University of Auckland
Human Participants Ethics Committee
(UAHPEC)

Guiding Principles for Conducting Research with Human Participants

Approved by Council on 7 March 2016
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1. INTRODUCTION

The ‘Guiding Principles for Conducting Research with Human Participants’ provide the means by which the University of Auckland, (hereafter “the University”) meets its obligation to ensure that all research with human participants that is conducted by members of the University conforms to the highest ethical standards. In this way, research participants are treated with respect and dignity and their privacy, safety, health, and personal, social and cultural sensitivities are protected.

Research with "human participants" is broadly defined. The University understands research to be ‘original investigation undertaken in order to contribute to knowledge and understanding and, in the case of some disciplines, cultural innovation or aesthetic refinement’ (see Glossary for an expanded definition). A human participant is a person with whom there is some intervention or interaction that would not be occurring, or would be occurring in some other fashion, but for the research, or as a result of the research. Research with human participants includes the acquisition and study of data through intervention or interaction with the individual or from individually identifiable information. It also includes research on human remains, tissues or bodily fluids. For the University, it is understood to include also research using anonymous questionnaires, research within teaching sessions and research carried out as part of coursework, conducted within and outside the University.

The Guiding Principles set out the key ethical considerations that researchers should be guided by when designing and conducting their research projects. For more information about how the principles contained in this document should be put into practice, researchers should refer to the Applicants’ Reference Manual. The manual gives detailed guidance on the mandatory items that must be included in the ethics application and includes other information essential for making ethics applications. The manual can be found at http://www.auckland.ac.nz/uoa/re-uahpec

2. SCOPE OF THIS DOCUMENT

This document has been developed for members of the University involved in research with human participants. In particular, the document is intended to provide guidance to researchers conducting research with human participants, ethics advisors and members of the University of Auckland Human Participants Ethics Committee (UAHPEC). Researchers should refer to both the Guiding Principles and the Applicants’ Reference Manual when designing research projects and
when applying to UAHPEC for ethics approval. The Guiding Principles requires review and approval by Council every three years.

3. ROLE, FUNCTION AND MEMBERSHIP OF THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE

3.1 Overview

The University recognises the need for research studies in which people serve as research participants. At the same time, the University is aware of its responsibility to ensure that the welfare, privacy, safety, health, and personal, social, and cultural sensitivities of participants are adequately protected. Thus, the University has established a committee – the University of Auckland Human Participants Ethics Committee (UAHPEC) - to review and approve the adequacy of protection for human participants.

It is the policy of the University that, prior to commencement of research, all staff or student research projects as well as research within teaching sessions that involve human participants must receive approval from UAHPEC.

UAHPEC does not grant retrospective approval.

No research project involving human participants can be carried out by members of the University without the approval of UAHPEC, unless an exemption applies. This is subject to the proviso that for health and disability research that falls within the scope of a Health and Disability Ethics Committee (HDEC) review, a Ministry of Health HDEC must approve the research. Exemptions from obtaining ethics approval are listed in the Applicants’ Reference Manual, section 3.8.

The requirement for all staff and student research projects that involve human participants to obtain approval is set out in the University of Auckland Human Participants Ethics Committee Policy at: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/ethics/ethics-review-of-proposals-involving-human-participants-policy.html

3.2 Terms of reference
UAHPEC’s terms of reference are as follows:

- To ensure that research involving human participants conducted by members of the University community complies with the highest ethical standards
- To protect the interests of participants, the researcher and the University of Auckland
- To promote awareness within the University community of ethical issues relating to research with human participants
- To provide an avenue for handling complaints or queries made by any interested person.


3.3 Function of UAHPEC

The function of UAHPEC is to review proposed research involving human participants that is conducted by members of the University.

The UAHPEC will:

- review and where satisfied that it is appropriate, approve submitted research for compliance with ethical principles
- review and where satisfied that it is appropriate, approve submitted amendments to an approved study
- provide advice and assistance to anyone undertaking such research
- receive, record and respond to information concerning adverse events

In assessing applications, UAHPEC reserves the right to seek expert opinion, including from relevant committees such as the Health Research Council Ethics Committee (HRC EC), Standing Committee on Therapeutic Trials (SCOTT), Gene Technology Advisory Committee (GTAC), Ethics Committee on Assisted Reproductive Technology (ECART), the National Ethics Advisory Committee (NEAC) and the Health and Disability Ethics Committees (HDECs).

The attention of researchers applying for ethical approval is drawn to Section VI of the University of Auckland Charter 2003 acknowledging the Treaty of Waitangi:
UAHPEC will respond to requests for advice on ethical matters concerning research prior to application for ethical review and / or in relation to research that is ongoing and has been approved by the committee.

3.4 Membership of UAHPEC

The committee membership profile reflects the requirements of the University and Health Research Council (HRC) approval requirements. As far as is possible, the committee should include the representatives specified below. Overall, the committee will have a balance of institutional and lay members, at least two Māori members, representation of the community-at-large, expertise in clinical aspects of the social sciences, appropriate ethnic and gender balance, and a balance of disciplines and expertise.

UAHPEC operates with a two-tier structure, comprising an over-arching committee (UAHPEC) and two sub-committees (HPEC-A and HPEC-B), each serving a similar function and having the same roles and responsibilities.

3.4.1 Membership profile

As a minimum, each of the sub-committees will include:

- One member nominated by the Dean of the Faculty of Arts (Institutional)
- One member nominated by the Dean of the Business School (Institutional)
- Two members nominated by the Dean of the Faculty of Medicine and Health Sciences (Institutional)
- One member nominated by the Dean of the Faculty of Science (Institutional)
- One member nominated by the Dean of the Faculty of Education and Social Work (Institutional)
- One member nominated by the Dean of the Faculty of Engineering (institutional)
- One member with legal expertise nominated by the Dean of Law (Institutional/Lay)
- Deputy Vice Chancellor (Research) or nominee (Institutional)
- One member who has expertise in the area of moral philosophy appointed by Council on the advice of the Head of Department of Philosophy (Institutional/Lay)
- Pro Vice-Chancellor (Māori) or nominee (Institutional/Lay)
3.4.2 Term of membership
The term of membership is two years with the exception of student representatives for whom the membership term is one year. Appointments may be renewed, but no member shall serve more than four consecutive terms.

3.4.3 Chair
The Chair is appointed by Council, in consultation with the committee if necessary. Either the Chair or Deputy Chair is a lay person. The term of the Chair is two years. Appointments may be renewed, but no Chair shall serve more than four consecutive terms.

3.4.4 Reporting to Council
UAHPEC reports to Council annually, and at other times as requested by Council.

3.4.5 Quorum
A quorum consists of not less than eight members of the sub-committee membership (i.e., in either HPEC-A or HPEC-B).

4. ETHICS FRAMEWORK FOR RESEARCH WITH HUMAN PARTICIPANTS

4.1 Introduction
The University requires research with human participants to be designed and carried out to the highest ethical standards. The four key principles of ethical research which UAHPEC requires to be applied to the design, conduct and ethics review of research are autonomy, beneficence, non-maleficence and justice. The value underlying these principles is respect for people.

4.2 Key principles

(i) Autonomy

The principle of autonomy requires that research participants’ capacity for self-determination is treated with respect. Participants should freely consent to their participation in the research study and their consent should be informed by relevant information provided by the researchers. Autonomy may also refer to the autonomy of groups in society.

(ii) Beneficence

The principle of beneficence is about acting in the public good; it includes all actions which are intended to promote the good of other people. Researchers should consider how their research study might be of benefit to participants, groups and/or wider society. There may be direct benefits to the participant, for example through the intervention they receive, or to wider society through the results of the research.

(iii) Non-maleficence

Researchers have a duty to consider the harm that their research project might cause. Research should minimise and manage risks of harm, such as the risk of physical or psychological harm to research participants or researchers. The greater the risk of harm that might result from the research study, the greater the care that should be taken when addressing the ethical issues raised.

(iv) Justice

Justice is about treating others equitably and distributing burdens and benefits fairly. Researchers have a duty to ensure that the benefits of their research are achieved through just means; that the benefits and burdens of research are fairly distributed; and that there is fair treatment in the recruitment of participants.

4.3 Congruence with Health Research Council ethics framework

The above four principles are widely accepted as key principles that guide all research ethics communities. They are complementary and interdependent and how they apply, and the weight accorded to each, will depend on the nature and context of the research being undertaken.
UAHPEC expects that researchers will at all times respect and provide protection for their human participants. It also expects that the research will be conducted in a manner that conforms with the highest ethical standards and in accordance with the ethical guidelines of the researchers’ respective professional or disciplinary societies.

UAHPEC is an HRC-approved ethics committee; continuing approval is dependent upon the HRC Ethics Committee being satisfied that UAHPEC “is able to offer sufficient protection to the research participants and can maintain the reputation of ethical review in general.” (Health Research Council, 2012, p. 4).

5. APPLYING THE CORE PRINCIPLES TO THE DESIGN, CONDUCT AND ETHICS REVIEW OF RESEARCH

5.1 Research aims and design

In requesting the time and input of participants, the researcher has an obligation to ensure that the research methods used are adequate to answer the research questions or to realise the research aims and objectives. To justify the involvement of human participants, studies must be well-designed.

The researcher is also obliged to ensure that research involving human participants has a value, be that real or potential, theoretical or applied, direct or indirect, that justifies participants’ time and input.

5.2 Recruitment of research participants

The researcher should choose a method or methods of approaching potential research participants that takes account of potential imbalances of power between researchers and participants.

5.3 Inducements, compensation and reimbursement

Where research participants incur costs, it is appropriate to reimburse them. The committee also considers that it is ethically acceptable to compensate participants in some way for their time. However, payments, or other forms of compensation, should not be so large as to unduly induce individuals to consent to participate in the research.
5.4 Free and informed consent

Competent individuals should participate in research only if they have given their free and informed consent. Therefore, the researcher must provide participants with adequate information about the purpose of the research, methods of participant involvement, and intended use of the results. This information must be provided in a manner that most easily and effectively permits the potential participant to understand and voluntarily commit to participation in the project. Clear and comprehensible information that is appropriate to the particular context needs to be used in the Participant Information Sheet (PIS) and Consent Form (CF).

Special care in preparation of documents is required for studies including children, persons with special needs and individuals with diminished autonomy as participants. When dealing with these vulnerable individuals, the researcher must consider whether they are able to give free and informed consent or whether the consent of one or more guardians may be required.

5.5 Protection of research participants’ privacy and confidentiality

The researcher has a duty to safeguard participants’ privacy and confidentiality. This duty extends to the appropriate use of third parties to provide information about potential participants. The researcher must make clear to participants the extent to which their participation in the research will be known to others. The researcher must store data and disseminate results in a manner consistent with what the researcher has told participants about their privacy and in accordance with the University data storage policy, included in the Code of Conduct for Research (2012) which can be found at https://policies.auckland.ac.nz/policy-display-register/code-of-conduct-research.pdf

For more information about the Privacy Act 1993 and associated Codes of Practice, please see Appendix 1.

5.6 Limitation of deception

Research which involves deception violates the principle of autonomy, and the use of deception in research must be well justified. Justification must include reference to the significance of the potential knowledge to be gained, and demonstrate that there is no less deceptive means reasonably available. Participants must be offered a de-briefing session after the data-gathering in which the deception is explained. This debriefing must occur as soon as possible after data acquisition. UAHPEC will very carefully review any study
which proposes using deception and will require a clear justification from the applicant as to why the deception is considered necessary for the study and how participants will be safeguarded.

5.7 Minimising harm

Many research studies carry some risk of harm, but it is the duty of researchers to minimise that risk. Researchers have a responsibility to assess their research and to discuss any potential for harm to individuals or communities in their application for ethics approval. Whenever there is risk of harm, they should give careful consideration to possible alternative procedures. Researchers must be mindful of their own safety and well-being as well as that of participants and communities.

Researchers should consider both the seriousness of the harm and the likelihood of the harm occurring, and take account of the balance between these factors.

Potential participants must be made aware of potential risks and mitigations, and acknowledge these in consenting to participate in the research. This can be done by means of the PIS and CF. Appropriate monitoring and support procedures should be put in place during and after research activities. In their ethics application, researchers must stipulate what resources will be available, and what procedure will be followed, should participants experience harm or distress as a result of participating in their research study. If appropriate, the researcher should describe to UAHPEC the experience available in the research team to deal with such potential harm.

The University’s liability insurance programme includes the requirement to obtain ethics approval (see section 6.7). Further information on risk management and liability insurance is available from the University’s Performance and Risk Office (ext. 87834).

5.8 Conflict of interest

It is the duty of the researcher to avoid conflicts of interest and to declare in the ethics application form and PIS anything that could be perceived as a conflict of interest. The purpose, nature and funding of the research should be clearly stated. If the research is funded, the support and its source must be identified in the PIS and research reports. In addition, the researcher must be sensitive to possible conflicts of interest between the participants, such as those that might arise between parents and their children, principals or CEOs and their staff, clinicians and their patients, or teachers and their students.

5.9 Social and cultural sensitivity
The researcher has a duty to treat all participants with dignity and respect. Researchers must ensure that their actions and intentions are appropriately sensitive to participants’ cultural and social frameworks. Where appropriate, the researcher will provide information in the first language of the participants. When research involves particular cultural or social groups, the researcher has a duty to find and use appropriate channels to seek permission to work with such groups and, where appropriate, consult with them about the appropriate conduct of research.

5.10 Vulnerable participants and communities

Vulnerable individuals and communities are able to be included in research projects where appropriate, but special care needs to be taken when research involves vulnerable participants. The researcher should take special care to ensure that the interests of vulnerable participants and communities, whether participating in the research or affected by it, are protected. Furthermore, researchers should inform the committee as to how they will protect the interests of vulnerable participants and communities.

5.11 The Treaty of Waitangi / Te Tiriti o Waitangi

The Education Act 1989 specifically enjoins the University to give regard to the Treaty of Waitangi/Te Tiriti o Waitangi. The University recognises that all members of its community are encompassed by the Treaty of Waitangi/Te Tiriti o Waitangi with mutual rights and obligations. Research proposals must incorporate, where appropriate, the spirit of the Treaty of Waitangi/Te Tiriti o Waitangi. This means that all parties involved in the research project must respect the principles of partnership and sharing implicit in the Treaty/Te Tiriti o Waitangi.

The researcher has a duty of care to approach research pertaining to Māori in a culturally sensitive way. When research focuses on Māori, or if there are clear potential implications of direct interest to Māori, the researcher is required to show that appropriate consultation has taken place, such as discussing any issues relating to Māori cultural and ethical values with the whānau, hapū or iwi concerned.

The Pro Vice-Chancellor (Māori) has a nominee (Māori ethics advisor) in each faculty. Researchers who are conducting research pertaining to or involving interaction with Māori will require the sign-off from the Māori ethics advisor in their faculty.

The Pro Vice-Chancellor (Māori) has a nominee (Māori ethics advisor) in each faculty. Research involving interaction with Māori requires sign-off from a Māori ethics advisor in the relevant faculties.
5.12 Human remains, tissue and bodily fluids

All human remains, tissue and bodily fluids, such as blood samples, must be treated with respect and, in general terms, samples collected for one purpose must not be used for another without the consent of the donor. Further information is available in the Health Information Privacy Code 1994, see especially Rule 10 “Limits on the use of Health Information”: http://privacy.org.nz/assets/Files/Codes-of-Practice-materials/HIPC-1994-incl-amendments-revised-commentary.pdf

The Human Tissue Act 2008 regulates the collection, storage, and use of human tissue in research. Researchers working with human tissue need to demonstrate to UAHPEC that they have understood and taken account of the Human Tissue Act. For further information see: http://www.health.govt.nz/search/results/human%20tissue%20act

5.13 Incidental findings and discovering illegal activity

Research occasionally gives rise to findings that are unexpected and unrelated to the original purpose of the research, but which may have implications for the wellbeing and interests of participants. The most common examples of such incidental findings are when a study discovers a medical condition in a participant, or when a participant reveals in the course of the study that they are party to illegal activity. UAHPEC uses the standard of more-than-minimal risk to identify incidental findings: if a contingency is more likely to arise due to participation in the study than it would in everyday life outside of the study, then it deserves special attention.

The University expects researchers to have clear policies and procedures in place before the start of a research project to enable them to deal with incidental findings. The researcher must indicate how likely an incidental finding may be, and how large the impact of the finding may be to the participant. If researchers believe there is a reasonable probability of incidental findings, they have a responsibility to inform the participant of this in advance. If participants do not want to be informed of such a finding, they should be excluded from the research.

In the case of discovering illegal activities, what should happen will depend on the circumstances. UAHPEC requires the researchers to give consideration to this issue for research where this may be a concern. The researcher/s must explain to UAHPEC (and participants where necessary) how they intend to manage such discoveries.
When there are incidental findings, researchers are expected to advise participants within the limits of their expertise and put participants in contact with appropriate assistance. Nothing in regard to incidental findings should normally compromise participant confidentiality or privacy. However, researchers may have an obligation to breach confidentiality where they consider that appropriate disclosure is necessary prevent or lessen a serious threat to life or health of an individual (participant or non-participant). There may be legal requirements to report certain kinds of discoveries, and it is the researchers’ responsibility to be aware of these.

5.14 Adverse events

An important part of UAHPEC’s responsibilities is the evaluation of events in which research participants have been unexpectedly harmed.

The committee differentiates between “unanticipated problems” and “adverse events”, based on the guidelines developed by the Office for Human Research Protections (OHRP), USA, in their document: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007), available at:

(http://www.hhs.gov/ohrp/policy/advevntguid.html#AA)

5.14.1 Adverse event

Adverse events can arise in both biomedical and social and behavioural research. Serious adverse events are those that result in death, are life threatening, require hospitalisation, cause persistent or significant disability/incapacity, result in birth defects, or other conditions which, based upon appropriate medical judgement, represent significant hazards to the participants. Also included is psychological or emotional disturbance, or infringements of privacy or other rights (for example, from unauthorised access to identifiable personal information or disclosure of confidential information).

Where there is an adverse event, or serious negative effect, the first priority is that the researcher ensures that the affected participant(s) immediately receives care and assistance appropriate to the event or outcome.

If an adverse event affects researchers, then University of Auckland Health and Safety reporting procedures should be followed.

5.14.2 Unanticipated problem

The OHRP defines an ‘Unanticipated Problem’ to be an event which meets the following 3 criteria:

- The event is unexpected,
• It is related, or possibly related, to participation in the research, and
• It suggests that the research places the subjects or others at a greater risk of harm than was previously known or recognised.

In order to fulfill its responsibility to protect all research participants, to the extent that it is possible to do so, UAHPEC requires written reports to be submitted to the committee describing any unanticipated problems involving risks to participants or unexpected serious harm to participants. It is the responsibility of researchers (in the case of students, through their primary supervisor) to report adverse events to UAHPEC. The form for reporting adverse events is available from the Ethics Administrators in the Research Office.

Where there is an adverse event, the affected participant must be put in contact with appropriate assistance by the researcher.

5.15 Storage, security, destruction and retention of data

Information should be handled in a way that protects participants’ confidentiality and ensures the safe custody of the data. Care should be taken to protect the legitimate privacy of individuals, institutions, communities and ethnic groups. Where research involves the use of audio, video or electronic recording, special attention is required to protect confidentiality and security of data.

Clear indication should be given to UAHPEC and to participants regarding the storage and retention of data. Data stored for the purpose of the original research should be accessible by the researcher and supervisor only. Researchers should consider how participants who are under the age of 16 when they give assent to the use of their data can be given the option to consent to the use of their data when they reach the age of 16.

Storage of data for posterity and future research that involves transfer to a public repository may require a suitable release form negotiated with the participant that clarifies conditions of future access. Researchers are expected to advise the UAHPEC in their application of their intention to use such storage and the place and kind of access involved, and to include this in the PIS and CF for participants.

If data are to be disposed of or destroyed, this must be done securely. Clear indication should be given to UAHPEC and to participants regarding the timing and manner of this. If data are not to be destroyed, this must be indicated to participants along with the purpose of retaining them.
The University requires that Consent Forms be retained in secure storage by the researcher (in the case of student research, through the primary supervisor) for a period of six years, separately from the project data. Information relating to the timeframe for storage must be shown at the top of the Consent Form.

5.16 Dissemination of results

The researcher must give due consideration to the availability of research results as one of the public benefits of research studies. Whenever possible, the findings should be conveyed in a comprehensible form to those who participated in the research. The researcher is obliged to do this if they have given the participant the opportunity to receive results and the participant has requested them. Both the process by which results are to be disseminated and the timeframe within which this process will occur must be communicated to prospective participants.

5.17 Complaints procedure

A person wishing to raise a matter of concern or a complaint about research approved by UAHPEC and relating to the ethical standards of research on human participants conducted by members of the University, may do so in writing to the Chair of UAHPEC. The complaints procedure will encompass an investigation of the complaint by the Chair and Associate Director (Post-Award Support Services) using written statements from both the complainant and the researcher of the study. The complaint procedure is set out in full in Appendix 2.

6. APPLYING FOR ETHICS APPROVAL

6.1 Overview

Any member of the University who conducts research of any nature with human participants must apply for ethics approval unless an exemption applies. Exemptions from obtaining ethics approval are listed in the Applicants’ Reference Manual, section 3.8.

6.1.1 Research with ethics approval from other ethics committees

a. Where research is conducted in collaboration with a researcher from another institution with an ethics committee that has approved the research (other than an HDEC), the researcher must submit the ethics application and evidence of ethics approval to UAHPEC and the committee may either ratify the approval or require a full ethics application. Ratification is delegated to the Chair who may refer the decision to a meeting of a UAHPEC sub-committee.
b. Where research is conducted in collaboration with a researcher from an institution where ethics approval is not routinely required, a full application for ethics approval must be made to UAHPEC or one of the HDECs.

c. When a new staff member brings a research project to the University from another institution, unless the project has been approved by one of the HDECs, the original ethics application and approval should be submitted to the Chair of UAHPEC. After considering evidence of how closely the approval process matches that of UAHPEC, the Chair will decide whether it should be submitted to UAHPEC for ratification or not. In either case, the researcher must obtain written approval from the chair.

Failure to obtain ethics approval when it is required, and failure to comply with the policies established by UAHPEC, constitutes research misconduct and may occasion disciplinary action following standard University procedures. See the University of Auckland Code of Conduct for Research (2012) which can be found at https://policies.auckland.ac.nz/policy-display-register/code-of-conduct-research.pdf

If ethics approval has not been obtained, the researcher will not be covered by University indemnity insurance in the event of a complaint or legal suit by a participant.

Researchers should also note that many outlets for the dissemination of research results, such as academic journals, will not accept research results for publication if ethics approval has not been obtained.

6.2 Disclosure

The ethics approval process requires disclosure of all known relevant information about the proposed research proposal to UAHPEC. The principal investigator needs to consider whether a particular piece of information is relevant to the ethics approval process even if the Guiding Principles do not specifically ask for that particular piece of information to be provided.

6.3 Overseas research

Where research is conducted involving participants in overseas localities, the principal investigator must demonstrate that they have considered the safety of the participants and researchers and taken into account ethical conditions appropriate to the area in which the research will take place. They must pay attention to contextual issues and show how they have addressed these.
UAHPEC also requires that local ethics approval is obtained if necessary or appropriate, and that local laws are complied with. A researcher is obliged to be familiar with local law, including in relation to the protection of privacy and data, and must assure UAHPEC that they will comply with local law.

6.4 National Institutes of Health (NIH) funded research

Research on human participants conducted at the University that is supported by U.S. Federal Funds, or research where this institution is a part of a multi-centre study with NIH funding, is subject to special requirements. In order to fulfill the terms of the Federal-wide Assurance with the Office of Human Research Protection, researchers should contact the Human Ethics Administration, ext. 83711, for advice prior to taking up the research grant.

6.5 Coursework-based research

UAHPEC recognises that research may take place in class time with students acting as participants. Such research is usually applied for in a ‘Coursework Application’. Individual student research projects undertaken by students for their dissertation or thesis do not qualify as coursework research.

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6.5.1 Types of Coursework-based research

(i) Laboratory-based coursework
Laboratory participation is a formal requirement of these courses and is stated to be a requirement for the course in the University calendar, Department handbooks and other course descriptions. Individual students are not required to give written consent as their enrolment in these courses is taken as consent. Students may be involved in this research as research participants and/or researchers. The coursework research is explicitly pedagogical, it contributes directly to the course content and objectives, and the information collected is not for wider dissemination. Acquiring research skills may be one objective of laboratory or course-based research.

(ii) Students as participants
Some courses include a research activity that takes place in class time, with students from the course acting as participants. UAHPEC requires that participation in these types of research exercises remains voluntary and that alternative activities are provided for students who choose not to participate.
Consent to participate should be obtained from each student participant.

(iii) Some courses include student research projects that either have a common set of research questions and procedures that do not vary from student to student, or students choose their own research questions and procedures as long as these do not vary significantly from those of other students in the course. It is the responsibility of course coordinators to ensure that students understand and observe the ethical principles and requirements applicable to such projects and for ensuring compliance with UAHPEC requirements.

6.5.2 Research in class time
This is research undertaken during class time for research purposes of a staff member or student who may or may not be a member of the teaching staff of that course.

It is University policy that research in class time is not permissible except under the following three conditions:

- the research is directly related to course content
- the express written consent of the course coordinator is given to conduct the research in class time, and
- the course coordinator is satisfied that the students will be debriefed as to the aims, hypotheses and, where possible, results of the research. Such assurances should be included in any application to UAHPEC.

If a research project meets these criteria, the ethics application must be completed as a research application and not a coursework application.

6.6 Funded research

Funded research projects, including those funded by external funding sources and commercial contracts via UniServices, are subject to the same ethical review as all other research projects.

6.7 Liability insurance

The University maintains a liability insurance programme which extends to the performance of clinical trials. The policy conditions include the requirement to obtain ethics approval and to adhere strictly to the approved protocol. For more information please contact the University’s Planning and Risk Office.
7. REFERENCES


8. GLOSSARY

**Adverse events in research**

An adverse event is any untoward or unfavourable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

Serious adverse events are those that result in death, are life threatening, require hospitalisation, cause persistent or significant disability/incapacity, result in birth defects, or other conditions which in the judgement of the
researchers represent significant hazards.

**Anonymity**

A response is anonymous when neither the researcher nor those who read the published results of the research can identify a given response as belonging to any particular participant.

**Assent**

Assent is the agreement to participate in research offered by someone able to understand what is required but not of an age or ability to give his or her consent. Assent may be given verbally. The researcher should keep a record of it.

**Child/Young person**

UAHPEC regards young persons aged 16 or above as usually able to give consent for their own participation in research. Participation in research by children under the age of 16 years requires the consent of their parent(s) or guardian(s). This consent should be obtained prior to also obtaining assent from the child themselves if they are of an age (usually 7 or above) to understand the project and their role in it. Assent by itself is not sufficient for research participation. In some circumstances researchers may make a case to UAHPEC for not obtaining parent or guardian consent in the case of children under 16, but it will usually be required that parents are informed about the research even where their consent is not required.

**Clinical trials**

UAPHEC adopts the definition of clinical trial of the World Health Organisation and New Zealand Ministry of Health. That definition is “a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”.

**Requirements for ethical approval of a clinical trial**

The Health and Disability Ethics Committees (HDECs) have Standard Operating Procedures (SOPs) that define rules and guidance on the health and disability research that they review as well as the role and review process of HDECs. The SOPs can be found at:

http://ethics.health.govt.nz/operating-procedures

**Confidentiality**

A person’s identity is confidential when the participant’s identity is known to the researcher, but the researcher will not disclose it in any discussion or report of
the research. Confidentiality of information means that any report or discussion of the information given by the participant will be done in a way that does not identify the participant as the source of the information.

It may be misleading to describe the information collected during the research as confidential if it will be reported or published.

**Consent Form**

A consent form is a document stating the terms upon which a person agrees to participate in research. It is signed by the participant and retained by the researcher. UAHPEC may give permission for consent to be obtained orally, where there are cultural, safety or other special reasons.

The consent form must be retained by the researcher and stored on University premises under the control of the supervisor or principal investigator for a period of 6 years.

**Guardian/caregiver of a child**

A guardian/caregiver of a child is the person who has legal responsibility for the day-to-day care and decision-making in relation to a child.

**Intervention study**

In an intervention study, the investigator controls and studies the intervention(s) provided to participants, for the purpose of adding to knowledge of the health, or other, effects of the interventions(s). The term ‘intervention study’ is often used interchangeably with ‘experimental study’. Many intervention studies are clinical trials.

**Observational study**

In health research, observational studies are distinguished from intervention or experimental studies as those where no intervention other than recording, classifying, counting and analysing of data takes place. The investigator has no control over study variables and merely observes outcomes. Most observational health research is epidemiological or health services research. In Social Sciences and some other disciplines, observation is a particular research methodology which may be included alongside other research activities.

**Participant Information Sheet**

The Participant Information Sheet is the document that informs the participant about the research and the nature of the involvement required. The participant retains it. Generally, the Participant Information Sheet must be in a written format. However, in the case of telephone research, or in research in
predominantly oral cultures, a researcher may make a case to present the information orally. In these cases a copy of the information to be presented orally must be submitted to UAHPEC for review.

**Questionnaire**

A questionnaire is a written or electronic list of questions to be answered by participants.

**Research**

In defining “research” for the purposes of the UAHPEC, the PBRF definition of research is used. This is as follows:

*Research is original investigation undertaken in order to gain knowledge and understanding. It typically involves enquiry of an experimental or critical nature driven by hypotheses or intellectual positions capable of rigorous assessment. It is an independent, creative, cumulative and often long-term activity conducted by people with specialist knowledge about the theories, methods and information concerning their field of enquiry. Its findings must be open to scrutiny and formal evaluation by others in the field, and this may be achieved through publication or public presentation. In some fields, the results of the investigation may be embodied in the form of an artistic work, design or performance.*

*Research includes contributions to the intellectual infrastructure of subjects and disciplines (e.g. dictionaries and scholarly editions). It also includes the experimental development of design or construction solutions, as well as investigation that leads to new or substantially improved materials, devices, products or processes.*

*The following specific activities are excluded:*

- Preparation for teaching;
- The provision of advice or opinion, except where it is consistent with the definition of research;
- Clinical trials, except where they are consistent with the definition of research;
- Scientific and technical information services;
- General purpose or routine data collection;
- Standardisation and routine testing;
- Feasibility studies (except into research and experimental development projects);
• Specialised routine medical care;
• The commercial, legal and administrative aspects of patenting, copyrighting or licensing activities;
• Routine computer programming, systems work or software maintenance (but note that research and experimental development into applications software, new programming languages and new operating systems are included); and
• Any other routine professional practice (e.g., in arts, law, architecture or business).

Research participant

A research participant is a person about whom a researcher obtains either data through intervention or interaction with the person, or identifiable private information. There are special requirements for ethical approval where the participants are involved in the research because of their membership of a particular community that is the focus of the research.

Unanticipated Problem

In defining “Unanticipated Problem” for the purposes of the UAHPEC, the OHRP definition is used (http://www.hhs.gov/ohrp/policy/advevntguid.html#AA).

An Unanticipated Problem is any incident, experience, or outcome that meets all of the following criteria:

• unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
• related or possibly related to a subject’s participation in the research; and
• suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

Vulnerable people

In defining vulnerable people, NEAC Guidelines for vulnerable people is used (http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research). Vulnerability is a broad category. It describes people who have restricted capability to make independent decisions about their participation in the study. It also encompasses people who may lack the ability to consent
freely or may be particularly susceptible to harm either because of their health status, physical or mental capacity or employment status, or as a result of imprisonment.
9. **APPENDICES**

9.1 **Appendix 1: The Privacy Act 1993**

The protection of privacy is both a legal requirement and also a significant ethical concern. Naturally, UAHPEC does not provide legal advice on these matters; nor can the committee provide anything more than basic guidance. The Privacy Commissioner provides a significant amount of information, including Codes of Practice which supplement the Act (and in some circumstances these may set out more stringent requirements). For more information visit [www.privacy.org.nz](http://www.privacy.org.nz).

The University’s policy relating to privacy can be found at [http://www.auckland.ac.nz/ua/home/privacy](http://www.auckland.ac.nz/ua/home/privacy). This policy gives guidance on the collection, use, disclosure and correction of data held by the University. The University has a Privacy Officer who deals with the policy and issues arising.

The UAHPEC looks to ensure that both legal requirements relating to the Privacy Act and ethical standards relating to privacy issues are met as part of its process of reviewing whether to grant ethical approval. For that reason, the following points should be noted, as they may be important in a particular case.

In the first place, compliance with the requirements of the Privacy Act and any relevant code is relevant to ethical approval in two separate ways. Firstly, there is the requirement that researchers collect and store information in a manner that complies with legal and ethical requirements relating to privacy. Secondly, where the research involves reviewing data that has been obtained by another organisation, it is necessary for researchers to ensure that the organisation that is hosting the research or allowing access to data it has collected is complying with its privacy obligations in allowing access to that information for research purposes.

Of the ‘information privacy principles’ set out in the Privacy Act 1993, some are of particular relevance to researchers. The implications of most of these principles are self-evident, but the committee has added some emphases and comments:

1. Personal information can only be collected for a lawful purpose. [That would include research purposes.]

2. It shall be collected from the individual unless it is publicly available, or
authority has been given for it to be collected from someone else, or it would not prejudice the interests of the person, or non-compliance is necessary for law enforcement and the like, or compliance would prejudice the purposes of the collection, or compliance is not reasonably practicable, or the information will not allow the individual to be identified, or will be used for statistical or research purposes and will not be published so as to identify the individual. [Note that the various exemptions are relevant only to the question of whether it is possible to collect personal information other than directly from the individual: see 10 and 11 below for the principles relating to the use of information.]

3. Where information is collected from individuals, they have to know the purpose and the intended recipients etc. However, this is subject to exceptions that are similar to those under principle 2. [Again, this is relevant only to the question of the collection of the information: see 10 and 11 below for the principles relating to the use of information.]

4. Only lawful and fair means shall be used to collect information. [This may have an impact on the methods used in research.]

5. Information has to be stored securely. [This explains the requirements the UAHPEC has about the storage of information collected.]

6. People have a basic right of access to information held about them where it can be retrieved readily.

7. People are entitled to seek correction of any inaccuracies.

8. The holder of information shall not use it without taking reasonable steps to ensure that it is accurate, up to date, complete, relevant and not misleading.

9. Information may not be kept for any longer than is required for the purposes for which it may lawfully be used.

10. Information obtained for one purpose shall not be used for another purpose unless it is publicly available, or authority has been given by the person, or it is necessary for law enforcement and the like, or to prevent or lessen a serious or imminent threat to public health or safety or the life or health of the individual or another, or the purpose is directly related to that for which the information was collected, or the information is used in a form that will not allow the individual to be identified, or will be used for statistical or research purposes and will not be published so as to identify the individual. [Note that there are some differences between the exceptions applicable under principles 2 and 3: in particular, the exceptions for not prejudicing the interests of the person or compliance not
being reasonably practicable are missing. This principle and principle 11 below are of clear importance when a researcher is reviewing material stored by another organisation. UAHPEC will look at what consent was given to the organisation at the time it collected the data as to the circumstances in which the information might be used further for the purposes of research, and if no express consent has been given for that further purpose, the committee will look to whether or not any identifying material might be released, including to those involved in carrying out the research. It should be noted that the basic principle is that people have the right to control access to their private data and so express consent to the use of data is the most obviously suitable scenario: reliance on other circumstances may nevertheless be ethical on the facts of a particular case.]

11. The body holding information cannot disclose it unless it is for a purpose for which it was obtained (or a directly related purpose), or it is publicly available, or has been authorised by the individual, or non-compliance with this requirement is necessary for law enforcement and the like or to prevent or lessen a serious or imminent threat to public health or safety or the life or health of the individual or another, or the purpose is directly related to that for which the information was collected, or the information is used in a form that will not allow the individual to be identified, or will be used for statistical or research purposes and will not be published so as to identify the individual.

12. Unique identifiers are to be used only when necessary.
### 9.2 Appendix 2: Complaints procedure

An important part of UAHPEC’s responsibilities is the investigation of complaints received as well as the evaluation of events in which research participants have been unexpectedly harmed.

a. A person wishing to raise a matter of concern or a complaint about research approved by UAHPEC and relating to ethical standards of research on human participants conducted by members of the University, may do so in writing to the Chair of UAHPEC.

b. The complaint, or expression of concern, should be set out in sufficient detail in a completed Complaints and Adverse Event Form to enable the Chair to identify both the research and the issues of concern. The Report Form for adverse event and complaints can be obtained from the ethics administrators.

c. The Associate Director of Post-Award Support Services (the Associate Director), in consultation with the Chair, will determine if the complaint or concern will be investigated and, if so, the process to be followed.

d. The Associate Director will ask the Principal Investigator to complete the Report Form for Adverse Events and Complaints and to submit this to the Chair within 15 working days of receipt of the complaint.

e. The Associate Director will co-ordinate the investigation in consultation with the Chair.

f. UAHPEC will be informed that a complaint or alleged adverse event has been received or reported. The information will be recorded and the documentation held confidentially in the Research Office.

g. To protect the privacy of the complainant or informant, the researchers, and research participants, all information about a complaint or alleged adverse event will initially be treated as confidential to the Chair and the Research Office. The Associate Director, in consultation with Chair, will determine the appropriate levels of confidentiality throughout the proceedings.

h. A complainant or informant may request confidentiality, but must understand there will be circumstances where such a request will mean the complaint cannot be investigated. The complainant or informant will be advised if this is the case.

i. If the Associate Director, in consultation with the Chair, considers there are good reasons to protect the identity of the complainant or informant and the investigation can still proceed in a procedurally fair manner, the identity of the complainant or informant may initially remain confidential.
j. Procedural fairness will normally require that details of the complaint or concern and sufficient information about the source of the complaint or concern will be made available to those about whom the complaint is made.

k. The Associate Director will ask the subject of the complaint or concern for a written response, if this is not the Principal Investigator.

l. In all cases, if the reported alleged adverse event or matter of complaint is of a serious nature and an investigation needs to be conducted urgently, the Associate Director and the Chair will take whatever steps they consider necessary.

m. After considering the response from the Principal Investigator and in consultation with the Chair, the Associate Director may seek such further information as may be necessary to pursue the resolution of the matter.

n. If the Associate Director, in consultation with the Chair, comes to the view that there has been a breach of conditions set by UAHPEC or there is evidence of misconduct in research, a response will be sought from the researcher.

o. Complainants/informants will be kept informed about the progress of their complaint.

p. At any stage of the investigation, the Associate Director and the Chair may determine that in the interests of the welfare of research participants, it is necessary for a disclosure to be made to specific persons who can assist those research participants.

q. At the end of an investigation where the matter is resolved, the Chair will advise parties of findings and will, where necessary, refer the findings to the appropriate person or agency for any consequential action.

r. Where the investigation determines that there may be a breach of the University’s Code of Conduct for Research, the Associate Director will inform the Chair, and refer the matter to the Deputy Vice-Chancellor (Research) (DVC(R)). In such circumstances, the Chair will inform the complainant or informant and the subject of the complaint or concern accordingly.

s. UAHPEC will be informed of the outcome of the investigation. Normally UAHPEC will only be informed of the identity of the researcher and the research project where the complaint (or parts thereof) is upheld or if it can be established that an adverse research event did indeed occur.

t. Where the matter is not resolved through this investigation, the Associate Director will inform the DVC(R), and advise the complainant/informant and the Principal Investigator accordingly.

u. The DVC(R) shall determine if further steps are to be taken within the
University to address the matters raised by the complainant/informant.

v. Where the complaint remains unresolved at the University level, the complainant/informant may refer it to the Health Research Council Ethics Committee for an independent opinion.

w. If the complaint is about the Chair, or if the complainant/informant is dissatisfied with the Chair’s response, the complainant/informant should, in the first instance, write to the Associate Director who will then direct the complaint or concern to the DVC(R).

x. Complaints concerning another ethics committee must be made to that committee.