



**UNIVERSITY OF AUCKLAND**  
**HUMAN PARTICIPANTS ETHICS COMMITTEE**  
**(UAHPEC)**

**APPLICANTS' REFERENCE MANUAL**

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## **1. THIS DOCUMENT**

### **1.1 Purpose**

This document is written specifically for members of the University of Auckland involved in research with human participants. It is intended to provide guidance to researchers and ethics advisors on the conduct of their research projects, and on the process of applying for ethics approval from the University of Auckland Human Participants Ethics Committee (UAHPEC). The manual highlights issues to which particular attention needs to be paid during the design and conduct of research.

### **1.2 Aims**

The aims of this manual are to:

- Provide a clear statement of the ethical principles and standards by which research involving human participants at the University of Auckland should be guided
- Draw attention to ethical issues that might arise in the course of a research project and suggest strategies for responding to them
- Provide exemplars, and examples of appropriate wording in the application form and research documents
- Provide information about further resources that may be helpful to the researcher.

This manual is not a technical guide to the online application process. For help with the technical aspects of the process, please consult the user guides on the Human Participants Ethics webpages.

## 2. ASSOCIATED DOCUMENTS

Researchers who intend to undertake research involving human participants also need to spend time reading and understanding the following associated documents and their requirements.

<b>Document Title</b>	<b>Document Purpose</b>	<b>Location</b>
<i>The University of Auckland Code of Conduct for Research (2012)</i>	This briefly outlines the guiding principles and responsibilities of research, along with relevant examples.	<a href="https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf">https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf</a>
<i>Research Guide for Academic Staff (2017)</i>	This comprehensively sets out processes for planning research, the support provided, obtaining funding, the ethics approval required, managing research projects and reporting research	<a href="https://cdn.auckland.ac.nz/assets/staff/research/documents/Research%20Guide%202017.pdf">https://cdn.auckland.ac.nz/assets/staff/research/documents/Research%20Guide%202017.pdf</a>
<i>Policy on Ethics Review of Research Proposals involving Human Participants (2011)</i>	This defines research and human participants, outlines UAHPEC policy on approval for projects involving human participants, and lists relevant legislation/university statutes or regulations.	<a href="https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/human-participants-ethics-committee-policy.pdf">https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/human-participants-ethics-committee-policy.pdf</a>
<i>Guiding Principles for Conducting Research with Human Participants (2016)</i>	This describes UAHPEC, the ethics framework for research with human participants, the key ethical considerations that researchers should be guided by when designing and conducting their research projects, and applying for ethics approval.	<a href="https://cdn.auckland.ac.nz/assets/central/documents/2011/Guiding%20Principles%20for%20Research%2024%20Feb%2010-%20Bookmark.pdf">https://cdn.auckland.ac.nz/assets/central/documents/2011/Guiding%20Principles%20for%20Research%2024%20Feb%2010-%20Bookmark.pdf</a>



<b>Document Title</b>	<b>Document Purpose</b>	<b>Location</b>
<i>Research Office Human Ethics Module Electronic Application User Guide</i>	This user guide provides information about using the Human Ethics Module (InfoEd system) for Ethics Applicants	<a href="https://www.auckland.ac.nz/content/dam/uoar/Research%20PUBLIC/Researcher%20Quick%20Guide.pdf">https://www.auckland.ac.nz/content/dam/uoar/Research%20PUBLIC/Researcher%20Quick%20Guide.pdf</a>
<i>Student Survey Policy</i>	The purpose of the Student Survey policy is to ensure a coordinated cross-university approach to surveying student opinion.	<a href="https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/student-survey-policy.pdf">https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/student-survey-policy.pdf</a>
<i>New Zealand Legislation</i>	There are also other pieces of legislation which have an impact on the design and conduct of research projects. These include the Privacy Act 1993, Health Research Council Act 1990, Human Tissue Act 2008 and Animal Welfare Act 1999. For a list of relevant New Zealand legislation, refer to the University's Legislative Compliance Register	<a href="https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/legislative-compliance.html">https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/legislative-compliance.html</a>
<i>Health Information Privacy Code 1994</i>	This code of practice recognises those expectations that health information should be treated differently. It applies specific rules to agencies in the health sector to better ensure the protection of individual privacy.	<a href="https://privacy.org.nz/the-privacy-act-and-codes/codes-of-practice/health-information-privacy-code/">https://privacy.org.nz/the-privacy-act-and-codes/codes-of-practice/health-information-privacy-code/</a>

<b>Document Title</b>	<b>Document Purpose</b>	<b>Location</b>
<i>Films, Videos and Publications Classification Act 1993</i>	This is an Act to consolidate and amend the law relating to the censoring of films, videos, books, and other publications; and to repeal the Indecent Publications Act 1963, the Films Act 1983, and the Video Recordings Act 1987.	<a href="http://www.legislation.govt.nz/act/public/1993/0094/latest/DLM312895.html">http://www.legislation.govt.nz/act/public/1993/0094/latest/DLM312895.html</a>
<i>Children, Young Persons and Their Families Act 1989</i>	This is an Act to reform the law relating to children and young persons who are in need of care or protection or who offend against the law.	<a href="http://www.legislation.govt.nz/act/public/1989/0024/latest/DLM147088.html">http://www.legislation.govt.nz/act/public/1989/0024/latest/DLM147088.html</a>
<i>Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (2007)</i>	This is set of guidelines on Adverse Events in Research and has been developed by the Office for Human Research Protections (OHRP) (Dept of Health and Human Services, USA)	<a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/</a>

### **3.UNIVERSITY REQUIREMENTS AND ETHICAL PRINCIPLES**

The University of Auckland has an obligation to ensure that all research conducted by members of the University conforms to established ethical standards.

#### **3.1 Definition of “Research with Human Participants”**

For the purposes of this document, research with human participants is defined as follows:

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.

UAHPEC Guiding Principles (2016), p.3

#### **3.2 Key principles**

In line with international guidance on research ethics, the four key principles of ethical research that UAHPEC requires to be applied to the design, conduct and ethical review of research are autonomy, beneficence, non-maleficence and justice. The value underlying these principles is respect for persons. Researchers should adhere to these principles when planning and undertaking their research.

These principles are outlined briefly below.

##### **(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 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 might cause. Research should minimise and manage risks of harm, such as the risk of physical or psychological harm to research participants. 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. (*UAHPEC, Guiding Principles for Conducting Research with Human Participants, p.8*).

The four principles listed above are widely accepted as key principles that guide the conduct of research. They are complementary and interdependent. How they apply, and the weight accorded to each, depends on the nature and context of the research being undertaken.

## **3.3 The University of Auckland Human Participants Ethics Committee (UAHPEC)**

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.

(See: <https://www.auckland.ac.nz/en/about/research/re-ethics/re-uahpec.html>)

### **Membership of UAHPEC**

The committee membership profile reflects the requirements for the University and Health Research Council (HRC) approval. As far as possible, the committee aims to include the representatives specified in the "Guiding Principles for Conducting Research with Human Participants" Overall, the committee aims to

have a balance of institutional and lay members; at least two Māori members; representation from the community at large; an 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 Roles and responsibilities**

The primary responsibility for maintaining ethical standards in research rests with the research team and, in particular, with the principal investigator. The ethical review process provides advice on appropriate ethical standards for specific research protocols, but applicants remain responsible for maintaining all ethical standards throughout the research project.

UAHPEC is primarily concerned with approving applications to conduct research involving human participants. It is not responsible for other ethical matters such as research involving animals or research misconduct.

UAHPEC expects that researchers respect and provide protection for participants at all times. It also expects that the research is conducted in accordance with the ethical guidelines and frameworks of the researchers' respective professional or disciplinary societies.

UAHPEC's key ethical principles are consistent with the Health Research Council's ethics framework. 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"* (HRC Guidelines for Approval of Ethics Committees, 2012, p.4).

In reviewing applications, UAHPEC reserves the right to seek expert opinion, from individual experts or from relevant committees such as the Health Research Council Ethics Committee (HRCEC), 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).

### **3.5 Research requiring approval**

All research involving human participants undertaken by University of Auckland researchers, as defined in the Code of Conduct for Research policy, must obtain ethics approval from either UAHPEC, another HRC approved ethics committee or institutional ethics committee, or a Health and Disability Ethics Committee (HDEC) of the Ministry of Health. HDECs review health and disability research. However, not all health and disability research requires review by an HDEC.

Research exempted from HDEC consideration typically requires UAHPEC review.

To avoid any doubt, in addition to research being conducted by, or under the direction of, University of Auckland staff, the following kinds of research require UAHPEC approval:

- Teaching involving student-led research within class teaching time with other students
- Student-led research with human participants who are not class members
- Research carried out as part of coursework, conducted within and outside of the University
- Research by any person seeking to conduct a University-wide student survey for research purposes, as defined in the University's *Student Survey Policy*. Such applications must be submitted to, and endorsed by, the Planning and Quality Office, ext. 84642, prior to submission to UAHPEC
- Coursework proposals in which students take part as participants in research exercises, such as laboratories, in full or partial fulfilment of their course requirements.
- Audit investigations that have a research component (see Section [13.9](#))

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.

Research projects can commence only after UAHPEC approval has been given. There are no exceptions to this rule and ethics committees do not grant retrospective approval.

### **3.6 Research methodology**

Researchers must ensure that the research methodology they have chosen is appropriate to answer their research question. UAHPEC's *Guiding Principles* note that:

*"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"* (section 5.1, p. 16).

The committee acknowledges that student research often has some weaknesses in methodology but that this is counterbalanced by the value of providing training in methodology.

### **3.7 Complying with the University of Auckland's Code of Conduct for Research**

Research must meet the requirements of the University of Auckland *Code of Conduct for Research (2012)*:

<https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf>

### **3.8 Exemptions**

No ethics approval is needed from UAHPEC for the following proposals:

- Teaching and course evaluations within the University, including all Education Committee-approved surveys listed in the Student Survey Plan, that are not for the purpose of research
- Departmental reviews and similar evaluations
- A solitary interview with a participant who is asked to discuss his or her area of expertise and who can reasonably be regarded as having sufficient seniority and experience to be aware of, and protect, his or her own interests with regard to the research and its publication. However, a series of interviews with a single person or a number of persons on the same topic does require approval
- A solitary interview with an individual public figure about public matters. However, a series of interviews with a single person or a number of persons on the same topic does require approval
- Observational studies in public where participants are not identified
- Discussions of a preliminary nature that will assist in the development of a research protocol or instrument, but will not provide data to be incorporated into the research dataset
- Research involving publicly available data
- Research that is undertaken independently of the University (for example, in private consultancy), so long as the participants are told at the outset that the research is not connected with the University. Under no circumstances should the name of the University, the researcher's University title or the University logo be used. In these circumstances researchers are advised to check any independent institutional ethical review requirements
- Research that is approved by an HDEC
- Research that is approved by the Ethics Committee on Assisted Reproductive Technology (<http://www.ecart.health.govt.nz/>).

Research that has been approved by another HRC-approved ethics committee or an institutional ethics committee may be exempt. The documents must be provided to the UAHPEC Chair for ratification of the application form and approval (see sections [3.9](#) and [3.10](#)).

### **3.9 Transferring research**

In those instances where a new staff member brings with them a research project from another institution, unless the project has been approved by one of the HDECs, the original ethics application and approval must be submitted to UAHPEC. If no ethics approval was previously obtained, then an application needs to be submitted to the UAHPEC. 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. In either case, the researcher must obtain written approval from the Chair prior to undertaking the research.

### **3.10 Collaborations**

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.

### **3.11 Pilot studies**

A pilot study is one in which preliminary research protocols are trialled. Since a pilot study involves human participants in research procedures, it requires the approval of UAHPEC. Approval from UAHPEC is required separately for the main study in a new application.

A pilot study should be distinguished from any preliminary discussions with key informants to assist with the development of the research aims or design. Preliminary discussions may lead to revisions of research processes or instruments, but are not intended to provide data for analysis in the study. Such preliminary discussions do not require the approval of UAHPEC.

### **3.12 Projects with multiple phases**

If a project has multiple phases, this should be clearly indicated in the application. A pilot study is not considered to be one of the phases in the research. Separate applications for disparate phases of a study may be required by UAHPEC.

### **3.13 Research conducted without ethical approval**

Failure to obtain ethics approval when it is required, and failure to comply with the policies or conditions set out by UAHPEC, constitute research misconduct and



may give rise to disciplinary action according to standard procedures at this University.

Researchers who do not gain approval risk not being able to publish their research in reputable journals and, in the event of a complaint or legal suit, will not be covered by the University's indemnity insurance.

### **3.14 Liability insurance**

The University has professional indemnity cover in place that covers "all activities of a researcher" for and on behalf of the University of Auckland. This professional indemnity cover is designed to cover the University's (which includes the researcher's) legal liability to a third party (that is, the research participant), subject to the terms and conditions of the policy. **The researcher will not be covered by the University's indemnity insurance if ethics approval has not been obtained.**

## **4. EXTERNAL COMPLIANCE REQUIREMENTS**

### **4.1 New Zealand legislation**

The University must ensure that research carried out by its staff and students conforms to various statutory requirements. The Education Act 1989 requires the University to exercise its academic freedom in a way that is consistent with the highest ethical standards.

“In exercising their academic freedom and autonomy, institutions shall act in a manner that is consistent with –

(a) the need for the maintenance by institutions of the highest ethical standards and the need to permit public scrutiny to ensure the maintenance of those standards” (Education Act 1989, section 161(3a))

Other legislation may also have an impact on the design and conduct of research projects involving human participants. These include the Privacy Act 1993, Health Research Council Act 1990, Accident Compensation Act 2001, Human Tissue Act 2008, and Vulnerable Children Act 2014. For a list of relevant New Zealand legislation, refer to the University’s Register of Compliance at:

<https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/legislative-compliance.html>

### **4.2 Compliance with Health Research Council requirements**

UAHPEC must meet the HRC’s requirements in order to maintain its status as an HRC-approved ethics committee.

### **4.3 Compliance with professional codes**

Professional codes can impose requirements on researchers in particular professions. Research should be conducted in accordance with professional codes. However, where there is inconsistency between the University’s policy on research and a professional code, the researcher should inform, and seek advice from, UAHPEC.

### **4.4 Requirements of other organisations**

A research project may have requirements imposed upon it by an organisation outside the University (such as a funding organisation or a journal in which the researcher wishes to publish). These requirements may affect the design of the study or use of research data and may raise particular ethical issues, such as conflict of interest between researchers, the University, and the outside organisation. Researchers should detail the requirements in their ethics application and explain how these will be met, within the guidelines and requirements of UAHPEC and the University.

#### **4.5 Requirements of the Health and Disability Ethics Committees (HDECs)**

Research in the health and disability field may require approval from a Health and Disability Ethics Committee. The HDECs are Ministry of Health committees (established under section 11 of the [New Zealand Public Health and Disability Act 2000](#)), whose function is to secure the benefits of health and disability research by ensuring that it meets or exceeds established [ethical standards](#).

According to the *Standard Operating Procedures for Health and Disability Committees* (August 2014, <http://ethics.health.govt.nz/operating-procedures>) health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. There are two main types of health and disability research:

- intervention studies, and
- observational studies.

Currently there are four HDECs: Northern A, Northern B, Central and Southern.

The online HDEC application system allows researchers to select review by the closest HDEC or to submit their application to the next available committee meeting (which may or may not be the nearest committee).

Details of HDEC meetings can be found at: <http://ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes>

In general, research requires HDEC review, if it involves one or more of the following:

- Human participants acting as consumers of health or disability services, or as relatives or caregivers of consumers of these services, or as volunteers in clinical trials
- Human tissue, unless informed consent has been obtained for its use and it has not been made available to researchers in a form that could reasonably be expected to identify the individual concerned or there is a statutory exception to the need for consent
- Health information, unless its use has been authorised by the individuals concerned, or unless the researchers receive it in a de-identified form and it cannot be matched by the researcher to another dataset that could identify individuals. <http://ethics.health.govt.nz/operating-procedures>

The HDEC provides a summary flowchart for confirming whether a research study requires HDEC review. See:

<http://ethics.health.govt.nz/system/files/documents/pages/HDEC%20scope%20summary.pdf>

If UAHPEC judges it necessary to pass on an application to an HDEC for review, the applicant will be advised. Sometimes it may be appropriate for an HDEC to refer applications to UAHPEC because it may fall outside the scope of review of the HDECs. However, a research project should be reviewed by a single HRC approved committee.

Sponsor authorisation:

Before an HDEC application is submitted online, it requires authorisation by the University of Auckland as sponsor.

A sponsor is defined in the Standard Operating Procedures for HDECs as “the person or organisation with responsibility for the initiation, management and financing arrangements of a study”. The use of “sponsor” in this context should not be confused with a funding provider.

The study sponsor and the Coordinating Investigator have the primary responsibility for monitoring approved HDEC applications to ensure that their health and disability research is conducted lawfully.

This authorisation has been delegated to the Research Office, and will be given upon sighting of sign-off by the HOD/HOS. The required form is available from the website (see link below), and is added to the online HDEC form as an attachment (in the “Other” category).

For information about how to apply to an HDEC for review go to:

<https://www.auckland.ac.nz/en/about/research/re-ethics/health-and-disability-researchethics-committees.html#4ace40d13b4605a4591a65bfec94e37e>

#### **4.6 Requirements of the Ethics Committee on Assisted Reproductive Technology (ECART)**

For the purpose of the HDECs, health and disability research does not include research that creates or uses a human gamete, human embryo or hybrid embryo. Such “human reproductive research” requires approval by the Ethics Committee on Assisted Reproductive Technology. See:

<http://www.ecart.health.govt.nz/>

## 5. APPLYING FOR ETHICS APPROVAL

All applications to UAHPEC for ethics approval, including those for research as part of student coursework, must be made via the online InfoEd system in the Human Ethics Module: <https://researchmanagement.auckland.ac.nz>.

The application may still be drafted using the [Word](#) copy of the online form on the [UAHPEC website](#), but the content of the final version will need to be copied into the online form.

When completing the application form, applicants should use language that is free from jargon and is comprehensible to laypeople. If English is not the applicant's first language, seek advice from someone who can assist with grammar, syntax and spelling as necessary.

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

Only the PI can submit an application for ethics approval. For Doctoral, Masters and Honours research, applications should be submitted by the primary supervisor who will be named as the PI.

If the supervisor is unavailable to submit an application, a delegate can be set up in InfoEd to submit the application prior to the supervisor becoming unavailable. Please contact the Ethics Administrators for assistance.

All correspondence regarding individual ethics applications is addressed to the PI, and also copied to the co-investigator(s), student researcher(s) and the HOD/HOS, as applicable. It is the responsibility of the PI to ensure that the research team members are aware of any relevant correspondence from UAHPEC. For example, Honours and fourth year students, and team members not associated with the University will not receive the correspondence automatically from InfoEd.

After submission, applications are routed automatically by the online system to the appropriate person(s) for sign-off in each department. Hard copy signatures of ethics advisors and heads of department are no longer required. Faculties may have additional requirements for the submission of ethics applications to UAHPEC, and applicants are responsible for checking with their faculty ethics advisor if this is the case.

UAHPEC will not review the application until it is completed to an appropriate standard. Incomplete and/or poorly constructed applications will be returned to the PI.

## 5.1 Online application support

Please note that the online application form in InfoEd works best with Mozilla Firefox or Google Chrome browsers.

For any online system or technical problems:

Please log a call with the Staff Service Centre (ext. 86000 or [staffservice@auckland.ac.nz](mailto:staffservice@auckland.ac.nz)) and it will be referred to the relevant team in the Research Office or ITS.

Please ensure that access to the system is available on campus before attempting off-campus access using the Virtual Private Network ([VPN](#)).

For assistance with navigating the online application system, please refer to the user guides that are available on the Human Ethics website:

- Researcher's guide to the online system: [Quick Guide](#) or go to <https://www.auckland.ac.nz/uo/re-uahpec>
- Faculty sign off: [Quick Guide](#) or go to <https://www.auckland.ac.nz/en/about/research/re-ethics/re-uahpec.html>

The Ethics Administrators can assist with phone and remote one-to-one training support. Please contact: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz) or ext. 83711.

## 5.2 Submission deadlines

UAHPEC meets fortnightly from February to December. The agenda closes around three weeks prior to a meeting to allow for pre-screening of the initial application, for revisions to be made as a result of pre-screening and for a preliminary review of the application by committee members prior to the meeting. Applications received after the deadline are included in the agenda for the following meeting.

After an application has been submitted it is routed automatically to the appropriate person(s) for sign-off in each department. Researchers should therefore **submit applications at least one week before the next committee deadline** to allow sufficient time for departmental sign-off and subsequent receipt of the application in the Research Office by the agenda closing date.

Research Office staff are unlikely to be aware of applications until they have been submitted online. If you are concerned about the progress of your application, contact the Ethics Administrators at: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz) or ext. 83711.

The UAHPEC meeting dates and the deadlines for submitting applications for review are available online at: <https://www.auckland.ac.nz/uo/re-uahpec>

## **6. DOCUMENTS TO BE INCLUDED**

All information in the documents needs to be consistent with that provided in the body of the application.

### **6.1 Documents for participants**

Documents for participants may include Participant Information Sheet(s), Consent Form(s), advertisements, email invitations, questionnaire(s), list(s) of interview questions, web pages and confidentiality agreement(s). All documents intended for participants and/or third parties should be completed to a high standard of written English and must be submitted to UAHPEC in final format on the University of Auckland departmental letterhead. Documents intended for participants should not include headers such as 'Appendix A'.

All documents that will be given to participants should clearly state that the research study was approved by UAHPEC. Standardly, the Participant Information Sheet(s), Consent Form(s), email invitation(s) and any advertisement should include UAHPEC's approval statement at the end of them, as follows:

Approved by the University of Auckland Human Participants Ethics Committee on ..... for three years. Reference number .....

Date of approval and reference number details must be completed following approval and before the advertisement and/or other participant documentation is used.

### **6.2 Advertisements for recruiting participants**

Any advertisements for recruiting participants, including email invitations and all other electronic invitations, must be submitted to UAHPEC in the format intended for viewing by prospective participants. The advertisement must include enough information about the research so that potential participants can decide whether they might like to participate in the study.

The advertisement should include the source of research funding and contact details for the researcher(s), but does not need to be on University letterhead.

The advertisement should state that the research is being conducted by the nominated researcher(s) and not that the research is being conducted by 'the University of Auckland'.

All advertising material, including flyers, advertisements, invitation emails, and all other electronic invitations must include the UAHPEC approval wording (Approved by the University of Auckland Human Participants Ethics Committee on [insert approval date] for three years. Reference number XXXXXX).

The Committee does not encourage use of personal mobile phone numbers for recruitment purposes unless it is a phone dedicated to this research study. University email addresses should be used rather than personal email addresses.

### **6.3 The Participant Information Sheet (PIS)**

The purpose of the PIS is to give enough detail so that prospective participants can make an informed decision about taking part in research. The PIS should be seen as an essential element, but not the *only* element, in the process of obtaining informed consent from participants. It is an aid to the conversations that form part of the process of obtaining consent and should be a stand-alone document that the participants can take away to share with others and consider in their own time and place.

The PIS should use easy-to-understand language and contain sufficient information so that the participant can understand the following key aspects:

- What the study involves – what will be done by whom, what they have to do and the purpose of what has to be done
- Potential benefits and risks and how risks will be managed, reported or compensated, including any payments that participants may receive
- The rights of the participant, including voluntary participation and the right to withdraw, the management and protection of their rights to privacy and confidentiality, and their rights to their own or new personal information
- What will happen after the study, including how the results will be communicated and disseminated, and the storage, retention and destruction of data and samples
- The PIS should be offered to the participant to keep and therefore should be presented separately from questionnaires, consent forms or other material that will be returned to the researcher.

### **6.4 Essential elements for the Participant Information Sheet**

The following is a guide to what should be included in a PIS. However, please bear in mind that different research projects require different kinds of information to be included in the PIS.

#### **6.4.1 Format and language**

A PIS should not be written in the style of a letter.

The PIS must be written on University of Auckland letterhead that includes the full postal address, as well as telephone and email contact details of the Department/School.

Layout should be as simple as possible with font in a style and size that is easy to read. The University style guide recommends Verdana, size 11.



The PIS should be written in the first and second person (that is, 'I' and 'you') as if the researcher is addressing the prospective participant. Where consent is required from participants who speak English as an additional language and have limited English language skills, the PIS must be translated into a language that the participant can readily understand.

Avoid jargon as much as possible and use language appropriate to the participants (for example, to their age and expected knowledge of the subject).

#### **6.4.2 Introducing the research project – a checklist**

- Include a clear, unambiguous title for your research project
- If your research has more than one kind of participant, address the document to the participant by role; for example, 'Participant Information Sheet (Manager)'.
- Include the name(s) of all the researchers and whether they are a staff member or student. If a student, state the name of the degree and department or faculty enrolled in, and include the name of your supervisor.
- Include any current position the researcher holds so that potential participants can gauge for themselves if there are any possible conflict of interest issues (for example, if you are a University of Auckland student, but also employed at a different institution).
- Invite potential participants to be involved in the research and explain why and how they have been selected.
- State that the invitation to participate in the research study can be declined without penalty.
- State the rationale for the research.
- State the research methods and procedures to be used in the project, including the time requirement from potential participants.
- State the duration of the project.
- State the risks and benefits of the project.
- State if the project has any funding from any organisation and if any third party is involved in the research and/or will be privy to the data and results.
- If the research involves a group (such as students in a class) and some members of the group may decline to participate, indicate what these non-participants will do while the research is being conducted and indicate how the anonymity of non-participants will be preserved.
- If the primary researchers come from more than one institution please provide all of the relevant institutional contact details.

#### **6.4.3 For workplaces, schools and other participating organisations**

If the research is to be conducted in any organisation such as a business, government organisation or school, provide a separate PIS for the chief

executive officer, school principal/school board of trustees or business owner (that is, the effective employer) seeking permission to access the organisation's site and employees as participants.

This PIS should:

- Clearly seek their permission for access to the organisation's facilities and employees/teachers/staff/students. If the researcher needs the organisation's assistance to recruit the participants, this request should be contained in the organisation's PIS (see above)
- Not indicate or suggest that they can give permission on behalf of the employee to participate, withdraw their data or be recorded in any way
- State what and when information will be reported to them, and how the confidentiality of participants will be protected. In most circumstances, it would not be appropriate for the chief executive officer, principal or owner of the business to have access to information that compromised the confidentiality of an employee, teacher, staff member or student. Any proposed exceptions to this provision should be clearly explained in the application form
- Explicitly seek assurances that participation or non-participation will not affect the employment status/grades of the participants, the participant's relationship with the organisation or access to its services. Any proposed exceptions should be clearly explained in the application form.

Where the research is to be conducted with students in a school, separate PISs need to be provided for:

- The Board of Trustees and Principal – seeking permission to access the teachers and site, and requesting assurance about participation/non-participation
- Teachers – for access to their classrooms
- Parents of participating students under 16 years of age
- The students themselves.

Additionally, the researcher must describe how non-participating members of the class/group will be managed and whether any information will be obtained about non-participants in the course of the research.

#### **6.4.4 For children under 16 years of age**

If participants are under 16 years of age, parents, guardians or caregivers should first be asked for their consent.

The 'assent' of participants aged under 16 years of age is also required if they are of an age (usually 7 or above) to understand the project and their role in it. 'Assent' means agreement to participate in research by persons who are too young to give their informed consent but are old enough to understand the research project, the possible benefits and expected risks of the research and

what they would be expected to do as participants. Even children younger than 7 may be able to understand a simple explanation of what you would like them to do, and agree to it (or not). **Please note that assent by itself is not sufficient**; if assent is obtained, consent must still be given by the participant's parent(s), guardian(s) or caregiver(s).

In some cases children under the age of 16 may be able to consent without parental approval. However, researchers must justify to the committee why they would prefer not to ask for parental consent. In such cases, researchers will normally still be expected to inform parents/guardians of the research.

It is important that the language used in the PIS for under 16 year olds and/or in the assent form is at a level that can be understood by the child.

The researcher must also consider whether the language used in the PIS to describe the research is appropriate for the parent or guardian.

#### **6.4.5 Right to withdraw from participation**

Participants have the right to withdraw from participating in the research at any time without giving a reason.

Participants have the right to withdraw their data from the research up to a specified date or period of time unless it is in a form where withdrawal is not possible (for example, the data are anonymised, or are part of a focus group recording). If data cannot be withdrawn, this must be clearly explained.

*"Participants will have the right to withdraw from a focus group meeting at any time without having to give a reason. However, they will not be able to withdraw their data because of other focus group members' information on the same recording."*

#### **6.4.6 Anonymity and confidentiality**

Please see Sections [9.11](#) and [13.2](#) for detailed explanations of what is meant by 'confidentiality' and 'anonymity'.

If participants' and non-participants' identities cannot be kept confidential, this should be indicated.

If confidentiality is offered, it should be made clear how the information that participants provided will be reported or published.

It may be appropriate in some research situations to offer participants (e.g. experts) the option of being identified in reports of the research. This possibility should be made clear in any PIS and explicitly responded to in a CF.

If the research involves focus groups, interviews with small numbers of individuals, or interviews with well-known members of the community, researchers should emphasise that they will do their best to preserve

confidentiality of participants, but cannot guarantee that confidentiality will be maintained, and that others may identify participants by their comments.

If identifiable data will be seen by third parties, for example for translation or cultural comment, state who will see the data and why; and how the confidentiality of the participant will be preserved. A confidentiality agreement signed by the third parties needs to be submitted along with the application for ethics approval.

#### **6.4.7 Use of audio, electronic or other media**

(See Section [9.15](#)).

If audio, video, electronic or other means of recording are involved this should be indicated.

If the recording is essential to the research, participants cannot ask for the recording to be stopped. Therefore, the PIS should contain an explicit statement informing participants that the recording cannot be stopped.

If the recording is optional, the PIS should explain the option to participants. The PIS should also state, *"Even if you agree to being recorded, you may choose to have the recorder turned off at any time"*.

The Committee prefers that participants are offered an opportunity to review recordings (audio, video, or photographs) of their responses, and the process for doing this should be clearly explained.

If third parties are involved (such as for transcription, translation and/or editing), the researcher should explain to the participant how confidentiality of information and participation will be preserved.

The PIS for third parties, such as chief executive officers, or boards of trustees, should indicate that interviews will be recorded only with the consent of the interviewees (e.g., teachers or employees). Normally, recorded interviews of this type cannot be shared with these third parties, but if this is intended, it must be clearly explained for all concerned.

Participants can withdraw from focus groups, but recording devices cannot be turned off during the discussion or information subsequently withdrawn. You might like to use the following wording:

*"You may refuse to answer any questions and are free to leave the group discussion without having to give a reason. However, because of the nature of the group situation, the recording device cannot be turned off during the discussion and, if you withdraw from the research, information you have contributed up to that point cannot be withdrawn."*

#### **6.4.8 Research outside New Zealand**

Provide local contact details for the research project at the overseas location, as well as contact details at the University of Auckland.

It may be appropriate to allow for notification of withdrawal at a local address in the overseas location.

#### **6.4.9 Research involving Māori**

If the research involves participants who are recruited because they are Māori (or the research involves a topic of particular interest to Māori), the Māori researcher should list his or her tribal affiliations.

Contacts for advice on protocols can be obtained from the Office of the Pro Vice-Chancellor (Māori), ext. 82525, or from the nominee of the Pro Vice-Chancellor (Māori) of each faculty. Please refer to the faculty webpages to ascertain the appropriate nominee.

As with other translated materials, any Māori translations of research documents should be provided to UAHPEC following approval of the research.

#### **6.4.10 Distress and discomfort**

If the research involves any procedure that may reasonably be expected to cause physical, psychological or social discomfort or incapacity this must be indicated, as should plans for subsequent assistance or referral. Assistance or referral could include having someone present who has a first-aid certificate or who is medically qualified, and/or giving participants a list of counsellors. (Please note, only enrolled students can access support from the University Health and Counselling Service).

#### **6.4.11 Data retention and sharing**

According to the University Code of Conduct for Research, research data must be retained for at least six years, but preferably indefinitely.

Explain how, where and in what format data will be stored, how long it will be stored for and how it will be destroyed subsequently. Data can be stored in various forms including tapes, discs, videos, computer files and paper records.

State if data is to be transferred to a public repository or made available for secondary research. The conditions under which this is done must be acceptable to both the repository and the participant, and a copy of these conditions provided to UAHPEC.

#### **6.4.12 Research within the University**

If students in the department of the principal investigator or other researcher(s) involved in the project are prospective participants, there must be an explicit statement that neither grades nor academic relationships with the department or

members of staff will be affected by either refusal or agreement to participate. It should be made clear that participation is voluntary.

The assurance needs to be given by either the researcher or Head of Department (HOD) as explained below.

a. If there is **a possibility** of the researcher recruiting their own students; for example, because they have advertised in the department and in the rest of the University, only the PI has to give this assurance. The PI should direct participants to the HOD if they feel that this assurance has not been met.

The PIS could say:

“If you are a student of the researchers we give our assurance that your participation or non-participation in this study will have no effect on your grades or relationship with the University and that you may contact your HoD should you feel that this assurance has not been met.”

b. If the researcher is **specifically targeting their own students**, the assurance must be given as an explicit statement by the Head of Department in a PIS/CF (HOD) or at least in a letter of support/permission.

#### **6.4.13 Compensation, inducements and funding**

State the terms and conditions of any compensation or inducements being offered.

Reiterate the absolute right of participants to withdraw at any time, irrespective of whether or not inducements are given.

If funding for the research is being sought or has been obtained, this needs to be stated, as does the funding source.

#### **6.4.14 Closing statements**

At the end of the last page of the PIS, include the following:

- Contact details for the researcher, supervisor and head of department. This should include name, phone number, email and/or postal address for the University. Please do not provide any home phone numbers, personal mobile numbers, email addresses or home addresses. A mobile phone number can be provided when the phone will be dedicated to the recruitment and managing of the project.
- UAHPEC Chair contact details:  
*For any concerns regarding ethical issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711.  
Email: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)*

- UAHPEC approval wording, as follows (complete the approval date and reference number prior to distribution to the participants):

Approved by the University of Auckland Human Participants Ethics Committee on ..... for three years. Reference Number .....

#### **6.4.15 Example Participant Information Sheet**

The following pages contain an example of information required in a PIS. The intention is for the text to guide your thinking in making sure that you have provided your participants with sufficient information for them to make informed consent.



**Department Name**  
**Department address**  
**Department phone no**

**The University of Auckland**  
**Private Bag 92019**  
**Auckland, New Zealand**

## **PARTICIPANT INFORMATION SHEET**

(Address by category, e.g. Manager)

Project title:

Name of Principal Investigator/Supervisor:

Name of Student Researcher(s):

### **Researcher introduction**

Include the name of the researcher and appropriate identifying information, whether a staff member or a student. If a student, state the name of the degree and the department or faculty in which the researcher is enrolled. If a staff member, state the department and position.

### **Project description and invitation**

Invite potential participants to be involved in the research. State the rationale and aims for the project, using simple language appropriate for your audience. Explain why and how they have been selected. If the research involves a group (such as students in a class), members of which may decline to participate, indicate what these non-participants will do while the research is being conducted and indicate how the anonymity of non-participants will be preserved. It should be made clear that participation is voluntary.

### **Project Procedures**

Explain the procedures in which the participants will be involved (e.g., interviews, focus groups). Explain the length of time involvement, including any travel the participant may have to undertake. If the research involves any procedure that may reasonably be expected to cause physical, psychological, social discomfort or incapacity this must be indicated, as should plans for subsequent assistance or referral. If students in the department of the researcher (or supervisor) are prospective participants there must be an explicit statement that an assurance has been given by a person in appropriate position of authority that neither grades nor academic relationships with the department or members of staff will be affected by either refusal or agreement to participate. If compensation or reimbursements are offered the terms and conditions should be stated. If funding for the research is being sought or obtained, this needs to be stated, as does the source

### **Data storage/retention/destruction/future use**

Explain how, where, for how long and in what format data will be stored and subsequently destroyed. If data will be retained beyond the completion of the research for which it was collected, explain why. State if data is to be transferred to a public repository.

If audio, video, electronic, or other means of recording are involved this should be indicated, including a statement that the participant has the right to have the device turned off at any point (during interviews, but not during focus groups). If such recording is optional, the PIS should indicate this. If it is intended that a participant's recordings (audio, video, or pictures) can be reviewed by the participant,



the researcher should explain the process. If third parties are involved (for example, in transcription, translation, editing or cultural comment), indicate who will view the data, for what purpose, and how confidentiality of information and participation will be preserved.

The PIS for third parties, such as Chief Executive Officers, Boards of Trustees should indicate that interviews will be recorded only with the consent of the interviewee. Recorded interviews of this type cannot be shared with third parties. If this is intended it must be clearly documented for all concerned. The PIS should also include an explicit request for an assurance that participation or nonparticipation of employees/patients/students will not affect their employment/health care/grades or their relationship with the organisation.

### **Right to Withdraw from Participation**

Participants have the right to withdraw from participation at any time without giving a reason. Participants must be given the right to withdraw their data from the research up to a specified date or period of time. (Note: This cannot happen with anonymous questionnaires or focus groups.)

### **Anonymity and Confidentiality**

Ensure it is made clear to participants when one of the following applies:

- If anonymity with respect to the participant's identity cannot be guaranteed
- If anonymity with respect to the identity of non-participants cannot be guaranteed
- If confidentiality with respect to the participant's identity cannot be guaranteed

If confidentiality is offered, it should be made clear how the information provided by the participants will be reported or published.

If the research involves focus groups, interviews with small numbers of individuals, or interviews with well-known members of the community, it must be indicated that confidentiality with respect to the participant's identity cannot be guaranteed.

If the research is web-based, if encryption is used, or if some other method is used to preserve the anonymity of participants this should be described.

### **Contact Details and Approval Wording**

Include an invitation to contact the researchers or the HOD. Provide the contact details of the researcher(s), supervisor (if applicable) and HOD for participants to use if they require more information about the study. Include name, email and /or postal address, and phone and extension number.

- If the PI is also the HOD, the contact details for their Head of School or Dean should be provided.
- Only use a mobile phone number if it is specifically for use in the study, and not a personal mobile phone number.
- If the research is conducted outside New Zealand, provide local contact details, as well as those of contacts at the University.

Add the UAHPEC Chair contact details and approval wording:

For any concerns regarding ethical issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711.

Email: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)

Approved by the University of Auckland Human Participants Ethics Committee on ..... for three years. Reference Number .....

## **6.5 The Consent Form (CF)**

Typically, UAHPEC requires consent to be recorded on consent forms. The consent form must similarly be written on University of Auckland departmental letterhead that includes the full postal address together with telephone and email contact details.

If alternative methods of consent, such as verbal consent, are sought, this must be clearly explained and justified in the application. In such instances, the research process must include a procedure for documenting that consent has been obtained.

Where questionnaires are anonymous, UAHPEC accepts a completed written questionnaire as evidence of consent, provided that appropriate information has been provided about the research.

### **6.5.1 Example of a Consent Form**

The following page contains an example of information required in a consent form. The consent form must include acknowledgement of having read and understood the PIS and a specific statement of agreement to participate. It must also state any other issues requiring specific consent.



Department  
name  
Department  
address  
Department  
phone no

The University of Auckland  
Private Bag  
92019 Auckland,  
New Zealand

### CONSENT FORM

(Address by category, e.g.  
"Manager")

**THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS [or specify longer if appropriate]**

Project title:

Name of Principal Investigator/Supervisor:

Name of Student Researcher(s):

I have read the Participant Information Sheet, have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have had them answered to my satisfaction.

- I agree to take part in this research. [If there are optional components, provide Yes/No or "Agree/do Not agree" statements for each]
- I understand that I am free to withdraw my participation at any time, and to withdraw any data traceable to me up to a specified date (give an actual date) / period. [include only if appropriate]
- I agree / do not agree to be audio recorded. [include only if appropriate]
- I wish / do not wish to have my recordings returned to me. [include only if appropriate]
- I wish to receive a transcript of my interview for editing. [include only if appropriate]
- I wish / do not wish to receive the summary of findings. [include only if appropriate]
- I agree to not disclose anything discussed in the focus group. [include only if appropriate]

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Approved by the University of Auckland Human Participants Ethics Committee on .....  
for three years. Reference Number .....

## **6.6 Questionnaires and surveys**

### **6.6.1 Format**

A questionnaire is a specifically designed set of questions that a participant completes independently and returns to the researcher. Questionnaires should be submitted to UAHPEC in the final format in which they will be viewed by participants or, in the case of an online questionnaire, in a format that is as close as possible to the proposed final format. Minor editing changes (e.g., correction of spelling errors) can be made after approval of the questionnaire, but any other changes, e.g., to the wording of questions, or adding or removing questions, must first be submitted for approval by UAHPEC as an Amendment Request.

If an invitation email is used to recruit participants, the email could contain a link directly to the online questionnaire. In that case, the online questionnaire must include a PIS with all the relevant information about the study, including any funding information and, if the questionnaire is anonymous, that submission of the questionnaire will be taken as consent. Contact details for the researchers, HOD and the UAHPEC Chair must be provided, as well as the UAHPEC approval wording.

For all online questionnaires, researchers must ensure that participants are able to print and/or save the PIS section of the questionnaire for future reference.

If the questionnaire is only to be completed by adults, a tick-box should be added where participants can indicate that they are 16 years or older.

If a PIS is sent to participants prior to accessing the online questionnaire, the PIS could contain a link to the online questionnaire from where participants can access the questionnaire.

If participants will be invited to leave their contact details for a prize draw or to receive compensation after completing an online questionnaire, researchers must use an online tool that allows collecting this information separately from the questionnaire content.

If a printed questionnaire is to be used, researchers must ensure that there is a method of returning the completed questionnaires which protects the confidentiality of participants and of data they may have provided.

If the form is anonymous, it should be clearly explained that submission constitutes consent to participating in the research. Any signed consent form or identifying information (for example an email address for future contact) must be detachable from and stored separately from the completed questionnaire.

### **6.6.2 Reminders**

If the researcher wishes to send out a single reminder for a questionnaire, a statement to this effect should be included in the original Participant Information Sheet. Multiple reminders are not encouraged.

### **6.6.3 Gender**

When collecting demographic data, it is important to be inclusive of gender diversity. [Statistics New Zealand](#) uses three categories to classify [gender identity](#) (i.e., the self-identification of an individual's gender): Male, Female, Gender diverse.

The Committee recommends using Statistics New Zealand's categories, unless there is a clear reason not to. An option for 'decline to answer' may also be included.

### **6.7 List of interview questions**

If the research study includes interviews with participants, for example, structured or semi-structured interviews or focus groups, a topic guide or proposed list of interview questions must be provided for UAHPEC approval, and a clear indication of the kinds of questions to be asked provided for potential participants.

### **6.8 Confidentiality agreements**

Individuals hired to conduct specific research tasks, such as transcribing or editing data, must sign a confidentiality agreement.

Specific research tasks that require a confidentiality agreement include (but are not limited to):

- translating
- interpreting
- recording
- recording or editing sound or image data
- entering data
- destroying data.

The principal investigator must provide the committee with a copy of the proposed confidentiality agreement(s). The agreement should be kept simple and tailored to suit the research project. A statement about the confidentiality agreement needs to be included in the PIS.

#### **6.8.1 Example Transcriber Confidentiality Agreement**

Please note, the following is only an example and your form needs to reflect the work undertaken in your research:



[Department name]  
[Department address]  
[Department phone number]

The University of Auckland  
Private Bag 92019  
Auckland, 1142  
New Zealand

## TRANSCRIBER CONFIDENTIALITY AGREEMENT

### Project Title:

Researcher(s):

Supervisor:

Transcriber:

I agree to transcribe the audio-recordings/video-recordings for the above research project. I understand that the information contained within them is confidential and that I must not disclose or discuss it with anyone other than the researcher and his/her supervisor(s). I shall delete any copies that I may have made as part of the transcription process.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## **6.9 Translations of documents**

Some research studies include participants who are fluent in languages other than English and who would prefer to receive written information about the research in another language. If this is the case, documents such as the PIS and CF need to be translated into a language in which participants are fluent (usually their first language) so that they are able to understand the information provided and give informed consent.

UAHPEC approval is based on the documents submitted in English; it is the researcher's responsibility to ensure that translations are accurate. UAHPEC recommends using the services of a professional translation service. UAHPEC also recommends that translations be completed after UAHPEC approval, as amendments to the documents may be required during the review process. Copies of the translated document need to be sent to the Ethics Administrators in the Research Office once available.

## **7. APPLICATION PRE-SUBMISSION**

To increase the chance of an application moving smoothly through the process, researchers should follow the help notes for specific questions in the online ethics module. These have been informed by the changes that are most commonly requested by UAHPEC.

### **7.1 Faculty requirements**

Researchers are advised to check with their faculty before seeking ethics approval as a faculty may have particular requirements that need to be fulfilled before an application can be submitted.

### **7.2 Faculty ethics advisors**

Faculties and departments that submit a large number of applications have designated ethics advisors who can assist applicants in identifying and addressing the ethical issues, and who are familiar with the requirements of UAHPEC. Applications that have had ethics advisor input are more likely to proceed smoothly through the approval process and UAHPEC strongly encourages less experienced applicants to seek ethics advisor support.

Names and contact details of faculty and department ethics advisors are available from the relevant departments and faculties and can also be found on the Human Ethics webpage: <https://www.auckland.ac.nz/uo/re-uahpec>

### **7.3 Māori ethics advisors**

The Pro Vice-Chancellor (Māori) has a nominee (a Māori ethics advisor) in each faculty. Once submitted, applications for research that have impact on Māori persons as Māori, as outlined in Section F of the application form, will automatically be routed to the Pro Vice-Chancellor (Māori), who will then allocate the application to a Māori ethics advisor in the relevant faculty for review.

Once sign-off has been obtained from the Māori ethics advisor, the application will automatically be routed to the department for sign-off.

### **7.4 Research Office and UAHPEC advisors**

The Ethics Administrators in Post-Award Support Services in the Research Office can be contacted for advice and guidance on matters relating to the human ethics application process.

Researchers are welcome to contact UAHPEC, via the Research Office, for advice on ethical issues as the need arises; for example, if an unforeseen ethical issue arises during the course of a research project.

Please contact ext. 83711 or email [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)



## **8. ETHICS REVIEW PROCESS**

### **8.1 Human ethics review pathways**

There are three pathways to ethical review at the University: low-risk review, full review and expedited review.

#### **(i) Low-risk review**

A low-risk project is one in which there is deemed to be a low risk of physical harm, psychological harm, exploitation or other potential adverse effect.

For all applications, an initial determination of the risk level is made automatically on the basis of responses to questions in the application form. Applications that meet the criteria for low-risk review are initially assigned to the low-risk ethical review pathway. Applicants should be aware that during the low-risk ethical review, their application may be subsequently referred to the committee for full review.

The turnaround time for low-risk applications is usually about three weeks from the time of submission of the application.

#### **(ii) Full review**

Any research not considered to be low risk will be placed on the next UAHPEC agenda for full review. After each UAHPEC meeting the ethics administrators will inform principal investigators of the results of their applications, usually within five working days of the committee meeting.

#### **(iii) Expedited review**

An expedited review is a review that takes place outside the normal committee process. UAHPEC will consider a request for expedited review only in exceptional circumstances. Requests for expedited review must be made in writing by the principal investigator to the Chair of UAHPEC. An application accepted by the Chair for expedited review will be reviewed by four committee members, including the Chair. Decisions will need to be ratified at the following committee meeting.

### **8.2 Committee decisions**

The committee informs applicants of its decisions in an outcome letter. There are several possible outcomes:

#### **(i) Approved**

The ethics application is approved and the proposed research can proceed. The approval date and reference number should be inserted on all documentation intended for participants prior to the research commencing.

## **(ii) Approved with comment**

UAHPEC has given ethics approval and made some comments that do not necessarily require changes. However, any requested minor revisions to public documents such as the PIS and CF must be made. The researcher can proceed with the study, taking into account these comments and any changes required to public documents. The researcher does not need to resubmit the documents to UAHPEC. The approval date and reference number should be inserted on all documentation intended for participants prior to the research commencing.

## **(iii) Conditional approval**

UAHPEC requires the researcher to make revisions or provide further information or documentation before the research is able to receive final approval. The research cannot proceed until such final approval has been received.

The researcher must provide the requested revisions/modifications/clarifications/documents and highlight these in the text of the resubmitted documents using tracked changes. Each concern mentioned in the letter of outcome should be addressed in a covering memo with an explanation of the changes made and attached to the online form in the Attachment section.

The researcher must wait for an approval letter from the Ethics Administrators in the Post-Award Support Services team before commencing their research. The application does not have ethics approval until the PI has submitted the required responses and received an approval letter.

## **(iv) Pending resubmission**

In this instance, UAHPEC has not granted approval; this is usually because there are substantive ethical issues that still need to be addressed or are unresolved. The applicant will be encouraged to seek (further) advice from an ethics advisor and, in the case of students, from their supervisor. Low-risk applications cannot receive a pending outcome directly, but instead will be referred for full review.

The revised application must be resubmitted within two weeks of receiving the outcome letter in order for it to be added to the next UAHPEC agenda for full review. When submitting a pending application, sign-off will be required again from the Department and/or Māori Ethics Advisor. Any changes made should be listed in a covering memo and changes to the documents clearly indicated.

## **(v) Empowered**

The researcher must contact the nominated committee member and arrange a meeting/exchange of correspondence with them in order to clarify the concerns of UAHPEC. The researcher then makes the required changes and submits the revised documentation to the committee member who has the delegated

authority to decide the outcome of the application. When the committee member is satisfied with the changes, the researcher updates the applications and submits the revisions in InfoEd. The reviewer will inform the Ethics Administrators that the application is approvable. Once the researcher receives the letter of approval, the proposed research can commence and the approval will be noted at a UAHPEC meeting.

#### **(vi) Declined**

No approval is granted and the project cannot proceed. It is rare that an application is declined. The committee aims to facilitate researchers in bringing all research proposals up to the standard required for approval.

#### **(vii) Not relevant/Noted**

No approval is granted, but the project can proceed, because the proposed collection of data does not require approval from UAHPEC.

#### **(viii) Referred to HDEC**

UAHPEC cannot provide a review of the research because the proposed research falls within the health and disability research scope that requires review by an HDEC. The researcher must prepare an application using the HDEC online application form and submit it for HDEC review.

### **8.3 Period of ethics approval**

Ethics approval is normally given for three years.

### **8.4 Extension of ethics approval**

An extension of approval for a further three years can be requested. A researcher who wishes to request an extension of approval should submit an amendment request to UAHPEC through InfoEd at least one month before the expiry of the approval. If there are no changes to the documentation provided at the time of the original approval, this should be stated in the Amendment Request. If there are changes, even minor ones, resubmitted documents should clearly indicate the nature of the changes.

If ethics approval is still required for a project after a three-year extension, a new application is required.

## **9. ETHICAL CONSIDERATIONS IN RESEARCH DESIGN**

### **9.1 Recruitment of research participants**

In the application, the researcher must describe in detail how he or she will identify potential participants and the method by which participants will be invited to take part in the research.

Public records of names and addresses, such as the telephone directory, or the register of medical practitioners, may be used in the recruitment of participants.

Researchers can request that holders of records/databases that are not public forward information about the research to potential participants. Those indirectly contacted by this method can then approach the researcher to take part in the research if they are interested.

If the researcher has access to private records of names and addresses in a capacity other than that of researcher in the given project, or where the records are protected by the Privacy Act 1993, it is not acceptable for him or her to recruit participants on the basis of this access. In such a case, the researcher should seek the form of indirect contact described above, by formally requesting a senior administrator of those records to forward information to potential participants.

It will usually not be appropriate for the researcher to recruit members of their own family or friends. As an exception to this general rule, small-scale and minimal-risk research projects on topics that are not sensitive or controversial and conducted by students in the course of studying research methodology may involve the use of family and friends as participants, provided participants are aged 16 years or above.

Please see section [13.4.1](#) for information about conducting University-wide surveys of University of Auckland students.

### **9.2 Snowball sampling and direct recruitment**

Snowball sampling is an approach whereby current research participants are asked to identify additional potential participants who have expertise or interests relevant to the research project.

In such cases, UAHPEC considers that indirect recruitment should be used. Researchers may ask the current participants to contact other potential participants and pass on the researcher's contact details, and these potential participants can then contact the researcher if they are interested in learning more about the study.

In some studies researchers may consider that it would be more appropriate to contact the identified potential participants directly to introduce the research. If contact details have been collected for a purpose by a third party, the Privacy

Act prevents their use for other than that stated purpose. However, UAHPEC recognises that contact details held by individuals about other individuals, such as friends, relatives, workmates or schoolmates, are not typically covered by the Act. Where direct recruitment of potential participants is proposed, this must be clearly explained and justified to the committee.

In some studies, the researcher will know the participants because they are recruiting them from a small pool of experts or leaders in a particular field. The recruitment method in this case may be a combination of direct recruitment and snowballing. In cases such as this, researchers should clearly explain in their application the recruitment method and rationale, any potential problems with this method and how they will address those problems.

UAHPEC requires that researchers consider the sensitivity of the data to be gathered from potential participants. Where these data are sensitive, with the potential to cause harm to participants, it may not be appropriate to use snowball sampling.

### **9.3 Consent**

The principle of autonomy requires that research participants' capacity for self-determination is treated with respect. This section outlines the requirements that must be met for consent to participate in research to be valid. Further information is provided about aspects of consent in the sections concerning research with children (section [9.7](#)) and conducting research in schools (section [13.11](#)). [Section 6](#) includes an example of a consent form.

Explicit, informed and voluntary consent is required from competent participants in research, with few exceptions. Seeking consent to research is frequently a process, rather than a one-off event, and needs to be thoughtfully tailored to the individual research protocol. Researchers should explain how they have designed the consent process for a particular study, and why it is appropriate.

When enrolling incompetent participants, processes for gaining assent and proxy consent must be clearly described, where relevant. Where participants are not competent to give consent, their assent to research should be sought where possible.

### **9.4 Information for participants**

Researchers must provide participants with appropriate information about the research in a comprehensible manner. What information should be provided and how best to do so will vary, depending on the specific research proposal.

Section [6.4](#) indicates the essential elements of information for participants. Researchers should carefully consider how best to provide information on these core topics, as well as what additional information, specific to their project, should be provided.

## **9.5 Voluntary participation**

Consent to research must be voluntary, and participants can withdraw from research participation at any time (see Section [10](#)). Researchers should identify possible constraints on free decision-making, such as imbalances of power between researchers and participants, and describe how they can support participants being able to make free and voluntary decisions. In some cases, for example, participants may feel more able to reach a voluntary decision about research if recruited indirectly, rather than directly by the researcher.

## **9.6 Focus groups or interviews with more than one person**

Focus groups and interviews with two or more participants present specific ethical considerations:

- It is not possible to guarantee confidentiality
- Withdrawing information contributed by a participant is generally not possible, and risks compromising the integrity of the data from other participants who do not wish to withdraw from the research
- When a focus group or interview with two or more participants is to be recorded, it is not possible for individuals to decline to be recorded. This needs to be made clear in the PIS and participants need to be advised that they cannot ask for the recorder to be turned off, but that they can choose to not answer any question (that is, they can stay silent) or they can leave the room. On the CF, a bullet point must be included where participants can acknowledge their understanding that the focus group will be recorded.

Therefore, researchers must advise participants of these issues during the consent process and actively encourage participants to maintain the confidentiality of information shared under such conditions.

## **9.7 Children**

Children require special care to be taken if they are included in research. Research with participants under the age of 16 years should be undertaken only if there is a specific and demonstrable need to perform it, and no other reasonable route to the relevant knowledge is available.

UAHPEC usually requires parental or legal guardian consent for participants below the age of 16, but it has some flexibility in this regard depending on the nature of the research proposal. The informed *assent* of the child is also required if he or she is of an age to understand the project. While the researcher should endeavour to obtain written assent, there may be situations involving children where verbal assent is acceptable; for example, where there are language or literacy difficulties. Record should be kept of the fact that a child has given assent and how.

Where children are invited to participate in research they and their legal guardian, where required, must be given adequate information about the

research and what the child will be asked to do. The researcher must be sensitive to potential conflicts of interest between the parent, guardian or carer, and the child. Children must be given information about the research in a form that they can understand. In addition, each child must be advised of his or her right to decline to participate and his or her right to withdraw from the research at any time without giving a reason. Researchers must give the child an opportunity to ask questions and have them answered to the child's satisfaction.

Usually it is sufficient for only one of the child's guardians or caregivers to consent to the child's participation in research. However, the committee may require the consent of all the child's legal guardians in special circumstances, including where:

- the research is on a topic of particular sensitivity to the child and/or guardians
- there is any risk to the child's physical, emotional or psychological well-being
- the child will be asked to discuss any matter relating to their guardians.

In some circumstances (for example, children who may be considered capable of providing consent on their own behalf), the consent of the child rather than the parent is sufficient. For this to be the case, UAHPEC must be satisfied that the potential child participant will be able to understand their part in the research and the requirements of participation. However, even when the child's consent is accepted as sufficient, the committee often requires that the child's parent, guardian or carer will at least be informed about the research, even where there are no perceived risks (unless special circumstances dictate otherwise).

In determining whether the consent of legal guardians is required, UAHPEC gives consideration to the following:

- the nature of the research topic and whether it would normally be regarded as being within the comprehension of a child of the age and experience of the intended participants
- whether the research concerns a topic, or involves ascertaining the child's views on a matter, that a reasonable parent, guardian or carer would wish to be informed about because it may affect the child's relationship with them or may cause the child some concern
- whether the research methodology enables the child to have the information, time and support required to give informed consent. In certain circumstances, a child's competence to consent may need to be individually determined
- whether the research is designed or supervised and carried out by people experienced in working with children
- whether the consequences (educational, social, emotional or physical) of participation might be of concern to the parent, guardian or carer.

Where a child is not competent to give his or her own consent, the researcher should:

- Inform the parent, guardian or carer about the research and advise them of the child's right to decline to participate or to withdraw from the research at any time without giving a reason
- Give the parent, guardian or carer an opportunity to ask questions and have them answered to their satisfaction
- Obtain the consent of the child's parent, guardian or carer before the child is approached for their assent
- Obtain a child's assent to participate if they are able to understand the nature of the project and what participation involves. The researcher should check the child understands by asking them a few simple questions
- Provide a separate PIS for the child. The wording used should be appropriate for the child's age and reading ability. Where appropriate, assent may be given verbally. The researcher must keep a record of the written or verbal assent given
- Respect the child's right to refuse to participate whether or not the parent, guardian or carer has consented on behalf of the child.

If either the child or the legal guardian declines consent, the child cannot participate in the project. The child's decision not to participate in the research takes priority over any other valid proxy consent.

No financial inducements should be offered to parents, guardians or carers to persuade them to allow a child in their care to participate in a research project. However, after their participation, children may be offered small gifts, so long as the nature of the gift has been described in the PIS. Compensation for expenses incurred by reason of participation may be offered.

In any research where children are videoed there must be parental consent.

Please note that UAHPEC will not approve any research to be undertaken by a researcher on the researcher's own children unless exceptional circumstances apply.

## **9.8 Institutional approval**

When conducting research within an institution, researchers should determine what forms of institutional authority for the research to take place are needed, prior to recruitment of participants. Typically, executive officers must consent for the research to proceed in their organisation, but only the participant employees can give consent for their own participation.

If researchers consider that it is not appropriate to seek institutional approval, they must justify this in the application and ensure that they address how, in these circumstances, the employer's interests would be protected. An example might be where individuals with specific expertise from a range of organisations



will be recruited rather than research being conducted wholly or primarily within a single organisation.

For more information about research within institutions, see Section [13.4](#).

### **9.9 Documenting consent**

Typically, UAHPEC requires consent to be recorded on consent forms. See Section [6.5](#) for an example.

If alternative methods of consent, such as verbal consent, are sought, this must be clearly explained and justified in the application. In such instances, the research process must include a procedure for documenting that consent has been obtained.

Where questionnaires are anonymous, UAHPEC accepts a completed written questionnaire as evidence of consent, provided that appropriate information has been provided about the research.

### **9.10 The Privacy Act 1993 and use of private information in research**

The University's Research *Code of Conduct* states that:

*"The Privacy Act 1993 regulates the collection, holding, retention, use and disclosure of information about identifiable individuals. Most, and in some cases all, of the twelve Privacy Principles in Section Six of the Act will have direct application to personal information obtained for the purpose of research. All researchers who collect personal information about individuals should be familiar with Privacy Principles and ensure that they are faithfully observed in the conduct of research, the collection and retention of data, and the publication of its results."*

<https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf>

For further information about the Privacy Act and how it relates to research, please see:

<http://www.legislation.govt.nz/act/public/1993/0028/latest/DLM296639.html>

### **9.11 Confidentiality and anonymity**

The key principles of ethical research are underpinned by the value of respect for persons. Inherent in this is the need for researchers and UAHPEC committee members to consider how the privacy of research participants is protected and the confidentiality of data maintained.

Despite the importance of the terms 'anonymous' and 'confidential' in the context of research with human participants, the difference between them is not always well understood.

### **9.11.1 Anonymity**

An anonymous record, biological sample or item of information can in no circumstance be linked to an identifiable person.

Participation in a research study is 'anonymous' if it is impossible for the researcher or anyone else to connect a research participant with the data that the participant has provided. Participants who are personally interviewed by a researcher, or part of a focus group, are not anonymous.

A common practice in research projects is to assign codes to participants. A research study is not anonymous if the researcher assigns the codes to participants. Therefore, to preserve anonymity, a third party (someone other than the named researchers) must be used to separate the identifiers from the data which is then coded. The third party would normally be required to sign a confidentiality agreement.

Under normal circumstances, the anonymity of participants completing web-based surveys can be guaranteed, even when the IP address of the participant is known. The risks associated with anonymous online surveys are similar to those associated with anonymous paper-based surveys. However, there are some exceptions as explained in [Section 13.2](#).

If potential participants cannot be guaranteed anonymity, they must be told this in the PIS. It is likely that anonymity will not be able to be guaranteed where the number of participants is small, where the outcomes of the research will be released among a small group of informed persons or where research is being undertaken with identifiable members of a community. For example, in a survey of teachers in a school, it may be possible to identify respondents in the research report if sufficient details are given of age, gender, subjects taught and length of time at the school, even if the teachers did not provide their names in the survey.

Research design should also consider how to protect the anonymity of non-participants. For example, if a questionnaire is used in a class, the preservation of anonymity may make it appropriate that those who have declined to participate should return a blank questionnaire.

### **9.11.2 Confidentiality**

Confidentiality in research means that information is private to the researcher and participant; that is, the information is held by those who share the confidence. The data from the research study can still be linked to individual participants by members of the research team, but not by those who were not involved in the research.

Researchers need to have strategies in place to protect confidentiality and must outline these strategies in their ethics application. Consideration must be given to how data will be represented in research reports and to the management,

storage and destruction of data. All data should be stored securely, and identifying materials (including key words or codenames) should be stored separately from coded data.

It may be misleading to describe the information collected during the research as confidential if it will be reported or published. An appropriate phrasing for the PIS might be:

"If the information you provide is reported/published, this will be done in a way that does not identify you as its source."

"If the information you provide is reported/published, this will be done in such a way that its source cannot be identified"

Researchers can only give an assurance of confidentiality to the extent allowed by law. Some government agencies and departments, such as the Police, IRD, and Customs, have a legal right of access to certain information. In some circumstances a court has jurisdiction to require disclosure of information relevant to a matter being heard by the court. A disclaimer should therefore be included in any stated guarantee of confidentiality stating that confidentiality will be maintained to the extent allowed by law.

In addition, there is always a risk of inadvertent disclosure whenever information is collected and recorded.

If potential participants cannot be guaranteed confidentiality, this should be clearly stated in the PIS. For example, participants must be told that confidentiality cannot be guaranteed where participants meet together, such as in focus groups.

Where third parties (that is, people other than the named researchers) are given access to data that is not anonymous (for instance, for the purposes of transcription or translation), they must sign a confidentiality agreement (see exemplar, Section [6.8](#)). Also, the PIS for those who supplied the data should explain how confidentiality will be maintained. Any confidentiality agreement with transcribers or translators must be submitted with the application to UAHPEC.

Where there is a possibility that the researcher may be given information that reveals a reasonable possibility that the life or health of any person may be at serious risk, the researcher will most likely have moral and legal obligations to breach confidentiality and report that risk to the appropriate authorities and appropriate others. The PIS should inform the participant of this.

Where there is the intention, or desire, to make public the names of participants, this should be clearly stated in the PISs and consent gained in CFs.

### **9.12 Conflicts of interest**

The researcher must address potential conflicts of interests; for example, a conflict of interest between their activities as a researcher and their professional and/or personal interests. The researcher must declare in the ethics application form and PIS anything that could be perceived as a conflict of interest, and explain what actions they propose taking to resolve, avoid or minimise the conflict.

Researchers need to be sensitive to potential conflicts of interest if they seek to enrol as participants:

- their students
- those who are (or may perceive themselves to be) dependent on the researcher
- family members
- friends.

In addition, researchers must be sensitive to possible conflicts of interest between participants; for example, between parents and their children, principals or CEOs and their staff, or teachers and their students.

To avoid conflicts of interest, or the appearance of conflicts of interest, researchers may not recruit their own children as participants if they are under the age of 16, except in exceptional circumstances that must be justified to UAHPEC (see Section [9.1](#)).

The sponsorship or funding of a project must not compromise its research adequacy or ethical acceptability. If the research is funded, the support and its source must be identified in the PIS or PIS/questionnaire and research reports.

### **9.13 Minimising harm**

All research studies carry some risk of harm, but researchers must minimise that risk. Researchers should assess their research and discuss any potential for harm, to individuals or communities, in their application for ethics approval. Whenever there is risk of harm, researchers should give careful consideration to possible alternative procedures.

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.

Although researchers must do what they can to minimise risks, they can never completely guarantee the safety of research participants. Therefore, potential participants must be made aware of potential risks during the consent process and agree to them before enrolling in the research. In addition, researchers must be mindful of their own safety and well-being.

In their ethics application, researchers must stipulate what monitoring and resources will be available and what procedures will be followed should

participants experience harm or distress as a result of participating in the study. If appropriate, the researcher should describe to UAHPEC the experience available in the research team to deal with such potential harm.

Further information on risk management and liability insurance is available from the Manager, Performance and Risk (ext. 87834).

#### **9.14 Deception**

Some forms of research involve deceiving participants about the purpose of a research study until after it has been completed. For example, some information may be withheld from participants until study completion because giving them this information would jeopardise the validity of the research.

UAHPEC very carefully reviews any study which proposes using deception and requires a clear justification from the applicant as to why the deception is considered necessary and how participants will be safeguarded. In their application, researchers must explain the proposed deception in detail and how it varies from the PIS and CF for participants.

UAHPEC is unlikely to approve any deception of research participants unless:

- the reasons for it are well-justified, such as the significance of the potential knowledge to be gained
- there is no less deceptive means reasonably available
- the research is of minimal risk
- the extent of the deception is explained in the ethics application
- disclosure of the deception takes place as soon as practicable
- participants are offered a debriefing session after the data-gathering in which the deception is explained
- participants have the right to withdraw any data obtained from them by deception.

It is never appropriate to deceive the participants about the procedures they will have to follow, or the time the procedures will take, when they take part in the research.

#### **9.15 Audio, video or other forms of electronic recording**

##### **9.15.1 Consent to being recorded**

Some research studies include electronic recording of participants. If the recording is essential to the research, participants cannot ask for the recording to be stopped. If the recording is optional, the participant may choose to have the recorder turned off at any time. Suitable wording for the PIS might be:

*"Participants will have the right to withdraw from a focus group meeting at any time without having to give a reason. However, they will not be able to withdraw their data because of other focus group members' information on the same recording."*

### **9.15.2 Transcription or translation**

If someone other than the researcher or another member of the research team is going to transcribe a recording, an explanation should be added to the PIS about who will transcribe and/or translate the recording and how confidentiality of information will be preserved. In this case, the transcriber and/or translator must sign a confidentiality agreement.

### **9.15.3 Review and editing of recordings and transcripts**

The committee recommends that participants are offered the opportunity to review and edit transcripts of recordings and when possible, also to review and edit the recordings. Editing of transcripts is not usually appropriate for focus groups.

Only people who have been recorded should be given the opportunity to review their own recordings or transcripts. Chief executive officers, for example, should not normally be given access to recordings made of their employees or to transcripts of the recordings. If such access is proposed, this must be clearly explained to participants during the consent process. If those who have been recorded are permitted to review recordings or transcripts, a clear description of the procedures, including a timeframe for the editing to be completed, should be given in the PIS. A timeframe must be specific, for example, two weeks after receipt of the transcript.

### **9.15.4 Ownership and storage of recordings**

Indicate in the PIS who will own the recorded data and how the data will be disposed of at the completion of the study. Options include: participants retaining the recording; participants agreeing that the recording will be destroyed; or participants consenting to the recording being stored in a research archive. If the data have not been publicly archived, which requires the participant's agreement, stored data should be accessible only by the researcher.

### **9.16 Reimbursement and compensation**

Where participants incur costs, they can be reimbursed. However, compensation, payments, prize draws and gifts for research participants should not be so large as to unduly induce individuals to consent to participate in the research.

Researchers may reimburse research participants for reasonable expenses incurred as a result of participating in the research, such as bus fares. When there is evidence for actual costs (such as bus tickets), reimbursement should be processed through normal departmental reimbursement procedures.

It is also acceptable to compensate participants for their time and to give participants a gift to thank them for participating.

Researchers should take into account the following conditions regarding compensation or financial remuneration:

- No inducements should be offered to parents, guardians, or carers to persuade them to include children under the age of 16 in a research project
- No financial inducements should be offered to participants who are under 16 years. Small gifts, or opportunities to participate in modest prize draws by way of thanks for participation, may be appropriate
- Where the purpose of a gift or suchlike is to thank participants for agreeing to take part, the gift should apply to all participants, irrespective of whether they withdraw during the project
- The reason for, and the level of, reimbursement, compensation or gifts should be clearly explained in the PIS, CF and in any advertising or promotion of the research
- Participants should be given an opportunity to decline payment or seek recompense in an equivalent or culturally appropriate manner, such as a koha payment to an iwi
- The committee prefers financial inducements to be given in voucher form rather than in cash.

Researchers need to be careful about how they describe a payment made to recompense participants for expenses incurred as a consequence of their participation in the research. The term 'remuneration' implies that there is an employment relationship between the University and the participant and this has tax and administrative implications. However, the term 'reimbursement' means that the participant is being recompensed for their expenses. Therefore, researchers might like to use wording such as:

*"Research participants will be reimbursed for transport costs that they incur as a result of their participation in this research study."*

*"To recognise the costs involved in participating in this research, participants will be reimbursed \$20 for attending the two focus group sessions."*

*"To thank participants for their contribution to the research, each will receive a \$20 voucher."*

### **9.17 Social and cultural sensitivity**

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.

Research may involve recruiting members from particular communities, be they based on culture, geography, special interests or goals, shared situations or experiences. In such cases, the researcher has a duty to find and use appropriate channels to seek advice and, where appropriate, permission to work

with such groups, as well as consulting with them about the appropriate conduct of research.

### **9.18 Use of human remains, tissue and bodily fluids in research**

Ethics approval is required for research involving human remains, tissue and bodily fluids. Such research, when it intends to use, collect or store human tissue without consent, or to make human tissue available in a form that could identify the individual(s) concerned, should be submitted to an HDEC for review and approval. In all other cases, applicants must seek approval from UAHPEC to use human remains, tissue and bodily fluids for research.

Research and teaching involving human remains, tissues and bodily fluids should take place only if the wishes of the local community, ethnic groups, relatives, guardians and the wishes of dead persons, with respect to investigation, storage, and/or disposal, are known or can reasonably be inferred and complied with wherever possible and reasonable.

All human remains, tissue and bodily fluids (including blood samples and semen) must be treated with respect, irrespective of age, condition, origin, ethnicity, religion, gender, or nationality. In general terms, samples collected for one purpose must not be used for another without the consent of the donor.

Where application needs to be made through the Tissue Transplant Coordinator to obtain tissue from autopsy, or any cadaver or fetal material, for purposes of teaching or research, the details of the information provided by the coordinator, and details of any information to be given by the coordinator to those giving consent for the use of such material, must be provided in the application to UAHPEC.

In all cases of research or teaching involving human remains or tissue, the mode and place of storage and, where applicable, the ultimate disposal of the remains or tissue must be stated in the application to UAHPEC.

The Human Tissue Act 2008 regulates the collection, storage and use of human tissue in research and the ethical requirements for its collection, storage and current or future use:

<http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html>

The UAHPEC can only review applications involving human tissue, if the tissue was or will be used, collected or stored with full consent and is or will be de-identified. If the human tissue was or will be collected, used or stored without full consent or is not de-identified, the application may have to be submitted to a Health and Disability Ethics Committee. Please consult section 29.2 of the *Standard Operating Procedures for Health and Disability Committees (August 2014, <http://ethics.health.govt.nz/operating-procedures>)*.



## **9.19 Hazards**

### **9.19.1 General**

Many procedures are potentially hazardous in terms of the equipment used (for example, electrical equipment) or the environment in which a study is conducted. Many chemical substances, including medicines, are hazardous or potentially so. Applicants should take account of the safety or otherwise of proposed studies. UAHPEC may refer proposals to appropriate safety experts, including the relevant safety committee, as it deems necessary.

### **9.19.2 Radioactive substances**

The use of radioactive material or equipment capable of generating ionising radiation must be under the control of a person who possesses a licence issued by the National Radiation Laboratory.

Applications for approval for any research or other activity involving the administration of any radioactive substance, or exposure to ionising radiation, can only be undertaken after prior permission for the purpose has been obtained from the National Radiation Laboratory and a specific licence issued.

### **9.19.3 Biological safety**

The use of hazardous micro-organisms or genetically modified organisms must have approval from the University of Auckland Biological Safety Committee. UAHPEC will expect approvals to be included in applications, and it reserves the right to approach appropriate experts.

More information is available as follows:

- For general advice on safety matters contact the University Health, Safety and Wellbeing Manager on ext. 84896.
- The University's Hazards and Containment Manager on ext. 86714. Email: [d.jenkins@auckland.ac.nz](mailto:d.jenkins@auckland.ac.nz)
- The University of Auckland Biological Safety Committee webpages on the staff intranet: <https://www.staff.auckland.ac.nz/en/research/funding-and-ethics/applying-for-ethics-approval-and-ensuring-biological-safety/the-university-of-auckland-biological-safety-committee.html>

## **9.20 Secondary data analysis**

Some research studies make use of secondary data; that is, data that was originally collected for a purpose other than the current research purpose. Secondary datasets include censuses and clinical records. The same dataset can be a primary dataset to one researcher and a secondary dataset to a different researcher.

Permission of the custodian of the data is required for access to secondary data which is not publicly available and researchers considering giving access to data

sets should be aware of the requirements of the Privacy Act 1993, particularly Principles 10 and 11.

Ethical approval will sometimes be required for the use of secondary data; for example, if the data identifies individuals. Ethical approval for proposed research may sometimes be required by custodians of data prior to providing access.

If the personal information collected for a particular research project is to be used for statistical research purposes in a second project, and the information will not be published in a form that is likely to identify the individual concerned, no further ethical approval is required.

If you need to identify the person concerned, for another reason, such as fear of potential harm to that individual, or for the greater good of the public, you will need to obtain ethical approval from UAHPEC.

If the personal information is to be used for research that is not related to the original research, you will need to obtain ethical approval from UAHPEC.

For more details on the circumstances permitting the use and disclosure of personal information of research participants refer to *Principles 10 and 11 of the [Privacy Act, 1993](#)*.

## **10. WITHDRAWAL OF PARTICIPATION**

### **10.1 Withdrawal from participation in research**

Agreeing to participate, and continuing to participate in research, must be voluntary. A research participant is entitled to withdraw from a research project at any stage without explanation and this must be explained to them during the consent process.

### **10.2 Withdrawal of data from research**

As a general rule, a participant whose identity is known to the researcher is entitled to withdraw the data they have provided. The PIS must inform participants of this right and give a specific date or timeframe by which the right must be exercised, typically within a set period of time from the data being collected, or before the analysis of research results commences.

If the time constraints of the research or the method of recording data (for example, an audio recording of a focus group) make withdrawal of data by the participant impractical, this must be stated in the consent process and must be specifically consented to by the participant.

If anyone other than the person who provided the data is entitled to withdraw the data, this must be stated in the consent process.

## **11.STORAGE, RETENTION AND EVENTUAL DESTRUCTION OF DATA**

The University's general requirements for the storage, retention and destruction of research data are set out in the University of Auckland's *Code of Conduct for Research*, section 5.4 Research Records.

<https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf>

More detailed information for researchers seeking human ethics approval is set out below.

Information should be handled in a way that protects participants' confidentiality and ensures the authenticity, integrity and safe custody of the data. Take care to protect the privacy of individuals, institutions, communities and ethnic groups, as required by the Privacy Act 1993. 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 only by the researcher and supervisor. Researchers should consider how participants who are under the age of 16 years when they consent to the use of their data can be given the option to re-consent to the use of their data when they reach the age of maturity.

### **11.1 Storage considerations**

The principal investigator should consider where the information is to be stored, especially if it is in electronic format. Some kinds of storage, for example in the cloud, may have particular issues. The PI needs to address considerations such as where the cloud is located, who 'owns' the data, and what happens when the data are deleted. The PI also needs to consider the format in which the data are stored. The software will need to be something fairly stable and widely accessible; otherwise it may not be possible to access it in a few years' time. Removable media such as USB sticks are easily lost and corrupted.

Storage of data for posterity and future research that involves transfer to a public repository requires 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. For advice on such storage, see the Code of Ethical and Technical Practice devised by the National Oral History Association of New Zealand at <http://www.oralhistory.org.nz/index.php/ethics-and-practice/>

## **11.2 Retention and destruction of research data**

The University's *Code of Conduct for Research* states that

*"Original research data should preferably be kept indefinitely. At an absolute minimum, research data should be kept for at least six years, but where research data form the basis of a patent, they should be kept for a minimum of 21 years from the date the patent application was filed. In cases where an ethics committee approval requires data to be kept for a specified minimum period, this must be adhered to. It is important to keep data which have resulted in publication for sufficient time to allow reference to the data by other researchers and interested parties. For published research data, this may be for as long as interest and discussion persist following publication"* (p.5).

Unless it is intended to keep data indefinitely, then a fixed term should be stated rather than 'at least 6 years'. If data are to be kept indefinitely, this intention and the reasons should be made clear to potential participants.

If data are to be destroyed, clear indication should be given to UAHPEC and research participants regarding the timing and manner of doing this. If data are not to be destroyed, this must be indicated to participants along with the purpose of retaining it.

Destruction of electronic data involves more than just 'deleting'. The PI should seek advice as to the best method of complete destruction.

## **11.3 Storage of Consent Forms**

The University requires that Consent Forms be retained in secure storage by the researcher (in the case of students, through the primary supervisor) for a defined period of at least six years, separately from research data. Information relating to storage period must be shown at the top of the Consent Form (e.g., "This form will be kept for a period of six years").

## **11.4 Practical steps to ensure secure data storage**

Practical steps to ensure the security of the data might include:

- coded storage of information
- identification of participants through the use of key words or codenames
- separate storage of recorded information from transcripts or other identifying material
- where the material is in both paper and electronic format, there should be a link in each part referring to the existence of the other part to make sure that the complete data set is being managed
- having an audit trail to show who, if anyone, has accessed or attempted to access the data.

## **12. CONTINGENCY PLAN**

The PI needs to have a contingency plan in the event that a researcher leaves the University before the end of the stipulated storage time or in the event that the storage area is no longer available or accessible (this applies to electronic data as well).

University of Auckland data will remain the property of the University and become the responsibility of the academic unit involved. Individuals leaving the University may negotiate to take copies of the data and should contact the agreements team within the Research Office to facilitate such an agreement ([ro-agreements@auckland.ac.nz](mailto:ro-agreements@auckland.ac.nz)). Any arrangements made should be documented and the documentation should be stored with the data.

## **13. Research design – particular types of research**

### **13.1 Research for coursework**

Ethics approval for laboratory-based courses or other student research projects that involve human participants and are part of undergraduate or graduate coursework requirements should be obtained from UAHPEC by the course coordinator(s). The same UAHPEC application form is used for both research projects and student coursework. When completing the form, the applicant is asked to select whether their application is for a 'Research Project' or 'Coursework Application'.

The completion of a single application form to cover multiple research projects or laboratories can be acceptable in some circumstances, as long as the application relates to a single course and a detailed description is given of all projects.

Where there is a relevant course book or laboratory manual, this may be appended to a Coursework Application, but in any case the nature of the research activities should be clearly described in the application.

#### **13.1.1 Student research in courses**

Individual research projects undertaken by students for their dissertation do not qualify as coursework research.

Coursework applications are for class research projects that either:

- have a common set of research questions and procedures that do not vary from student to student (for example, in laboratories), or
- allow students to choose their own research questions and procedures, as long as these do not vary significantly from those of other students in their course.

Course coordinators are responsible for ensuring that students understand and observe the ethical principles and requirements applicable to such projects and for ensuring compliance with UAHPEC requirements.

#### **13.1.2 Student participants**

Some courses include a research activity that takes place in class time, with students from the course acting as participants.

A student does not have to participate in any particular research activity should he or she chooses not to. UAHPEC requires that participation in a given research exercise remains voluntary. Alternative activities should be provided for students who choose not to participate. Consent to participate should be obtained from each student participant.

Potential class participants should be informed about:

- the purpose of the research activity and its relevance to class objectives
- what the information they provide will be used for
- the extent to which their participation and information will be kept confidential
- any potential risks
- health and safety provisions as appropriate
- that participation is voluntary and what alternatives there are should they choose not to participate.

Where research is undertaken for the 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 informed of 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.

### **13.1.3 Laboratory-based coursework**

If laboratory participation is a formal requirement of the course, this should be stated in the University Calendar, department handbooks and other course descriptions. Individual students are not required to give written consent as their enrolment in the course is taken as consent. In such instances, the coursework research is explicitly pedagogical, it contributes directly to the course content and objectives, and the information collected is not for wider dissemination.

If laboratory participation is not a formal requirement of the course, or if the University Calendar, department handbooks and other course descriptions do not state this explicitly, written informed consent must be obtained from each student participant. If any students do not consent to participate, they should be required to complete alternative work as appropriate.

### **13.2 Internet research with human participants**

The Internet is a communication medium in which both social use and technology change rapidly. It is important that applicants using the Internet for research show awareness of the ethical implications of any technology they may use. The recommendations from the Association of Internet Researchers (AoIR) Ethics Working Committee highlight the complexities of Internet research involving human participants, and may help applicants to frame the ethical issues that arise in their own research.



All staff and students contemplating use of the Internet should ensure that their research observes the principles and requirements of UAHPEC. Applicants should also be aware that members of the committee may not be familiar with any given technology, so care should be taken to explain technical details in lay terms.

To avoid confusion, we use the term 'public sphere' in this document to refer to all data that are visible to members of the public. Although the data are visible, copyright and intellectual property rights may be retained by the owners of the data, and these rights must be respected. Research involving data that would normally be treated as 'personal' or that deals with sensitive issues should be considered particularly carefully.

### **13.2.1 Research involving data obtained from the 'public sphere'**

Works that are visible to a public audience (that is, in the public sphere) are not necessarily in the public domain. Formally, works in the public domain are those whose intellectual property rights have expired or are inapplicable. The term is not normally applied to situations where the creator of a work retains residual rights. Many of the works available digitally through the Internet (such as websites created and maintained by commercial organisations) are publicly available, but they are not in the public domain since the creator of the work retains copyright.

Researchers are normally exempt from the need to obtain UAHPEC approval for research where the data are collected from the 'public sphere'. However, there are a number of situations involving data in the public sphere that need careful consideration by researchers

- a. Digital data can be searched much more easily than more traditional media, and it is frequently possible to link data in a way that would be practically impossible with non-digital data. This introduces additional risks for contributors to the public sphere since it may be possible to identify the source of 'anonymous' posts through search engines. If data obtained from the public sphere are reported in such a way that the author of the data may be unintentionally identified, UAHPEC approval should be sought.
- b. The provenance of data in the public sphere is typically unknown. The data may have been obtained illegally, or (more likely) have been shared without the permission of the original owner. This is particularly problematic for social media sites in which photos that identify individuals, or an individual's personal data, are shared publicly without their consent. Researchers should avoid using data suspected of being released without permission of the owner.
- c. In some cases, automated search engines are able to access material, even when access for humans is restricted through a registration or log-on process. This makes the material sourced directly from search engines available

to a wider audience than intended by the original authors/owners. Researchers collecting information directly from search engines should attempt to determine if such information has been obtained from restricted websites. If this is the case, it does not properly belong in the public sphere and permission would need to be sought from the owner of the data, and UAHPEC approval obtained.

d. If researchers believe that data collected from the public sphere are likely to include information from vulnerable populations, or if data are collected from online discussions designed for children or young persons, for example, UAHPEC approval should be sought.

e. Data collected from the public sphere in which the researcher has participated, or has interacted with the participants, are considered to be problematic. Such research is not considered to be simply an analysis of publicly available archival data, but rather research in which the researcher influences the responses of participants in some way. For all such research, UAHPEC approval should be explicitly sought.

### **13.2.2 Consent for online research**

a. If data are not in the public sphere, such as sites in which registration is required prior to access, consent would be required from the organisation that manages access. However, consent may not be required from individual participants if the research is considered to be archival in nature.

b. Researchers performing research that requires online consent should be aware of issues around identity and should make an attempt to address these issues in their application where possible; for example, minors, impaired, and vulnerable subjects cannot be readily eliminated from the research.

### **13.2.3 Privacy and confidentiality of data**

a. A guarantee of privacy and/or confidentiality is problematic for researchers who wish to use quotations in research because of the relative ease by which text can be tracked to the original source by users who have access to the data. This is especially the case if the researcher does not control the data source (for example, the data source is a forum that is internal to an organisation) or does not control access to the data source (for example, the administrator of a forum may change the access to the forum from private to public).

b. Encryption of data transferred via the Internet is not typically required, although it is more secure than unencrypted data. However, for sensitive data, such as financial data, health data, and other highly personal data, encryption is expected as a normal part of data management to reduce risk.

#### **13.2.4 Anonymity**

As discussed in Section [9.11](#), *Confidentiality and anonymity*, under normal circumstances, the anonymity of participants completing web-based surveys can usually be assured, even when the IP address of the participant is known. However, there are some exceptions.

- a. In cases where data are sensitive and the preservation of anonymity is paramount (such as questionnaires involving illegal activities), researchers should take additional steps to ensure IP addresses are not tracked and to inform UAHPEC of these additional steps.

Where the researcher is using a standard third party provider (such as Qualtrics) they should check that the provider guarantees, and can provide evidence, that the IP addresses will not be collected during the course of the survey. As an added precaution, researchers can check that the data are encrypted during transfer.

If the researcher has created their own website to collect responses, they can (for example) assure UAHPEC that the server has been set to NOT record logs of access, or perhaps set up a proxy server to make the results anonymous.

- b. In the specific case where a researcher is administering a survey within an organisation and has access to the network within that organisation, the IP address may reveal the identity of the participant. It is possible that other circumstances may arise in which the IP address reveals the identity of the participant. In such cases, anonymity cannot be guaranteed.

#### **13.2.5 Respecting the wishes of participants and organisations involved in Internet research**

Much of the information available on the Internet is hosted through companies that may impose additional restrictions on use. Researchers using these services should be aware of the terms and conditions of use and adhere to them. Researchers who want to vary the terms and conditions of use could contact the owner and seek approval to use the information in the way their research requires.

### **13.3 Telephone research**

Where research is conducted by telephone interview, the researcher should:

- Provide UAHPEC with a copy of the research questions to be asked and a script of the information to be given verbally to participants, or make it available on a web platform.
- Confirm the potential participant is aged 16 years or over (by asking them if they are)
- Give the potential participant a verbal explanation of the research, and ask them whether they agree to participate in the research under the terms specified. Audio-record verbal consent if at all possible.

- Thank the participant, and provide a contact telephone number at the University in case of any complaints.

In some circumstances (for example, where potential participants are readily identified, their addresses are known, and the sample is not large) it may be appropriate to send an information sheet before conducting the research. This should state that the participant will be telephoned to be invited to participate in the research, or that, if interested, the participant can telephone the researcher.

### **13.4 Research in organisations**

Where an organisation, or part of its operations, is the subject of research, and the researcher proposes to include members of the organisation as participants, the researcher should usually approach the CEO or other relevant person in the organisation for permission for the research to take place. Where potential participants have different levels of status or authority within the organisation, the researcher needs to establish the most appropriate way of gaining access to them.

- While the organisation needs to give permission for the research to take place, each employee has the right to decide whether to participate or not, and to have their participation or non-participation kept confidential from their employers.
- Participants have the right to have the content of their participation kept confidential to themselves and the researcher.
- Participants have the right to an assurance, given by their employer, that their decision to participate or not in the research will not impact on their employment situation or relationship with their employer.
- Employers have the right to withdraw access to their employees at any time, but do not have the right to withdraw participant data already given to researchers as part of the study. This data can only be withdrawn by the participants (when data is identifiable).
- In situations involving participant observation, all potential participants should be informed of the observation and given the opportunity to minimise their participation if they so wish. If researchers propose not to provide such information, this must be justified to the committee.

Deviations from these rights need to be justified. At all times, the fact that employees are in a dependent relationship with their employers should be borne in mind.

If the organisation or any other party with an interest in the activities of the organisation or participants sponsors the research this must be stated in the PIS. If a report is to go to the organisation this must also be stated in the PIS. When participants' comments are reported to the organisation, this should be done in a non-identifiable way if possible. During the consent process, participants must be informed if non-identification will not be possible.

At times a researcher may want to speak with a person within an organisation because they may be a particular expert in a field, in which case they may be approached externally or separately to their organisation and in these instances there is no need to obtain consent from the CEO.

#### **13.4.1 University-wide Surveys of University of Auckland students**

The University carefully regulates University-wide questionnaires/surveys aimed at the students. The Student Survey Policy outlines the guidelines that govern such surveys. The Policy defines a "University-wide student survey" as a paper or electronic survey that either "targets a student population drawn from more than two faculties" or "spans a significant proportion of the student population". Any such survey must be part of the Institutional Quality Analyst's submission to the Education Committee for approval, which takes place early in the calendar year.

#### **13.5 Research with vulnerable participants**

Vulnerable individuals and groups may be included in research projects where appropriate. Indeed, it is unethical to exclude vulnerable people from research simply because of additional difficulties that this might cause.

Vulnerability is usually the result of limited capacity (such as mental capacity) or limited access to social goods such as rights and power. Both individuals and groups may be classified as vulnerable. Vulnerable people potentially include those with mental health issues, children under the age of 16 years, prisoners, the elderly and those with a diminished capacity for self-determination.

Health research studies that include vulnerable participants will most likely require review by HDECs. The HDECs use the definition of vulnerable people from the NEAC "[Ethical Guidelines for Intervention Studies](#)".

Vulnerable research participants will usually need to be treated with special care to ensure that their interests are protected. Researchers should also consider what measures they need to take to protect the interests of vulnerable individuals and groups who are not participating in the research but may be affected by it. Researchers will need to convince the committee that they will be able to protect the interests of vulnerable participants and communities.

Before a vulnerable person can participate in any research study, the researchers will need to obtain the individual's consent if they are competent to do so or a proxy consent (accompanied by the individual's assent, if possible). If a vulnerable person decides not to participate, their decision takes priority over a valid proxy consent.

#### **13.6 Overseas research**

Where research is conducted overseas, i.e., the researcher and participants will be located overseas, the researchers must demonstrate in the ethics application that the following aspects have been considered:

- the safety of researchers and participants
- the contexts in which the research will be conducted and their relevance to the ethical conduct of research
- local ethics approval (from the overseas country) requirements where necessary or appropriate
- the relevant local regulations, including those relating to the protection of privacy and data as well as requirements for a research visa

A statement that the researchers will comply with local regulations is usually expected in the relevant question on the application form.

Skype, email and similar means of communicating with participants in other countries are not counted as overseas research if the researcher is located in New Zealand. Researchers, however, should ascertain that the countries in which the participants are physically located have no restriction on the use of Skype, email or similar means of communication. Researchers should also ensure that any legislative requirements of the country in which participants are located are met.

### **13.7 Research into illegal activities**

Research involving the study of illegal activities and research that incidentally uncovers illegal activities raises complex ethical, moral and legal questions. What action a researcher may take will depend on the circumstances of the case, but the foremost consideration must be the principle of avoiding harm to participants and third parties and the need to act within the law at all times. The researcher must explain to UAHPEC how they intend to manage such discoveries.

Private citizens have no positive legal obligation to report illegal activities to the relevant authorities. While the legal obligations of a researcher are the same as any private citizen, academic staff and students have additional obligations under the academic freedom provisions of the *Education Act 1989* to act in a manner consistent with "*the highest ethical standards*" (section 161).

Where a researcher collects personal information from participants, the researcher must protect that information from disclosure, whether or not it includes information about illegal activities. However, where a researcher uncovers information about unlawful activities that has not been collected from participants, the researcher may be morally obliged to report such activities. For example, if a property owner has given permission for research to be undertaken on their property, information about unlawful activities on the property should be reported to the property owner (unless the information was given to the researcher in confidence by research participants). This may include such activities as the cultivation of cannabis or breaches of health and safety legislation. It is up to the property owner to take any subsequent action required.

During the informed consent process, participants need to be informed that if the researcher uncovers any activity that poses a serious threat to the health and safety of an individual or the public, the researcher will disclose that information to the appropriate authority.

Participants must also be informed when relevant, that where there is any risk that criminal activities will be disclosed, the researcher will make every effort to ensure communications with the participant are treated as confidential, but that such communications are not protected in the way that those with a lawyer or priest acting in their professional capacity are. While the confidentiality of communications with the researcher will be protected from disclosure, the researcher remains a compellable witness. If researchers refuse to testify, they may be in contempt of court and face a prison sentence. They may also be charged as party to the offence if there is any suggestion that they aided and abetted the offence.

While a researcher may be a compellable witness, the standard of proof required by a court of law, particularly in criminal proceedings, is unlikely to be met by information that may be in the possession of a researcher. Unless a researcher has actually seen an offence being committed, or can offer other hard proof of criminality, such as knowledge of the location of proscribed drugs, illegal weapons or stolen goods, most information that is garnered as research data would probably fall into the category of hearsay, if tested in court.

Researchers conducting forensic research and/or who may need to access objectionable publications must be aware of the provisions of the *Films, Videos and Publications Classification Act 1993*. Publication is widely defined to include anything with images or words imprinted on it. Objectionable material is banned. Objectionable is defined in section 3 of the Act in general terms as sex, horror, crime or violence likely to be injurious to the public good.

Researchers conducting research into activities that promote or encourage criminal acts or acts of terrorism, such as the manufacture of methamphetamine or explosives, sexual abuse or bioterrorism, need to get clearance from the Department of Internal Affairs Te Tari Taiwhenua ([dia.govt.nz](http://dia.govt.nz)) to access certain publications unless they are conducting research on behalf of a crown agency, such as the Police. They may also have to have their research outputs/publications embargoed to avoid breaking the law.

If a researcher requires access to material that is likely to be regarded as objectionable, application should be made to the Department of Internal Affairs Te Tari Taiwhenua for a publication to be classified, or if already classified, reclassified with restrictions so the researcher can use it. The Department can reduce or waive a fee for a member of an educational organisation on application. If there are a large number of publications for classification, these can be grouped together under one application.

Further information about the Office of the Censor is available in this recording of a lecture by the chief censor: [http://digitool.auckland.ac.nz/R/-?func=dbin-jump-full&object\\_id=460597&silolibrary=GEN01](http://digitool.auckland.ac.nz/R/-?func=dbin-jump-full&object_id=460597&silolibrary=GEN01)

### **13.8 Clinical trials**

UAHPEC adopts the definition of clinical trial of the World Health Organization 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*".

The University maintains a liability insurance programme for researchers, 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 Manager, Performance and Risk (ext. 87834).

Where ethics approval is being sought for a clinical trial, and the research does not fall within the scope of HDEC review, researchers need to explain whether or not the proposed research is being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

a) If the research study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out, the following information should be included in the PIS, under the heading 'Compensation'.

*In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.*

*If you have any questions about ACC, contact your nearest ACC office or the investigator.*

*You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.*



b) If the research study is a clinical trial conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out, the following information should be included in the PIS under the heading 'Compensation'.

*This clinical trial is being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out. This means that **if you suffer injury as a result of your participation in this trial, you will not be eligible for cover under accident compensation legislation.** Compensation will, however, be provided by (insert name of company) in accordance with the New Zealand Researched Medicines Industry Guidelines on Clinical Trials: Compensation for injury resulting from participation in industry sponsored clinical trials.*

*You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.*

Note: If the trial includes placebo/standard treatment, the investigators will need to verify with the company whether there is compensation for participants receiving placebo treatment. If there is no compensation for this, it should be stated in the last sentence of paragraph four of the declaration above. The declaration should also make it clear why participants on placebo are not covered, for example, because there are not the same risks involved.

### **13.9 Audits**

Audit investigations examine practice and outcomes in a particular time and place, and then compare the results with explicit predetermined standards. An audit is typically a retrospective analysis of de-identified data for comparison with previously set standards.

The primary aim of an audit is to inform and improve the delivery and management of a service rather than to add new knowledge. Audit of this kind does not require approval of UAHPEC. However, an audit may sometimes produce results that are of sufficient interest to be further analysed and may become the basis of a research publication. Thus the process of audit merges with research and an audit may be regarded as a type of research, albeit one with more limited ethical concerns, and in these cases, an application to UAHPEC for ethics approval will need to be made. Researchers should seek advice from an ethics advisor or the Chair of UAHPEC if they are unsure whether UAHPEC approval is required.

When a researcher plans to analyse de-identified data from an audit for the purposes of research, or compare de-identified data from an audit with data collected by the researchers, the UAHPEC applications must contain details of how permission for, and access to, audit data will be achieved, and how audit data will be used in the study.

The [NEAC Ethical guidelines for observational studies \(2012\)](#) identify 10 main types of audit and associated activities in the area of health and disability services as follows:

1. **Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.
2. **Programme evaluation** is a type of audit where a whole programme is evaluated, rather than specific interventions.
3. **Evaluation studies** aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.
4. **Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.
5. **Outcome analyses** involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.
6. **Benchmarking** aims to improve practice through the comparison of two or more health and disability support services.
7. **Public health investigations** explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.
8. **Public health surveillance** involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.
9. **Pharmacovigilance** (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).
10. **Resource utilisation reviews** evaluate the use of resources in a particular health or disability service activity. For example by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.

Comparable activities to many of these occur in other areas, for example in educational practice, in commercial activities and in social and public policy.

Where any such activities are combined with research aims or projects, UAHPEC review is required.

Audits and related activities are typically minimal-risk activities. Where they involve retrospective review of data which is de-identified and not potentially identifiable, they present few ethical issues. The permission of the custodian of such data is usually required for access to the data. Where researchers propose to access identified, partially de-identified, or potentially identifiable (e.g. key-coded) data, the issues relating to consent, privacy and confidentiality must be addressed.

UAHPEC requires that applications for approval of audit-based research provide evidence of permission to access data from the custodian of that data, and that either the data provided to the researcher is de-identified and not identifiable or that the researcher(s) who have access to it meet or observe appropriate confidentiality requirements.

Note that for any audits requiring access to clinical records held by Auckland District Health Board, *and* conducted with the purpose of obtaining data for research, the Clinical Records Services department require that UAHPEC approval is obtained before they will release any clinical records.

### **13.10 Practitioner applied research**

Practitioner applied research (particularly in one's own work setting) is a discrete field of methodological action, and it is often beneficial for students and other service users to have providers who are engaged in reflective practice with a view to enhancing and improving the services provided. However, practitioner applied research brings with it discrete ethical demands and raises particular issues with regard to ethical approval.

In cases where practitioner applied research is designed to take place in the practitioner's own workplaces, applicants for ethics approval must particularly consider all the ethical concerns that this raises and how they intend to address them. This helps UAHPEC to make informed and timely decisions.

The UAHPEC is not opposed to the conduct of research in the researcher's own workplace, nor views it as inherently unethical. Indeed, the UAHPEC appreciates the importance of this type of inquiry. However, research in one's own setting may carry with it some complex ethical issues, most notably power imbalances and/or conflicts of interest.

The questions below may aid in explaining to the Committee how these issues will be resolved. A response to these questions should be incorporated in the ethics application, either attached as a memo or as part of the application form responses. If it will not be possible to resolve these issues when the research is planned in your own setting, the Committee recommends that the research is then performed in a different setting.

Please make a clear statement about whether or not the research will be conducted in your own setting, and provide responses to the following questions in the application:

1. If you are in a position of authority (of any kind) in your setting, how will you manage potential power relationships and protect others from the possible or potential negative consequences?
2. How can you manage the potentially uneven benefits to you as the researcher and your participants? If you will be rewarded with a tangible benefit (such as a qualification), what benefits are there for your colleagues, clients, students or employees as a result of participating?
3. What are the potential or possible risks to the participants?
4. How, particularly in settings with small numbers of participants, will you retain confidentiality and/or anonymity?
5. How will you ensure that participation is voluntary and that potential participants do not feel under any pressure to participate?
6. When working with colleagues, how will you incorporate ways that your participants can withdraw from your study without any negative effects upon their employment or their relationships with their employer, you, and other colleagues?
7. When working with your own clients or students, how will you incorporate ways that your participants can withdraw from your study (such as not being involved in classroom observation)? How will you ensure that they are free to withdraw without any negative effects upon their grades or future status with you as someone who may continue to work with them once the research is concluded?

Researchers should also explain any permissions and agreements that have already been secured from the setting to do the work and attach copies of these permissions to the application.

It is appropriate to assume that 'leadership' (such as a school principal or social work team leader) corresponds with 'hierarchy' and that voluntary decision-making about research participation will be constrained if 'leaders' recruit participants.

### **13.11 Research in schools**

When researching in schools, researchers need to give due consideration to the vulnerability of children and the importance of instructional time and activities. In order to make the best use of school time and the participation of the students, and for the research to have maximum relevance and validity, educational researchers need to work cooperatively with schools to ensure that:

- the integrity of on-going school activities is maintained and principals are alerted to possible disturbances that may result from the conduct of the research
- research aims are communicated clearly to parents/guardians, students, boards of trustees and principals
- parents/guardians, students, boards of trustees and principals are updated about any significant changes in the research programme
- research findings and the practical significance of the research are communicated in clear, straightforward and appropriate language to relevant research populations, institutional representatives and other stakeholders as appropriate
- use of research techniques such as experimental interventions that might deprive students of important parts of the standard curriculum, and in this way have the potential for negative social consequences, are minimised.

### **13.11.1 Discipline-based Professional Inquiry (Education)**

In the field of education, it is recognised that teachers working in schools are required, as part of their professional responsibilities, to reflect on and inquire into aspects of their current practice with a view to improving their practice. This principle is made explicit in The New Zealand Curriculum that governs work in schools, and is framed as 'teaching as inquiry'. Such inquiry, which aims to determine evidence-based strategies to support student learning in different contexts, may be conducted with peers and/or students as part of a collective, professional review or development exercise. The latter may include a research aspect, but in this context it is important to recognise that different types of research may be employed to reach this goal. For the purposes of this manual, "research" will be taken to be the PBRF definition of "Research" as discussed in section 3.1, p.5, and inquiries falling outside this definition will be termed "professional inquiries".

### **13.11.2 Requirement for ethics approval**

Usually, professional development or inquiry take place in contexts of pre-existing ethical expectations and regimes. That is, schools act with a duty of care to students, and teachers are bound by the ethical requirements of the Education Council and are expected to act ethically. Also, when taking place in the context of normal classroom work, the primary purpose of which is to 'practise the profession', they are forms of professional inquiry and evaluation, and are not classified as research (using the definition of "Research" used by UAHPEC, see Section 3.1, p. 5). As such, ethics approval is not required.

However, when such inquiry is being undertaken as part of a wider research project or for a research qualification (honours, masters or doctorate) UAHPEC approval is required.

### **13.11.3 Professional inquiry**

Occasionally 'teaching as inquiry' coincides with, and is an expectation of, studies in professional qualifications (for example, students in pre-service teacher education programmes may be required, when working as teachers during practicum placements in schools, to undertake inquiry into their own work as members of a school community, and to report on outcomes). In these circumstances UAHPEC approval is not required. However, such inquiries must meet the following tests:

- data are derived from normal processes; that is, information to inform the evaluation of teaching and learning for purposes of professional development (which may include asking students for feedback on the work) is derived from what goes on in the classroom as part of the normal functioning and work of the class
- confidentiality is maintained; that is, in any subsequent reporting on the outcomes of the inquiry, whether to colleagues or others, the identity of class members and the school, if the principal so wishes, is protected from disclosure
- the safety and welfare of all participants are protected
- the use of the collected information is primarily intended to benefit those receiving input in the professional setting (that is, the primary purpose of the inquiry is to improve students' learning outcomes and teachers' teaching).

The intention to report on, or publish, the results of such inquiry does not mean that UAHPEC approval is required for undertaking the inquiry. However informed approval for public reporting of the outcomes of the inquiry should be obtained from appropriate authorities (e.g., the school principal)).

When such inquiry is being undertaken in the context of a professional qualification (such as a Graduate Diploma of Teaching), it is the responsibility of the course director to ensure that the inquiry to be undertaken meets the tests above. If a course director is unsure whether UAHPEC review of any particular activity is required, he or she should seek advice from an ethics advisor or the Chair of UAHPEC.

Please also refer to section 13.10 above for more information about practitioner applied research.

### **13.11.4 Consent process in schools**

In all research studies where consent is sought, parents or a person who has the legal authority to consent on behalf of a participant should be sent Participation Information Sheets and Consent Forms for each project.

The information given in [Section 9.7 Ethical considerations in Research design, Children](#) is applicable to research undertaken in schools. That is, students over the age of 15 years are usually deemed to be capable of providing consent in their own right; students between 14 and 16 years of age may be deemed capable of doing so, depending on the nature of the project.

Where parental/guardian consent is required, the PIS must request parents/guardians to discuss the research invitation with their child. The PIS needs to explain that even when parents'/guardians' consent to their child participating in a research project, the final decision is the child's.

Issues of anonymity and confidentiality need to be clearly explained in the PIS.

When parental/guardian consent is required, it is not acceptable to include children in the research in the absence of written consent being returned by parents/guardians. The presumption of consent in the absence of a signed CF is not acceptable. People should not be expected to identify themselves for the sole purpose of refusing consent.

The law does not allow schools to give consent for students in place of their parents/guardians.

#### **13.11.5 Research on teacher practice within schools**

When a research project involves only observing teacher practice in the classroom, there is no need to obtain student and parental/guardian consent. However, the students and parents/guardians should be informed in a PIS that researchers will be observing the teacher and that the focus will be on the teacher only.

#### **13.11.6 Recruitment and participation in research in schools**

If children in a classroom or other group setting are asked to participate in a research project, procedures must be put in place to protect the anonymity of those children who do not wish to participate, or whose parents/guardians do not wish them to participate.

Prior arrangements should be made with the school to provide alternative activities for children not participating in the research. These should be clearly specified in each appropriate PIS.

To the fullest extent possible, alternative activities should be of equal educational value and without social implications for the children.

In some cases it will not be possible to protect the anonymity of children; for example, where there are separate activities for those who wish and do not wish to participate.

If the research topic is of a sensitive nature, the researcher must explain what arrangements they will put in place for students who might suffer emotional harm or psychological discomfort.

### **13.13 Māori research**

#### **13.13.1 Overview**

Researchers should ensure that research projects that involve Māori as a cultural group, or that have clear potential implications of direct interest to Māori, are developed and conducted in a culturally appropriate way and in a way that is responsive to Māori.

#### **13.13.2 Guidelines**

Researchers proposing to carry out Māori research are advised to consult the following guidelines:

(i) The Health Research Council's [Guidelines for Researchers on Health Research involving Māori](#); and

(ii) [Te Ara Tika Guidelines for Māori Research Ethics](#): *A framework for researchers and ethics committee members*. Te Ara Tika is also included as an appendix in the HRC Guidelines.

#### ***Guidelines for Researchers on Health Research involving Māori***

These guidelines were produced to assist researchers planning to undertake clinical, biomedical or public health research involving Māori participants or research on issues relevant to Māori health. The guidelines are specifically for applicants for HRC funding but will also assist researchers applying for funding from other sources. The guidelines inform researchers about consultation with Māori and the processes to follow when initiating consultation with Māori.

#### ***Te Ara Tika – Guidelines for Māori Research Ethics***

This document outlines a framework for addressing Māori ethical issues within the context of decision-making by ethics committees. The framework was developed by Pūtaiora (Māori members of ethics committees) and the National Ethics Advisory Committee (NEAC). The framework draws on Tikanga Māori (Māori protocols and practices).

#### **13.13.3 Further advice and sign-off of proposals**

For advice on conducting Māori research, consult the Pro Vice-Chancellor (Māori) or a Māori ethics advisor in your faculty.

Researchers who are proposing to carry out research pertaining to, or involving interaction with, Māori need to have their research proposal signed off by the Māori ethics advisor in their faculty.



Research that is relevant to Māori will go before the Pro- Vice-Chancellor (Māori) for sign-off.

## **14. Conducting the research**

### **14.1 Changes to the research study**

If changes need to be made during the course of the research, an Amendment Request needs to be submitted through InfoEd using the same protocol number as the approved application, explaining the nature of the change(s). Amended documents such as the PIS and CF should be attached to the Amendment Request form when applicable. Please consult the [Quick Guide](#), which explains the Amendment Request process, and the [General Guidelines for amendment requests](#), which illustrate when to submit an Amendment Request. Both are available from <https://www.auckland.ac.nz/en/about/research/re-ethics/re-uahpec.html>

If the change is substantial, a new application for ethics approval may be required and these requests for change will be put on the next agenda for the committee to consider.

Minor changes are dealt with under delegation by the chair. Minor changes include:

- Changes of research personnel
- Extension/renewal of projects with low-level participant–researcher interactions
- Requests for change that do not increase the demands on participants or introduce new risks.

If a PI does not advise UAHPEC of changes to their research project they risk losing the ethics approval they originally received. Going outside of the approval granted by UAHPEC could detrimentally affect their project and ability to publish, and could be a disciplinary issue.

### **14.2 Incidental findings and discovering illegal activity**

Research occasionally gives rise to findings that are unexpected and unrelated to the original purpose of the research and which have implications for the well-being and interests of participants and the duties of researchers. The most common examples of such incidental findings are when a study discovers a medical condition in a participant or a participant reveals that they are party to illegal activity.

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, where the life or health of any person may be at risk researchers may have a legal obligation to breach confidentiality. In recognition of this, the Privacy Act permits

the disclosure of personal information in certain situations. See Principles 10 and 11 of the Privacy Act, 1993 for further details.

Researchers should 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 in the PIS. The PIS should also state that if a participant does not want to be informed of such a finding, they should not participate in the research.

### **14.3 Adverse events and unanticipated problems**

Assessing the safety of research procedures for participants and others is central to the design and implementation of ethical research. Well-considered research will identify possible negative effects for participants together with ways of minimising these and addressing any which may occur. Responding appropriately to an adverse event and reviewing participants' risk is a primary responsibility of researchers. In their application for UAHPEC approval researchers must identify possible harms or negative effects, and describe procedures for dealing with these. These should also be described in the PIS and CF.

The research overseen by the UAHPEC is wide-ranging and includes both observational and interventional research. The committee has chosen to follow 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)* the OHRP differentiate between "unanticipated problems" and "adverse events".

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

#### **14.3.1 Adverse Events**

Adverse events are broadly defined by the OHRP as:

*"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."*

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. For any serious adverse events the research must stop immediately. The event must be promptly reported to UAPEC by the researcher, and the research may not resume before a full review has been completed and the UAHPEC has given its approval to proceed under provision of whatever changes or conditions the committee might stipulate. The 'Report Form for Adverse Events and Complaints' is available from the Ethics Administrators: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz) or ext. 83711.

Serious negative events or effects are also possible in both observational and interventional research. These could include 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.

### **14.3.2 Unanticipated Problems**

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

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

The expectation of the UAHPEC is that adverse events, serious negative effects and unanticipated problems are recorded, evaluated and monitored by the primary investigator and their research steering committee. If a steering committee has not been assembled for a study, the Director of the Clinic or Laboratory or equivalent senior colleague will fulfil the role of the research steering committee.

Unanticipated problems are to be taken particularly seriously, and it is the responsibility of researchers (in the case of students, through their primary supervisor) to report all unanticipated problems to the UAHPEC on the 'Report Form for Adverse Events and Complaints'. This form is available from the Ethics Administrators: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz) or ext. 83711.

As well as reporting the Unanticipated Problem, the researcher should consider:

- what the research participants need to know about the problem and how this might best be communicated
- whether changes need to be made to the research design
- whether or not a change in description of risk is warranted in the protocol, PIS and Consent Form

Where a breach of privacy of any kind has occurred during the conduct of research, the University's Privacy Officer must be notified and may specify requirements for handling the response to the breach.

It is a requirement of the University that work-related incidents or accidents be reported to the Health, Safety and Wellbeing Manager within 24 hours of the event, using the HR Accident/Incident Report form.

### **14.3.3 UAHPEC responsibilities**

UAHPEC will assess all reported adverse events or unanticipated problem in order to address immediate issues of safety for participants, and any changes in protocol design and implementation needed to protect the interests of current and future research participants. When evaluating an adverse event report, UAHPEC will consider:

- how serious the event is
- the relationship of the event to the research
- the expectedness (or otherwise) of the event
- the appropriateness of the action taken or proposed by the researcher
- the need to inform current or future participants, either by change to the research documents or by written or verbal communication.

When appropriate, the UAHPEC will consult experts from within the University of Auckland to provide advice on the above considerations.

### **14.4 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 person wishing to raise a matter of concern or make 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.

a) A person wishing to raise a matter of concern about an alleged adverse event in a research project approved by UAHPEC or make a complaint may do so in writing to the Chair of UAHPEC. A Report Form for Adverse Events and Complaints is available from the Ethics Administrators.

b) A complaint or expression of concern about an alleged adverse research event should be set out in sufficient detail to enable the Chair to identify both the research and the issue of concern.

c) In consultation with the Chair, the Associate Director of Post-Award Support Services (the Associate Director) will determine if the matter will be investigated and, if so, the process to be followed.

d) The Associate Director will coordinate, or lead, the investigation in consultation with the Chair.

The Associate Director will consult the University's Privacy Officer with respect to any complaint which concerns or involves a breach of privacy.

e) UAHPEC will be informed that information about an alleged adverse event or complaint has been received. This information will be recorded and the documentation held confidentially in the Research Office.

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

g) The informant/complainant may request confidentiality, but must understand there will be circumstances where such a request will mean that the issue raised cannot be investigated. The informant will be advised if this is the case.

h) If the Associate Director, in consultation with the Chair, considers there are good reasons to protect the identity of the informant, and the investigation can still proceed in a procedurally fair manner, the identity of the informant may initially remain confidential.

i) Procedural fairness will normally require that details of the informant/complainant and sufficient information about the source of the information will be made available to the principal investigator of the research project in which the alleged event is said to have occurred.

j) 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 if that was not already completed.

k) The Associate Director will ask the subject of the complaint for a written response.

l) In all cases, if the reported alleged adverse research event or other 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 Chair, in consultation with the Associate Director, comes to the view that there has been a breach of the conditions set by UAHPEC or there is evidence of possible misconduct in research, a response will be sought from the principal investigator.

o) Informants/complainants should be kept informed about the progress of the investigation.

p) At any stage of the investigation, 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 Associate Director's 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 communicate this to the informant/complainant and the principal investigator 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 if it can be established that an adverse research event did indeed occur.

t) Where the matter is not resolved through the investigation carried out, the Associate Director will inform the DVC(R) and will advise the informant and the principal investigator accordingly.

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

v) Adverse events and complaints concerning another ethics committee must be made to that committee.

## **15. AFTER COMPLETION OF THE RESEARCH**

**The principal investigator must advise UAHPEC in writing that the research is complete.**

Please email [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)

### **15.1 Dissemination of results**

The researcher must give due consideration to the dissemination of research results. Whenever possible, the findings should be conveyed in a comprehensible form to those who participated in the research. The researcher must do this if they have given the participant the opportunity to receive results and the participant has requested them.

### **15.2 Publication of results**

Researchers should be aware that there is an ethical dimension to the formulation and publication of results and loss of copyright. The researcher must remain sensitive to the uses to which the research findings may be put. Whenever possible, a summary of the findings should be offered to participants.



## **16. GLOSSARY**

### **ACC**

ACC refers to where a person has cover and entitlements under the Accident Compensation Act 2001.

### **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 recording of it.

### **Audit**

An audit involves the planned and systematic evaluation of a set of known variables, and/or a system or set of procedures, and/or documents against a set of criteria.

### **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 Organization 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 Research Council provides Referral Guidelines that influence the decision to be made between ethical review at UAHPEC or a regional Health and Disabilities Ethics Committee.

## **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 (CF)**

A CF 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 CF must be retained by the researcher and stored separately from research data 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 effects of the interventions(s). The term ‘intervention study’ is

often used interchangeably with 'experimental study'. Many intervention studies are clinical trials.

### **Interview schedule**

An interview schedule is an outline of the topics to be discussed at an interview. The purpose of this schedule is to enable UAHPEC to determine whether the PIS adequately informs the participants of the nature of the interview. Such a schedule must be attached to the application.

### **Observational study**

In health research, observational studies are distinguished from intervention or experimental studies as no intervention other than recording, classifying, counting and analysing of data takes place. The investigator does not control study variables and merely observes outcomes. Most observational health research is epidemiological or health services research.

### **Participant Information Sheet (PIS)**

The PIS is the document that informs the participant about the research and the nature of the involvement required and is retained by the participant. Generally, the PIS 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.

### **Pilot study**

A pilot study is one in which preliminary research protocols are trialled. Hence, a pilot study involves human participants in research procedures and requires the approval of UAHPEC. Approval from UAHPEC will also be required separately for the full study.

A pilot study can be distinguished from preliminary discussions with key informants to assist with the development of the research aims or design. Such preliminary discussions do not require the approval of UAHPEC.

### **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 is 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.

## **Surveys**

Generally the UAHPEC prefers more precise wording than “survey”, such as “questionnaire”, “interview”, “review”.

## **Unanticipated Problem**

*In defining “Unanticipated Problem” for the purposes of the UAHPEC the Office for Human Research Protections definition is used.*

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

- 1) 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[Ethics Committee]-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- 2) related or possibly related to a subject’s participation in the research; and
- 3) 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.