1) the application is submitted to UREC;
- 2) students understand the principles and procedures set out by UREC;
- 3) the project is appropriately supervised;
- 4) the project is of an acceptable standard for the discipline concerned.

Form C – Application for Ethical Approval for a Research Component of a Teaching Programme

This application is to enable UREC to delegate authority to the applicants to approve non-contentious research (i.e. normally submitted under Form B) within a teaching programme. Approval for Research Components of a Teaching Programme can be for a maximum of three years. Teaching programmes cover:

- 1) student research projects;
- 2) courses that have a significant component of research;
- 3) research laboratories; or
- 4) class research exercises.

3.4. Submission of Application

Applications that are incomplete or lacking the appropriate signatures or submitted after the specified application deadline date will not be processed. This will mean delays for the project.

Applications must be submitted in the following formats:

One electronic copy complete with supporting documents to be emailed to the Ethics Secretary at:
ethics@unitec.ac.nz

One complete hard copy with appropriate signatures to be sent or hand delivered to the Ethics Secretary at:

UREC Secretary
Tūāpapa Rangahau
Partnering Research and Enterprise
Penman House
Building 55
139 Carrington Rd
Mount Albert
Auckland 1025

Or to:

UREC Secretary
Tūāpapa Rangahau
Partnering Research and Enterprise
Unitec New Zealand
Private Bag 92025
Auckland 1142

Phone: 815 4321 extension 8551

Email: ethics@unitec.ac.nz

If no signed hard copy can be provided, complete and fully signed e-copies of applications will be accepted. Note that email trails are unable to be accepted and are not considered valid in lieu of signature/s.

Completed applications must be received by the UREC Secretary by the due date and time deadline specified in order to be processed at the next meeting. UREC will promulgate meeting dates and deadlines from time to time. Late applications will not be accepted.

The applicant must send all completed forms plus attachments (i.e. survey instruments, information and consent forms) electronically to the UREC Secretary or the research supervisor, as appropriate. The signed declaration and any supporting information not able to be supplied electronically (such as letters of support) should be sent as hard copy by normal mail to the UREC Secretary.

The applicant is responsible for ensuring that the research supervisor and / or Head of Practice Pathway receive the application form and all relevant attachments in the form they prefer. These people must personally sign the declaration page after which the staff applicant or supervisor, as appropriate, is responsible for ensuring the signed copy is sent to the UREC Secretary.

Reading of the application cannot commence until all documentation is received. The primary reader may discuss the application with the applicant and / or supervisor as appropriate.

3.5. Approval by UREC

No research can be implemented until approval has been granted by UREC. Failure to comply with approval procedures can result in serious disciplinary action. Compliance with UREC approval policy and procedure will ensure both staff and students at Unitec are covered for personal liability as researchers under the insurance policies held by Unitec.

Under certain circumstances, UREC cannot approve some research projects. These include:

- 1) Research involving or affecting animals.
- 2) Research using genetic modification.
- 3) Some clinical trials using human participants, i.e. trials requiring completion of Statutory Declaration B (consult <http://www.hrc.govt.nz> or <http://ethics.health.govt.nz/system/files/documents/pages/HDEC%20scope%20summary.pdf>)
- 4) Research involving human remains.
- 5) Any clinical study requiring the approval of the Standing Committee on Therapeutic Trials (SCOTT), the Gene Technology Advisory Committee (GTAC) or the Environmental Risk Management Authority (ERMA).

For each of the above types of research projects, application must be made, using the appropriate forms, to an accredited animal or regional Health and Disability Ethics Committee, details of which can be obtained from the UREC Secretary.

Other examples of research projects that UREC cannot approve are given in the Standard Operating Procedures for Health and Disability Ethics Committees (SOP's) (consult <http://ethics.health.govt.nz/applying-review>). In such cases, application must be made to a Health and Disability Ethics Committee using their (or the national) application form.

UREC may from time to time redefine these exempt and modified categories or determine new ones.

Retrospective approval will not be given for any research already under way. Research conducted prior to obtaining ethical approval is in violation of Unitec Policy and will be subject to disciplinary procedures.

Where UREC has determined that research is not being conducted according to the protocol approved, UREC can **withdraw** approval for the research.

3.6. Exceptions from Approval Requirements

While ethical considerations must still be upheld, the following do not require specific approval from UREC:

- a) research that does not involve humans or animals and is not foreseen to adversely affect humans or animals;
- b) evaluations conducted within Unitec for quality assurance purposes;
- c) research involving existing, publicly available documents or data (e.g. analysis of archival records, which are publicly available);
- d) preliminary interaction or discussion where the exact research aims have not yet been formulated;
- e) research in which a single investigator is the subject of his or her own research, and where no hazardous outcomes are foreseen;
- f) one-off interviews with public figures, e.g. politicians, prominent authors;
- g) seeking a professional or authoritative opinion, except where this is part of a study of the profession or area of expertise;
- h) where harm minimisation criteria are not exceeded, and where certain student research projects are covered by an approved Research Component of a Teaching Programme (Form C).

3.7. Contentious and Non-contentious Ethics Applications

If research could involve humans as participants and/or could potentially harm humans, ethics approval must be obtained before the research is begun from UREC.

Humans are involved as participants in research if people:

- 1) Respond to surveys (e.g., questionnaires, interviews, focus groups).
- 2) Provide information about themselves, directly or indirectly.
- 3) Have some form of intervention imposed on them (e.g., medical, drug or physical treatment, physical manipulation, food or fluid supply/restriction, specific environmental conditions are imposed, exercise regimes, other activities of an experimental nature).
- 4) Are the participants of certain observational studies which may not protect their anonymity or the confidentiality of information collected about them.

Applicants should use the non-contentious application, known as 'Form B' if all of the following criteria can be met:

- 1) No vulnerable people or minors are involved as participants.
- 2) There is no deception involved in eliciting the information from them.
- 3) There is no potential for harm or stress.
- 4) No interventional 'treatment' is imposed on the participant (e.g., drugs, physical manipulation, exercise regimes, environmental conditions, food / fluid supply/restrictions).
- 5) No body tissue or fluid sample is removed from any participant.
- 6) The participants remain anonymous and cannot be identified from the raw or published data, either directly or by inference.
- 7) No personal information on an individual participant is collected, and sensitive questions are not asked.
- 8) The researcher(s) has (have) no significant conflict of interest in the research.
- 9) Particular ethnic groups are not deliberately targeted as participants.
- 10) The research does NOT have particular relevance to, nor affect or impact on, Māori.

Face to face Interviews may be conducted by the researcher as long as the above criteria is upheld throughout the course of research. Researchers should use the contentious application known as Form A if any of the above criteria cannot be met. If in doubt about what form to use, researchers may refer to the document Unitec Application Screening Questionnaire in order to assist them to decipher which form to use.

3.8. Ethics Application for Research Component of a Teaching Programme

This application is to enable UREC to delegate authority to the applicants to approve non-contentious research (i.e. normally submitted under Form B see above criteria) within a teaching programme. Approval for Research Components of a Teaching Programme can be for a maximum of three years. Applications should use a Form C. Teaching programmes cover:

- 1) Student research projects.
- 2) Courses that have a significant component of research.
- 3) Research laboratories, or
- 4) Class research exercises.

3.9. Liability and Insurance

Both staff and students of Unitec are covered for personal liability as researchers under the insurance policies held by Unitec, providing research is carried out according to the protocols approved by UREC.

In cases where clinical trials are being conducted by Unitec staff or students (for a definition and information on clinical trials, Unitec adheres to the HRC Guidelines on Ethics in Health Research regarding compensation for research participants) see sections 3.5 and 5.6 of the HRC Guidelines on Ethics in Health Research (consult www.hrc.govt.nz). Compensation may apply (but is not solely restricted) to Accident Compensation Corporation and Insurance Corporation Cover.

3.10. Complaints Procedure

3.10.1. Complaints Concerning the assessment of an application

Complaints regarding the assessment of an application for ethical approval and/or the procedures and/or the decision-making process used by UREC in reaching a particular decision will be investigated using the following procedures:

- 1) The complaint must first be submitted in writing to the UREC Secretary.
- 2) UREC will deliberate on the complaint. As part of its deliberation UREC may liaise with national or regional health bodies on services and treatment and with the Health Research Council (HRC) Ethics Committee on research and innovative treatment issues.
- 3) UREC will provide a written response to the complainant detailing out how the complaint was investigated and the result of their consideration of the complaint.
- 4) UREC will provide the complainant a reasonable opportunity to respond in writing and to attend a committee meeting for further discussion.
- 5) If the complainant responds in writing or attends a committee meeting, UREC will provide a final decision in relation to the complaint in writing to the complainant.

3.10.2. Appealing a decision of UREC

An appeal of a decision of UREC can be submitted if a final decision (application has been withdrawn or declined by the committee) has been provided by UREC. Appeals of a decision of UREC shall be submitted to the Chair of Academic Board and will be conducted according to the following procedure.

Grounds for Appeal: That there has been a material irregularity in the assessment of the application or in the procedures adopted by the committee, or there is substantive disagreement in regards to a decision of UREC.

Procedures:

- 1) An application for appeal shall be made in writing, summarising the relevant facts and setting out the grounds for appeal, no later than 90 days after the final decision of UREC has been made.
- 2) Within 10 days the Chair, Academic Board or their nominee, shall determine whether the appellant has established grounds for an appeal.
- 3) The Chair, Academic Board or their nominee, shall advise by written notice to the Chair of UREC that an application for an appeal has been received and include a copy of the Appellant's application for appeal. The Chair of UREC or delegate shall provide a written response relating to the Appellant's application to appeal, and shall provide a copy of all relevant documents, including a copy of any committee minutes or files notes relating to the decision. A copy of this written response will be provided to the Appellant.
- 4) An Appeal Committee shall be established, and shall be provided with the appeal documentation and the UREC response. The Appeals Committee shall consist of the Chair, Academic Board or their nominee, three senior academic staff and at least one member of a HRC accredited institutional ethics committee from another institution, and none shall be current members of UREC.
- 5) The appeal hearing shall be held at a time convenient to all parties, including the Appellant. The committee Convenor shall advise the Appellant of his/her right to appear at the hearing, to be accompanied by whānau or a support person, to appoint an advocate to speak on his/her behalf, to request an interpreter, and the right to request a Maori representative on the Appeals Committee.
- 6) The appeal hearing shall be an open consultative event with both parties to the appeal in attendance for each other's explanations. The hearing shall follow meeting rules as follows:
 - i) All comments and questions are addressed or asked through the Convenor; The Appellant and/or advocate is invited to present his/her case, followed by an opportunity for members of the Appeal Committee to ask any questions;
 - ii) The Chair of UREC or his/her delegate is invited to explain and clarify the decision made and then speak to matters raised in the appeal, followed by an opportunity for members of the Appeal Committee to ask any relevant questions'
 - iii) Either party may ask questions and the Convenor may also invite either party to present any additional information relevant to the hearing;
 - iv) All parties apart from the Appeal Committee are then requested to leave the meeting;
 - v) The Appeal Committee considers all the evidence presented and makes a decision.

Appeal Outcome:

The Appeal Committee shall either:

- 1) Reject the appeal, or
- 2) Uphold the appeal and require UREC to reconsider their decision. The Appeal Committee shall provide UREC with a detailed response and targeted advice on matters that require attention in considering the application.

3.10.3. Complaints regarding the ethical conduct of research

Complaints may be made to UREC that research is not being conducted according to protocol approved by UREC. These will be investigated according to the following procedure.

- 1) The complaint must be made in writing to the UREC Secretary. This complaint will be treated as confidential to the committee unless requested otherwise by the complainant.
- 2) At the discretion of the UREC chairperson, UREC will set up a subcommittee to investigate the complaint. This committee will include the Dean of Research and Enterprise, and at least one internal and one external member of UREC.
- 3) The chairperson or subcommittee will normally contact the researcher about the complaint. While the complaint is being investigated, UREC may request that the research be put on hold. UREC may seek advice from, or refer complaints to, other bodies as might be deemed appropriate.
- 4) A written response will be provided to the complainant and the researcher detailing the committee's findings.
- 5) The researcher will be given the opportunity to provide a written response to the committee's findings.

Outcomes:

UREC shall either:

- 1) Uphold the complaint and withdraw ethical approval for the research. All research must stop, and any data collected as a result of this research must be discarded and not used in future research or publications. Research may only commence again once a new application for ethical approval has been submitted and approved, or
- 2) Uphold the complaint and issue a warning to the researcher. A request for variation to the application is to be submitted to UREC if required.
- 3) Uphold the complaint and provide advice to the researcher on how to avoid ethical difficulties in their future research.
- 4) Find the complaint is unfounded with no evidence of misconduct identified in the investigation.

In all cases where any form of misconduct has been identified, appropriate parties at Unitec will be notified for follow up according to the relevant Unitec policies.

4. GUIDELINES FOR COMPLETING AN APPLICATION FOR ETHICAL APPROVAL

4.1. Project Information

4.1.1. Approval by another Pathway or Institution

Research conducted in community agencies will, in most cases, not involve another ethics committee. However, written consent from the head of any agency in which research is being undertaken or who is a collaborator in the research will in most cases be required. Exceptions can include where the subject of the research has no direct connection with the work of the agency, or where participants are clients of the agency (e.g., the agency is where they live), rather than employees.

In cases where more than one school or practice pathway of Unitec is involved in a research project, written approval must cover all relevant pathways.

In the case of projects where a student is the principal researcher, it is the responsibility of the principal supervisor to ensure all necessary consents are obtained from outside agencies and other pathways of Unitec.

4.1.2. Approval by another Ethics Committee

Aspects of a research project may need ethics approval from another institution external to Unitec. For example, if the researcher is using patients from a health service provider, ethics approval may be required from a Health and Disability Ethics Committee.

If the researcher is a student at another tertiary education institution (e.g., university or polytechnic) and ethics approval has been granted from that institution, UREC does not require a second and separate application, but a copy of that application and a copy of the ethics approval must be submitted to UREC as soon as it is available.

If the research is undertaken as part of a collaboration involving multiple organisations or institutions then ethical approval should be obtained from the primary investigators institution. Details of this approval should be provided to the Ethics Secretary for noting by UREC.

For approved research, liability will normally rest with the institution approving the research.

4.2. Project Details

This section covers information to consider when discussion Project Details, Participants and Data Collection.

4.2.1. Methodological Considerations

When designing research and choosing methodology, there are a number of ethical considerations to take into account. Some of these key areas are discussed below.

4.2.2. Research Design Adequacy

Researchers must ensure that their research design is adequate to allow ethically robust research to be carried out. This includes consideration of the following elements:

- 1) The aims and objectives of the project.
- 2) The value and benefits of the project.
- 3) Appropriate project duration.
- 4) Appropriate sampling procedures.
- 5) The selection of a suitable methodology and suitable methods.
- 6) The development of rigorous data collection tools.
- 7) Appropriate data analysis and reporting.

In the case of student research, the research supervisor can assist with research design adequacy. All student research proposals should be considered and approved by the appropriate body.

In the case of staff research, staff should consult appropriately and seek peer review for the proposal.

4.2.3. Anonymity

Generally, the best protection of the confidentiality of personal information and records is achieved through anonymity. Returned or recorded survey instruments (such as questionnaires and interviews)

should not include information that may directly, or by inference, identify an individual or organisation without their prior written consent to this effect (e.g., name, address, email address, phone numbers, and detailed description of person or organisation). Often code numbers are used merely to track responses and follow up on this. In some instances, which must be justified by the applicant, personal identifying information may need to be collected in order to follow up on the responses made by individual participants. This may be required when, for example, further selection is made from questionnaire responses to select a subset of participants for more detailed interviews. It is recommended that in such circumstances, a separate file linking response form codes to individuals be maintained with access limited only to the principal researcher. In all cases, this intent should be provided on the information sheet and agreed to in advance by the return of the questionnaire or signed consent form. Only the researchers in the project and their supervisors should have access to the data.

4.2.4. Limitations of Deception

Deception occurs when researchers represent their research as something other than what it is. This may take the form of deceiving participants as to the true purpose of the research, the methods that are being used to collect the data, the participants' actual role in the research, the uses to which the data will be put, or any other action that limits participants' understanding of what the research is actually about. Deception also occurs when a researcher omits data or analyses data in ways that reduce the validity of the research. The offering of inducements to potential participants may also constitute deception.

Researchers should consider carefully how deception will be avoided. UREC considers any deception inherent in a research project to be very undesirable.

4.2.5. Storage and access to data

It is necessary for research projects to ensure that arrangements for the storage of data are at least as secure as the source from which the data was obtained. Access to data should be restricted to the researchers and their supervisors and participant identifiers should be removed as soon as practicable.

Research files may contain confidential information, and it is essential that researchers ensure that this information is stored and dealt with appropriately and that access to the information only be given to authorised persons. Research data and consent forms must be retained for a period of 10 years. However, it may be that the conditions of informed consent to participate in a research procedure will themselves require that the data generated be destroyed once the research information is extracted. In presenting the results of the research, information that may directly, or by inference, identify an individual or organisation should not be given.

Consent forms should not be stored in the researcher's home. The expectation of UREC are for these to be stored securely on Unitec premises. In the case of student researchers it is the responsibility of the supervisor to ensure both consent forms and the data obtained in the course of the research are secured adequately and retained for the correct length of time.

4.3. Benefits/Risk of Harm

This section outlines issues you have to consider when discussing the benefits and risks of harm associated with the research.

4.3.1. Minimisation of Harm

The risk of harm is as important as actual harm. 'Harm' is defined as that which adversely affects the interests or welfare of an individual or a group. The types of harm extend to physical, psychological, economic and social harm. Harm includes discomfort, anxiety, pain, fatigue, embarrassment and

inconvenience. UREC adopts very strict criteria on harm minimisation. Listed below are the areas of concern.

- 1) Lack of anonymity for participants.
- 2) Lack of confidentiality of information.
- 3) Requests for sensitive information.
- 4) Use of deceit.
- 5) Use of medically invasive procedures.
- 6) Cultural insensitivity.
- 7) Use of 'vulnerable' participants or those unable to give fully informed and voluntary consent.

4.3.2.Harm or risk of harm

In general there are three kinds of impact which a research procedure may have on those participating: physical harm, psychosocial harm, and the risk of either (as opposed to its actuality).

Physical harm	What is called for is the minimisation of the harm and the maximisation of the good that results. A change in procedure (even at more inconvenience to the researcher) might reduce or eliminate the harm while leaving the good to be produced unaltered.
Psychosocial harm	Psychosocial harm ranges from the invasion of privacy and the diminution of social reputation, to the creation of enduring psychological fears and confusions. Procedures must be established to minimise psychosocial harm. The procedures extend to processing, publication, storage and disposal of information. All information generated in the course of the research may contain sensitive details of individuals' private lives or may contain information affecting their assessed medical status and so on.
Risk of harm	Often what will be involved is not actual harm of any sort to participants but the risk of some harm. As in the case of harm itself, what is called for is the minimisation of the risk and the maximisation of the good that results.

4.3.3.Permissible levels of risk

Copies of the questionnaires, focus group and interview schedules and / or protocols, and / or experimental protocols and procedures used, must be submitted with the application to UREC. Where these are necessarily provided to participants in a language other than English, a translation into English of any such questionnaire must also be submitted if required by UREC. Where translation has occurred the researcher must submit evidence that the translation has been professionally verified.

Arguably, some participative research paradigms limit the degree to which methods and tools can be explicit at the point of application. In such cases, protocols describing the relationship of the

participants to the applicants, and letters of support from the participants or their representatives would be important.

4.4. Informed and Voluntary Consent

4.4.1. Informed Consent

Informed consent is generally required in written form. It may be more appropriate to acquire verbal consent from individuals, whānau members and members of a hapu or iwi. This is acceptable as evidence for informed consent.

Verbal consent should be documented in the researcher's notes, indicating the time and place the verbal consent was obtained and who provided the consent. If possible digital recordings of consent should be obtained.

4.4.2. Limitations to consent

Any relationship between researcher and participants that may compromise informed consent or the truthfulness of participant reports must be stated. In some special cases it will not be possible to obtain informed consent because those participating are not competent to offer such consent. In these cases it is essential to ensure that there are care-givers who may speak responsibly on their behalf and to ensure that the informed consent of those authorities is obtained. All participants under the age of 16 require the consent of parents or care-givers, where appropriate. Refer to Appendix 2 – Ethical Guidelines for Intervention Studies, Revised Addition for more information (<http://neac.health.govt.nz/>).

There are potentially other participants whose ability to give informed consent may be compromised or limited in some way or other, for example, students, employees, legal minors, persons with diminished capacity (e.g., having an intellectual or psychiatric condition), or people in institutional settings (hospital patients, prisoners).

4.4.3. Information Sheets

It is all too easy to manipulate a person's 'voluntary' consent by exploiting their ignorance, fears and respect for experts or superiors. Applications for projects must therefore be accompanied by Participant Information Sheet/s that describe, in the participant's language, the essential points which any reasonable person would wish to know before agreeing to participate, including:

- 1) What the research is about.
- 2) What they are being asked to do.
- 3) What the likely consequences are for them should they participate.
- 4) That there are no disadvantages / penalties / adverse consequences to not participating or withdrawing from the research.
- 5) Any special conditions of the research that might affect their participation, e.g., that there will be audio-taping, videotaping or photography.
- 6) How confidentiality of information will be preserved.
- 7) A schedule for the destruction of personal identifying information, and the disposal of any human tissue or body fluids collected.
- 8) The host institution for the research.

-
- 9) The researchers who will actually make direct contact with the participants.
 - 10) The supervisor for the project.
 - 11) A means (for example, a telephone number) by which participants are able to contact the researchers, the supervisor and the secretary of UREC to ask further questions.
 - 12) The Unitec Approval Statement.
 - 13) Information on compensation available to participants if relevant.

It is essential that the Unitec Approval Statement be included as this clearly shows that the research has the approval of the Unitec Research Ethics Committee.

There are some cases where it is not appropriate to provide a written information sheet (for example, with young children it would be more appropriate to provide them with a verbal explanation). A Dialogue Statement of the verbal information that will be communicated should be provided.

It is also important to consider what, if any, inducements might be offered to potential research participants and whether or not such inducements will influence the voluntary nature of participants' involvement.

4.4.4. Consent Forms

Wherever possible, written informed consent of the person is required. This should be done using a consent form. Consent forms must have a brief explanation of the research, the Unitec Approval Statement and include statements about being fully informed, voluntary choice, confidentiality, appropriate time for consideration and understanding the complaints process. (See 'Complaints Procedures' within this document). People from whom tissue or body fluids are obtained are regarded as participants in terms of informed consent.

Where appropriate, the consent form used must be provided with the application to UREC. The researcher should advise the participant that a copy of the information sheet and consent forms should be retained by the participant. Where these are necessarily provided to participants in a language other than English, a translation into English of any such questionnaire must also be submitted if required by UREC. If translated documents are used in the research then you must provide UREC with confirmation that the translations are correct and have been professionally verified.

It is acceptable to present a consolidated information sheet / consent form as long as the participants are provided with a copy of the document and have been given an opportunity to reflect on the document before indicating their consent. Consent forms should be held securely, on Unitec property (unless justification can be made for this not being the case), separate from the data, until the latter are destroyed.

Exceptions to written consent might be mass-distribution questionnaires and very simple procedures (e.g., hearing tests) and procedures where the participant's ignorance of the intended research objective is essential (this must be exercised with extreme caution and with proper justification). For some questionnaires (particularly anonymously returned questionnaires), the return of the questionnaire can be reasonably taken as an indication of voluntary consent to participate, and this fact should be clearly stated on the questionnaire and information sheet.

4.5. Conflict of role/interest

4.5.1. Funding

Researchers must indicate whether the project is being funded in any way, either through cash or in-kind support, by any person or organisation both internal and external to Unitec. Any financial interest

of the researcher, the host institution and / or a sponsoring agency in the outcome of, or involvement in, the project should also be fully disclosed.

4.5.2. Avoidance of conflict of interest

It is important for the researcher to declare any special relationships that exist with the research participants, e.g., friend, whānau/family, colleague- colleague, student-teacher. Aspects of the research design that will minimise the effect of such relationships must be carefully considered and clearly articulated to UREC. Where the relationship involves power being exercised, or potentially exercised, by one person over another, e.g., employee-employer, principal- teacher, these considerations are particularly important. Issues of gender, ethnic group and age may also be relevant here. Where this involves staff-student relationships specifically pertaining to intellectual property and authorship, please refer to the Intellectual Property Policy and Guidelines for further information.

4.5.3. Commercial Relationships

Any benefits to the researcher, the host institution or a sponsoring agency that will or might arise from a particular research outcome or from involvement in the research, must be disclosed. Where commercial relationships have the potential to influence outcomes, procedures must be adequately described so that an ethical judgement can be made as to the independence and transparency of the research.

4.6. Treaty of Waitangi

4.6.1. The Treaty of Waitangi (and Maori participation in research)

Unitec states its commitment to the Treaty of Waitangi through the Partnership document, Te Noho Kotahitanga. This document includes values that support Unitec in developing a meaningful partnership with Māori. In relation to research and research ethics, Te Noho Kotahitanga states that 'Unitec accepts responsibility as a critical guardian of knowledge' or 'taonga mātauranga', therefore, UREC will act as kaitiaki to ensure that Māori knowledge and processes in research be protected. In the spirit of the partnership, all researchers have a right to include Māori in their research projects and with this right is the responsibility to consult appropriately and conduct research in a culturally sensitive and respectful manner.

The Unitec Research Ethics Committee (UREC) has produced guidelines to assist researchers who intend undertaking research that may involve Māori participants (through random selection), involve Māori, Māori-centred research and kaupapa Māori research.

For further guidance, contact the Māori Development Centre (MAIA) on 09 815 4321 ext 8695 or, refer to the Guidelines for Researchers on Health Research Involving Māori (consult www.hrc.govt.nz).

4.6.2. Non-Maori researching Maori

Non-Māori are able and encouraged to include Māori participants into their research so that all New Zealanders can benefit from the research. The inclusion of Māori in research gives Māori the right to benefit from a share in what is ultimately state funded (tertiary) research. It is important that an appropriate education in cross cultural research skills and cultural safety be available for the researchers. At Unitec you can contact MAIA, the Dean, Teaching and Learning Mautaranga Maori or faculty advisors.

4.6.3. Research that MAY involve Maori

Researchers whose intended research project may involve Māori participants through random sampling, or involve Māori as participants where Māori data is sought and analysed, are asked to outline the protocols and processes used throughout the research. Researchers should identify the person / people who have been consulted and their role in this project. Advice from UREC members

can be sought. It is expected that at least preliminary consultation will have occurred before the submission of your application for ethical approval.

4.6.4. Research that Involves Maori

Consultation with either the Māori UREC members, appropriate members of the Unitec community or the wider community will be required, if the research proposals involve Māori as participants or where Māori data is sought and analysed. This should occur before your ethics application is submitted.

4.6.5. Maori-Centred Research

Consultation with Māori UREC members, appropriate members from the Unitec community or from the wider community will be required, if Māori are significant participants and where an analysis is undertaken which produces Māori knowledge.

4.6.6. Kaupapa Maori Research

Kaupapa Māori research is research where Māori are significant participants, where the research team is typically Māori, a Māori analysis is undertaken and Māori knowledge is produced. Māori tikanga (protocols) and processes are followed throughout the research from the beginning to the dissemination of results to participants. Consultation with Māori UREC members will be required, or with appropriate staff members within Unitec, or appropriate members from the wider community.

4.6.7. Kaupapa Maori Workshops and Training

Periodically, workshops on Kaupapa Māori research and methodologies are held for Unitec staff. For more information about these workshops, contact the Research Office, MAIA, Pukenga or Te Puna Ako.

4.6.8. Supervision

It is advisable that Māori advisors/supervisors assist with research projects that include a Māori kaupapa or where Māori are significant participants.

4.7. Cultural Issues (Ethnic/social groups other than Maori)

4.7.1. Cultural and social sensitivity

It is important that issues of cultural safety are addressed when research involves participants from various ethnic or cultural groups, even when small numbers from each group are involved. Where a particular ethnic or cultural group is the subject of the research, consultations must be undertaken with appropriate parties and this process outlined in the application.

The Health Research Council has the following advice to consider in relation to health research, but the principles described here should be considered in all research.

People of different cultures hold differing basic beliefs, have different value systems and regard differing modes of behaviour as acceptable to them. Since health involves matters which are often deeply personal and private, procedures for health research can very easily cause offence both to individuals and to ethnic groups, even though none has been intended.

Not only must there be due recognition of the indigenous culture of the Māori as the tangata whenua (indigenous people) but also due allowance for the increasing diversity of culture and religious belief which is now appearing in New Zealand society.

Practices and beliefs of an ethnic and / or religious nature must be fully respected. Research must be undertaken in a culturally sensitive and appropriate manner, in full discussion and partnership with the

research participants whatever their ethnicity or religious affiliation, and the results of any investigation should be appropriately disseminated in a full and frank manner.

Participants have the right to receive, in language that they will easily understand, information about proposed research in which they are being invited to participate. Where large numbers of participants from an ethnic group are being recruited, a translation of the participant information sheets and the consent form should be provided. In seeking informed consent, the involvement of a trained interpreter is highly desirable. If the number of participants from any ethnic group is small, the use of trained interpreters to read and discuss the information sheet with the participant may obviate the need for a printed translation. However, a translation of the consent form should be provided. In certain circumstances, a verbal consent is considered appropriate (p. 21, HRC Guidelines on Ethics for Health Research, 2002 – consult www.hrc.govt.nz).

Where participants are sought from a particular social group, e.g. rest home residents, people with English as an additional language, the particular needs of these participants must be considered including how harm minimisation concerns might be best addressed.

4.7.2. Pacifica Research

The Centre for Pacific Development and Support is available to provide support in many ways including academic assistance. For more information contact the centre directly on 09 815 4321 ext 7349.

4.7.3. Consultation

The purpose of consultation is to ensure that the research practices are appropriate and that research will be conducted to ensure safety for the participants, the researcher and Unitec. Appropriate consultation endeavours to establish a foundation for a collaborative relationship between researchers and participants.

4.8. Sharing research findings

4.8.1. Intellectual property

Researchers should check Unitec's intellectual property policy for guidelines on intellectual property ownership. See the section titled 'Commercialisation and Intellectual Property'.

4.8.2. Cultural property

Researchers should check Unitec's intellectual property policy for guidelines on intellectual property ownership. See the section titled 'Commercialisation and Intellectual Property'.

Researchers should carefully consider how the results of their research will be most usefully shared with and used by the participants and by the wider group(s) to which the participants belong. Where research information is disseminated in inappropriate or untimely ways, harm may be caused to participants. Consultation with participant groups should direct the researcher to the most appropriate processes in this regard.

Researchers should consult with the Māori members of UREC if issues of intellectual and cultural property ownership of Māori are likely to arise in the context of their research. The Health Research Council publication Guidelines on Health Research Involving Māori (1998) provides detailed advice on these matters (consult www.hrc.govt.nz).

4.9. Invasive procedures/physiological tests

4.9.1. Definition of clinical trial

The definition of clinical trial varies depending on the context in which it occurs.

A ‘clinical trial’ is defined by the Ministry of Health as “a pre-planned, controlled clinical study designed to evaluate prospectively the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans”.

The definition adopted in the context of the accident compensation legislation defines a clinical trial as “any research on human participants conducted to gain new knowledge into mental and physical health and disease” (Ministry of Health and ACC, 1993). It would exclude research based on the analysis of secondary sources of health information. Clinical trials often involve a wide range of health professionals with different qualifications, skills and expertise and would usually be conducted in hospitals, other health care settings, the community and academic host institutions. This definition is somewhat broader but is acceptable for the purposes of government-sponsored compensation to participants.

For ethical review by UREC, the broader interpretation is preferred to ensure the protection of participants’ rights, safety and welfare. Therefore, declarations for Accident Compensation coverage may need to be completed by the applicant.

4.9.2. Medical research involving human tissues or fluids

UREC may approve research that involves routine and simple methods of tissue or fluid collection, involves only minimal risk in obtaining such samples, and which it has the expertise to review. Any significant medical research or clinical trial will require ethics approval through an accredited Health and Disability Ethics Committee. In either case, the use of any invasive medical procedures or use of drugs must be identified, along with the safeguards that will ensure against infection, damage or risk to health. Declarations for Accident Compensation coverage may need to be completed.

Where the researcher intends to use tissues or body fluids, details of storage and the manner of disposal must be described. Issues of cultural sensitivity and accident compensation should also be addressed. Research involving human remains must be referred directly to a Health and Disabilities Ethics Committee for approval. Contact either the Health Research Council Ethics Committee or a Health and Disability Ethics Committee for the full procedures for ethical approval of such health research.

4.10. Declaration and Indemnity

All applicants are required to sign a declaration guaranteeing the accuracy of the information provided, and that the ethical conduct of the research as approved by the Unitec Ethics Committee will meet the requirements of Unitec research policies and procedures.

Any significant departure from the project approved, particularly around issues of consent, confidentiality, sensitivity and potential harm to participants, must be notified to the committee and approval sought before proceeding with the changes.

Provided the research is properly conducted within the limits of the approval, the researcher is indemnified against and accident or misadventure that may occur.

REFERENCE DOCUMENTS

- 1) Guidelines on Ethics in Health Research (consult www.hrc.govt.nz)
- 2) Guidelines for Researchers on Health Research Involving Māori (consult www.hrc.govt.nz)
- 3) Guidelines for Institutional Ethics Committees to Refer Research Studies to a Health and Disability Ethics Committee (consult www.hrc.govt.nz)

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- 4) Application for Ethical Approval – Form A
- 5) Application for Ethical Approval – Form B
- 6) Application for Ethical Approval – Form C
- 7) Research Ethics Policy
- 8) Guidelines for Researchers Regarding Maori Social and Cultural Responsiveness
- 9) Participant Information Sheet Template
- 10) Consent Form Template – Participants
- 11) Consent Form Template – Organisations
- 12) Confidentiality Agreement Template
- 13) Unitec Application Screening Questionnaire
- 14) Checklist For Applicants

DOCUMENT DETAILS

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