University of Auckland | Waipapa Taumata Rau

Guiding Principles for Conducting Research with Human Participants

Approved by University Council on 14 March 2022

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1. INTRODUCTION

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

The University adopts the Performance-Based Research Fund (PBRF) definition of research as an 'original, independent investigation undertaken to contribute to knowledge and understanding and, in the case of some disciplines, cultural innovation or aesthetic refinement' (the term 'independent' does not exclude collaborative work). The University also understands it to include supervised student projects (see section 8. Glossary).

Research typically involves inquiry of an experimental or critical nature driven by hypotheses or intellectual positions capable of rigorous assessment by experts in a given discipline.

Research includes work of direct relevance to the specific needs of iwi, communities, government, industry and commerce. In some disciplines, research may be embodied in the form of artistic works, performances or designs that lead to new or substantially improved insights.

Research findings must be open to scrutiny or formal evaluation by experts within the field. This may be achieved through various forms of dissemination including, but not limited to, publication, manufacture, construction, public presentation, or provision of confidential reports.

Research with "human participants" is broadly defined. A research 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. Research with human participants includes the acquisition and study of data through intervention or interaction with an individual (a participant), or from personal information even if acquired without direct interaction with the individual. It also includes research on human remains, tissue or bodily fluids.

For the University, human participant research is understood to include research using anonymous questionnaires, research within teaching sessions and research carried out as part of coursework, conducted within and outside the University.

The University of Auckland Human Participants Ethics Committee (UAHPEC), Te Komiti mō ngā Tāngata Whai Pānga Matatika o Waipapa Taumata Rau, and the Auckland Health Research Ethics Committee (AHREC) are institutional ethics committees that review and approve the adequacy of protection for human participants in research studies that fall outside the eligibility criteria for review by a Health and Disability Ethics Committee (HDEC)

UAHPEC reviews research (involving human participants) conducted by the University's staff and students that is not 'health/clinical research' (see section 8. Glossary), while AHREC reviews health research conducted by staff of the Auckland DHB and Counties Manukau DHB (hereafter CM Health), (or other DHBs that might join AHREC), and studies that fall under the definition of 'health/clinical research' by the University's staff and students. This document outlines the guiding principles and key ethical considerations to guide the University's researchers when designing and conducting their research projects involving human participants.

For more information about how to put the principles contained in this document into practice, researchers should refer to the UAHPEC and AHREC Applicants' Reference Manuals. These manuals give detailed guidance on the mandatory items that must be included in the ethics application as well as other information essential for making ethics applications. The manuals can be found at:

UAHPEC:
https://www.auckland.ac.nz/en/about/research/re-ethics/re-uahpec.html

AHREC:
https://www.auckland.ac.nz/en/research/about-our-research/human-ethics/ahrec.html

2. SCOPE OF THIS DOCUMENT

This document has been developed for members of the University involving human participants in their research. In particular, the document is intended to provide guidance to researchers conducting research with human participants, ethics advisors and members of the University's Te Komiti mō ngā Tāngata Whai Pānga Matatika o Waipapa Taumata Rau, Human Participants Ethics Committee, (hereafter "UAHPEC") and the Auckland Health Research Ethics Committee (hereafter "AHREC"). Researchers should refer to both the Guiding Principles and the relevant committee's Applicants' Reference Manual when designing research projects and when applying for ethics approval.

The Guiding Principles document requires review and approval by the University Council every three years.

3. ROLE, FUNCTION AND MEMBERSHIP OF THE HUMAN PARTICIPANTS ETHICS COMMITTEES

3.1 Overview

The University recognises the need for research studies in which people serve as research participants. At the same time, the University is aware of its responsibility to ensure that the welfare, privacy, safety, health, and personal, social, and cultural sensitivities of participants are adequately protected. To fulfil these obligations, the University has two human ethics committees – UAHPEC and AHREC - that review and approve the adequacy of protection for research participants.

It is the policy of the University that, prior to commencement of research that involves human participants, all staff or student research projects, as well as research within teaching sessions, must receive approval from either UAHPEC or AHREC as institutional ethics committees, or from an HDEC for eligible health and disability research, unless an exemption applies.

AHREC undertakes review of all health and disability research studies that are not eligible for review for ethics approval by a Health and Disability Ethics Committee (HDEC) and conducted by Auckland DHB or CM Health employees (or other DHBs that might join AHREC) or employees or students of the University of Auckland.

All other research studies, including all coursework applications, must be reviewed by UAHPEC, unless an exemption applies.

UAHPEC and AHREC do not grant retrospective approval.

The requirement for all staff and student research projects that involve human participants as well as for research within teaching sessions to obtain approval is set out in the Ethics Review of Research Involving Human Participants Policy at:

https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/ethics/ethics-review-of-proposals-involving-human-participants-policy.html

3.1.1 Exemptions

The following are exempt from ethics approval:

- 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 or publication
- Departmental reviews and similar evaluations
- Surveys, questionnaires or interviews by University members undertaken not for the purposes of research but only for improving the teaching and administrative activities of the University
- A solitary interview with an individual public figure about public matters, or an interview with a single 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
- Observational studies in public where participants are not identifiable
- Discussions of a preliminary nature that will assist in the development of a research study or instrument, but will not provide data to be incorporated into the research dataset
- Research using only published or 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 for any independent institutional ethical review requirements.

Notes:

- Teaching and learning exercises where some students may act as model patients/clients for others within the teaching of clinical skills or disciplinary technical skills do not constitute research and do not require ethics committee approval. Technical skills may be taught in similar ways in a number of disciplinary areas. For example, skills that would be used in clinical settings could include physical examination skills, use of technological apparatus, practical procedures, communication skills, and management.
- An ethics application approved by either an HDEC or the Ethics Committee on Assisted Reproductive Technology (ECART) does not also require approval from UAHPEC or AHREC.
- Research that has been approved by another HRC-approved ethics committee or a

comparable institutional ethics committee may not require additional approval. The ethics application and approval documents for such approvals must be provided to either the UAHPEC or AHREC Chair (according to the nature of the research project). That Committee may either ratify the approval or require a new ethics application. Ratification is delegated to the Chair of each Committee who may refer the decision to a Committee meeting for review.

3.2 Terms of Reference

3.2.1 UAHPEC Terms of Reference:

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

3.2.2 AHREC Terms of Reference:

- To ensure that the research studies reviewed by AHREC comply with the highest ethical standards
- To protect the interests of participants, the researcher and the institutions that are part of AHREC
- To promote awareness within the communities of the organisations that are part of AHREC of ethical issues relating to research with human participants
- To provide an avenue for handling complaints or queries by any interested person.

3.3 Function of UAHPEC and AHREC

The function of UAHPEC and AHREC is to review proposed research involving human participants conducted by members of the University. AHREC also reviews applications from researchers at the Auckland DHB and CM Health, or other DHBs that may join in the future.

The Committees will:

- review and, where satisfied that it is appropriate, approve submitted research for compliance with ethical principles
- review and, where satisfied that it is appropriate, approve submitted amendments to an approved study
- provide advice and assistance to anyone undertaking such research
- receive, record and respond to information concerning adverse events, queries and complaints about research approved by UAHPEC or AHREC, and research carried out by University staff or students without ethics approval.

The two ethics committees will respond to requests for advice on ethical matters concerning research prior to the submission of an application for ethical review and / or in relation to research that is ongoing and has been approved by the committee.

In assessing applications, the two ethics committees reserve the right to seek expert opinion, including from relevant committees such as the Health Research Council Ethics

Committee (HRC EC), Standing Committee on Therapeutic Trials (SCOTT), Gene Technology Advisory Committee (GTAC), Ethics Committee on Assisted Reproductive Technology (ECART), the National Ethics Advisory Committee (NEAC) and the Health and Disability Ethics Committees (HDECs).

The attention of researchers applying for ethical approval is drawn to Section VI of the University's Charter 2003 acknowledging the Treaty of Waitangi, available from: https://www.auckland.ac.nz/en/about-us/about-the-university/the-university/official-publications/university-of-auckland-charter-2003.html

3.4 Membership and responsibilities

The Committee membership profiles of UAHPEC and AHREC reflect the requirements of the University and the Health Research Council Ethics Committee (HRC EC) approval requirements. AHREC membership also includes representatives from participating DHBs. As far as is possible, the Committee should include the representatives specified below.

Overall, the Committees will have a balance of institutional and lay (non-institutional) members, at least two Māori members, representation of the community-at-large, 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 as well as meeting the membership composition required by the University and the HRC EC.

3.4.1 UAHPEC Membership profile

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

- One member nominated by the Dean of the Faculty of Arts (Institutional)
- One member nominated by the Dean of the Business School (Institutional)
- One member nominated by the Dean of the Faculty of Medical and Health Sciences (Institutional)
- Two members nominated by the Dean of the Faculty of Science (Institutional)
- Two members nominated by the Dean of the Faculty of Education and Social Work (Institutional)
- One member nominated by the Dean of the Faculty of Engineering (Institutional)
- One member with legal expertise nominated by the Dean of Law (Institutional/Lay[1])
- One member nominated by the Dean of the Faculty of Creative Arts and Industries (Institutional)
- Deputy Vice-Chancellor (Research) or nominee (Institutional)
- One member with expertise in the area of moral philosophy appointed by Council on the advice of the Convenor of Programme in Philosophy (Institutional/Lay)
- Pro Vice-Chancellor (Māori) or nominee (Institutional/Lay)
- One Student Representative nominated by Auckland University Students' Association (AUSA) Executive Committee (Lay) and/or Postgraduate Students' Association (PGSA)(Lay)
- Two lay members approved by Council (Lay)

[1] A lay member in this context is anyone who is not an employee of the University or the DHBs that are part of AHREC

Additional co-opted members as required to ensure the appropriate breadth of expertise.

3.4.2 AHREC Membership profile

- One member with expertise in the area of moral philosophy (Institutional/Lay)
- One member with legal expertise (Institutional/Lay)
- Two lay members approved by AHREC Governance Board (Lay)
- At least two nominees of the Auckland District Health Board (Institutional)
- At least two nominees of CM Health (Institutional)
- At least two nominees of the University of Auckland, Waipapa Taumata Rau (Institutional)
- At least two Māori members, including a representative from Ngāti Whātua (Institutional/Lay)
- At least one non-medical health professional (Institutional/Lay)
- Where practicable, one or more early career researchers (Institutional).

3.4.3 Term of membership

The term of membership is two years, with the exception of UAHPEC student representatives for whom the membership term is one year.

Appointments may be renewed, but no member shall serve more than four consecutive terms.

3.4.4 Committee Chairs

The UAHPEC Chair is appointed by Council, in consultation with the Committee if necessary. The Committee should have a Lay Chairperson and a non-lay Deputy Chairperson.

The AHREC Chair is appointed by the AHREC Governance Board, in consultation with the Committee if necessary. The committee should have a Lay Chairperson and a non-lay Deputy Chairperson.

The term of the Chair is two years. Appointments may be renewed, but no Chair shall serve more than four consecutive terms.

3.4.5 Reporting

UAHPEC and AHREC report to the University Council annually, and at other times as requested by Council. AHREC also reports annually to the AHREC Governance Board, and both Committees report annually to the HRC EC.

3.4.6 Quorum

A quorum consists of not less than half the members of each Committee's membership (including the UAHPEC sub-committees).

3.4.7 Declaration of Conflicts of Interest

Members must declare any conflict of interest when reviewing applications and at Committee meetings when applications are to be discussed for which they are the named PI or a member of the research team.

3.4.8 Confidentiality

Committee members have a responsibility to respect confidentiality of information with which the Committee deals. This includes matters tabled or discussed at Committee meetings, as well as any additional issues raised outside meetings.

4. ETHICS FRAMEWORK FOR RESEARCH WITH HUMAN PARTICIPANTS

4.1 Introduction

The University requires research with human participants to be designed and carried out to the highest ethical standards.

The University's Taumata Teitei, Vision 2030 and Strategic plan 2025 expresses a commitment to fundamental Te Ao Māori principles and working in a way consistent with the emerging Waipapa framework. The principles reflect our foundational relationship with tangata whenua and commitment to Te Tiriti o Waitangi. Embedded in the framework is a commitment also to mana enhancing relationships, represented as 'Kia whakamana i te tangata':

i. Manaakitanga
   Caring for those around us in the way we relate to each other

ii. Whanaungatanga
   Recognising the importance of kinship and lasting relationship

iii. Kaitiakitanga
   Valuing stewardship and guardianship and our relationship with the natural world

To guide researchers in conducting their research to the highest ethical standards, the University acknowledges an ethics framework that encompasses two sets of principles sitting alongside each other. Te Ara Tika is a framework for researchers and ethics committee members developed by the Pūtaiora Writing Group with support from the National Ethics Advisory Committee (NEAC), the Health Research Council (HRC) and Ngā Pae o te Māramatanga (NPM). Te Ara Tika principles are drawn from tikanga Māori (Māori protocols and practices) and its philosophical base of mātauranga Māori (traditional knowledge), and integrate understandings from Te Tiriti o Waitangi, Indigenous values and Western ethical principles[2].

Alongside the tikanga principles is a set of Western bioethics principles shaped over many years in response to international events impacting research and the ethics landscape.

The partnership of these principles is more explicitly described in the National Ethical Standards for Health and Disability Research and Quality Improvement (National Ethics Advisory Committee, 2019, as modified in April 2021), and researchers are encouraged to use these Standards for guidance to ensure that the ethical principles are reflected in their research projects, even if the project is not health-focused.

The primary values underlying these principles is respect and care for people.

4.2 Key Ethical Principles

The principles set out below are accepted as key principles that guide research ethics in New Zealand[2]. They are complementary and interdependent and how they apply will depend on the nature and context of the research being undertaken.

4.2.1 Te Ara Tika Principles:

i. Whakapapa

Whakapapa refers to relationships: the quality of relationships and the structures or processes that have been established to support these relationships. The relationship between researchers and participants (and New Zealand communities) must involve trust, respect and integrity.[2]

ii. Mana

Mana refers to power, prestige, leadership or authority bestowed, gained or inherited individually or collectively. It infers that each individual has the right to determine their own destiny upon their own authority.[2]

Shared knowledge upholds the mana of research participants. Mana relates to equity and distributive justice in terms of the potential or actual risks, benefits and outcomes of research.[2]

iii. Tika

Tika refers to what is right and what is good for any particular situation. Importantly, in the context of ethics it relates to the design of a study, and whether the research achieves proposed outcomes, benefits participants and communities and brings about positive change.

Tika requires respectful relationships with Māori in all studies, regardless of the research design and methods. Researchers should engage with communities about which research questions are important, and reflect on the ethical issues associated with their study.[3]

iv. Manaakitanga

Manaakitanga refers to caring for others, nurturing relationships and being careful in the way we treat others. Aroha (respect, love), generosity, sharing and hosting are essential to manaakitanga, as is upholding the mana of all parties.

As well as gathering data, researchers should collaborate with and give back to the community (for example, through koha and sharing ideas).[2]

4.2.2 Bioethics Principles:

i. Respect for people

This principle is frequently phrased as respect for autonomy, but is wider in that it

[2] NEAC National Ethical Standards for Health and Disability Research and Quality Improvement

[3] Te Ara Tika Guidelines for Māori Research Ethics: A Framework for Researchers and Ethics Committee Members

also encompasses respect and protection for people who may not be capable of exercising full autonomy. It 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 ofgroups in society.

ii. Beneficence

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

iii. Non-maleficence

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

iv. Justice

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

4.3 Congruence with HRC ethics framework

UAHPEC and AHREC are HRC EC-approved ethics committees, and continuing approval is dependent upon the HRC EC being satisfied that the Committee "is able to offer sufficient protection to the research participants and can maintain the reputation of ethical review in general." (Health Research Council guidelines for Approval of Ethics Committees (Approval Guidelines), 2012). The University's Guiding Principles reflect the HRC EC and National Ethics Advisory Committee (NEAC) guidelines, and extend to human participant research not normally covered or considered by the HRC, for example, social science research and artistic performance.

The University expects that its researchers will at all times respect and provide protection for their human participants. It also expects that the research will be conducted in a manner that conforms with the highest ethical standards and in accordance with the ethical guidelines of the researchers' respective professional or disciplinary societies.

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

5.1 Research aims and design

To justify the involvement of human participants, studies must be well-designed. 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.

The researcher should also show consideration for the guiding principle of beneficence to ensure that research involving human participants has real or potential value or benefit to participants or the community that justifies participants' time and input.

5.2 Recruitment of research participants

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

5.3 Koha, gifts, compensation and reimbursement of expenses

Where research participants incur costs, the Committees consider it appropriate to provide commensurate compensation. Researchers must ensure they are conforming with University policy in this area. The Committees also consider recompense for participation to be ethically acceptable. However, koha, gifts, payment or other forms of compensation should not be so large as to unduly induce individuals to consent to participate in the research. In no case does compensation for research participation constitute an employment relationship with the University or other institutions involved.

5.4 Free and informed consent

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

Consent of a parent/guardian is normally required for research participation of children under the age of 16, as well as the assent of the child. If a person is not capable of giving informed consent for themselves, then their participation will usually require the consent of a legal guardian, someone holding an enduring power of attorney for health and welfare, or someone with an equally valid legal authority to act on behalf of the potential participant.

The ability to give consent may not be an all or nothing situation, and some people with diminished capacity may be able to give consent to some kinds of research participation, perhaps with assistance from an appropriate support person to understand what is involved.

Researchers should consider how participants who are under the age of 16 when they give assent to the use of their data, may be able to give consent when they reach the age of 16 to any continued storage or further use of their data.

5.5 Limitation of deception

Research that involves deception contravenes the principle of autonomy, and the use of deception in research must therefore be well justified in the application to the Committee. Justification must include reference to the significance of the potential

knowledge to be gained, and demonstrate that there is no less deceptive means reasonably available. Participants must be offered a de-briefing session after the data-gathering in which the deception is explained. This debriefing must occur as soon as possible after data acquisition. The Committees will carefully review any study which proposes the use of deception and will require a clear justification from the applicant as to why the deception is considered necessary for the study and how participants will be safeguarded.

5.6 Minimising harm

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

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

Potential participants must be made aware of potential risks and mitigations, and must acknowledge these in consenting to participate in the research, usually by means of providing a Participant Information Sheet (PIS) and a consent form (CF). Appropriate monitoring and support procedures should be put in place during and after research activities.

In their ethics application, researchers must stipulate what resources will be available, and what procedure will be followed, should participants experience harm or distress as a result of participating in their research study. If appropriate, the researcher should describe to the reviewing Committee the experience available in the research team to deal with such potential harm.

Information on risk management and liability insurance is available from the Risk Management and Audit team (risk@auckland.ac.nz).

5.7 Protecting participants' privacy and confidentiality

All research conducted by members of the University must comply with the University's Privacy framework. The researcher has a duty to safeguard participants' privacy and confidentiality. This duty extends to any use of third parties to provide or process information about potential participants.

5.7.1 Respecting participants' confidentiality

Respecting participants' autonomy and protecting them from harm require protection of confidentiality with respect to their participation in a research project and any personal information which may be provided.

The researcher must make clear to participants the extent to which their participation in the research will be known to others. If participants' identities cannot be kept confidential, as may be the case in focus groups or in performances linked to creative practice research, participants should be informed explicitly that confidentiality with respect to participation or information provided cannot be guaranteed. In some kinds of research (for example, where participants are providing expert assistance) it may be appropriate

that participants are identified in reporting the research. This should only be done with the knowledge and explicit consent of the participant.

Researchers should ensure that any third parties used to collect, provide or process information about potential participants also respect confidentiality of the research participants.

Researchers working with or holding de-identified data should be mindful of any possibility of re-identification of data donors through mixing of data sets and ensure that such re-identification does not breach assurances of confidentiality which may have been given to participants.

The researcher must share results only in a manner consistent with the confidentiality assurances provided to the participants and with the University's Privacy Framework. The University's Privacy statement is available from:
https://www.auckland.ac.nz/en/privacy.html

5.7.2 Protection of research participants' privacy

Research with human participants involves the collection, use, disclosure and storage of personal information about research participants. At times, this information may be sensitive, particularly where research relates to health.

Privacy is different from confidentiality. It describes the way researchers must manage personal information throughout the information life cycle, whether or not they have made promises that the information will not be disclosed.

Researchers must meet relevant legal privacy requirements and, as members of the University, comply with the University's Privacy Framework. This Framework requires the University to ensure:

- **Data minimisation** – limiting *the amount of personal information the University collects and retains*. Researchers should request from participants only that information which is necessary to their project and not retain information unnecessarily.
- **Transparency** – *being open and honest about what information the University collects and how it will be used*. This is particularly important if research involves the collection of personal information from children or young people. As part of securing informed consent to participation, researchers should explain clearly in participant information what information they are seeking, for what purpose, and how they propose to use or disclose this information.

  Researchers can also provide research participants with a copy of the University's Privacy Statement, which includes general information on data security and rights to access or correct personal information.
- **Security** – *protecting the personal information the University holds from harm*. Researchers must ensure that research data is stored securely and not accessed by, or shared with, unauthorised persons. See section 5.15 for more information.
- **Use limitation** – *making sure the University uses and discloses personal information only when necessary and with a lawful basis*. Researchers must ensure that they use personal information only in the ways they have notified to the research participants, and the participants have consented to. Any secondary uses of data must be managed in accordance with section 6.4.
- **Privacy rights** – *helping the University's data subjects to exercise their privacy rights and maintain some control over their information*. Requests for access to, or correction

of, personal information by research participants should be managed in accordance with the University's Personal Information Request Procedure.

Make sure overseas disclosures are safe
Principle 12 of the Privacy Act 2020 requires researchers to ensure that personal information they disclose to an overseas recipient (such as a university in another country) is protected by safeguards comparable to those required by the Privacy Act 2020.

Personal information can be disclosed to recipients in the European Union (EU), the United Kingdom (UK), Australia, or any countries with EU adequacy. Otherwise, recipients must be asked to agree to protect personal information to the standards of the Privacy Act 2020. More information is available in the University's Disclosure of Personal Information Procedure.

Take extra care if research participants are in the EU
If a research project includes participants located in the EU, researchers must also ensure that they are complying with the EU General Data Protection Regulation (GDPR). In this case, make sure to check this FAQ: ***If we're running a research project that targets participants in the EU, does the GDPR apply?*** in the Privacy Guidelines. In summary, the University's Privacy Framework will ensure that most GDPR obligations are covered, but there are a few additional things to watch out for:

- Sensitive personal information – such as information about health, genetics, race, ethnicity and sexuality – is treated differently.
- When consent is used to collect or process personal information, the consent must meet strict requirements to be valid.
- The GDPR gives people extra privacy rights, like the right to withdraw consent and the right to delete information.
- Check with the Privacy Officer before using new service providers (like AWS or Microsoft).
- Keep a record of the information you process for a research project.

For more information about privacy, the University Privacy Framework, and international privacy laws that may affect us (such as the EU General Data Protection Regulation), check the Privacy FAQs or ask the Privacy Officer.

The University Privacy statement is available from:
https://www.auckland.ac.nz/en/privacy.html

The University Personal Information Policy and Procedures is available from:
https://www.auckland.ac.nz/en/about/the-university/how- university-works/policy-and-administration/human-resources1/access-and-storage- of-information/access-to-personal-information-policy-and-procedures-.html

5.8 Conflict of interest

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

5.9 Social and cultural sensitivity

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

5.10 Vulnerable participants and communities

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

5.11 Te Tiriti o Waitangi

The Education and Training Act 2020 acknowledges the principles of Te Tiriti o Waitangi for all members of communities. The University recognises that all members of its community are encompassed by Te Tiriti o Waitangi with mutual rights and obligations. This means that all parties involved in a research project must respect the principles of relationship and sharing implicit in Te Tiriti. Research proposals must therefore incorporate, where appropriate, the spirit of Te Tiriti o Waitangi.

The principles of partnership, participation and protection underpin the relationship between the University and Māori under Te Tiriti o Waitangi. When research focuses on Māori, or if there are areas of interest and potential implications for Māori, the researcher is required to show that these have been considered and consultation, which may also involve koha, has taken place where appropriate, such as discussing any issues relating to Māori cultural and ethical values with the whānau, hapū or iwi concerned. The Pro Vice-Chancellor (Māori) has a Ko Ngā Mātanga Matatika Māori ethics advisor in each faculty, nominated by the Dean.

Cultural advice is also available for researchers with projects involving participants in Auckland DHB and CM Health.

5.12 Human remains, tissue and bodily fluids

All human remains, tissue and bodily fluids, must be treated with respect and, in general terms, tissue samples collected for one purpose must not be used for another without the consent of the donor.

The Human Tissue Act 2008 regulates the collection, storage, and use of human tissue in research. "Human tissue" is defined in section 7 of the Act. Examples of human tissue listed in section 7 are blood, bone marrow, nails, hair, mucus and urine samples. Human tissue is also defined in the Ministry of Health "Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes" as "any material collected from a living or deceased person that is or includes human cells".

Researchers working with human tissue need to demonstrate to the reviewing Committee that they have understood and taken account of the Human Tissue Act 2008. In particular, the HDEC Standard Operating Procedures (section 29.2) provide guidance about the ethics

review of projects where human tissue samples are collected.

All applications for collection and use of tissue must be submitted to AHREC, if the study is out of scope for HDEC review. AHREC only reviews applications for collection of tissue samples where full consent has been obtained from the donors and their samples are provided to the researchers in an anonymised manner. Researchers should consider the availability of Te Ira Kāwai – Auckland Regional Biobank (ARB) to assist and help in the collection of samples in an anonymised manner.

When tissue samples will be retained for future unspecified research, specific consent must be obtained from participants for storing and using their sample(s) for future unspecified research, and additionally, HDEC approval must be obtained for creating a tissue bank. A tissue bank is defined in the HDEC SOPs as "a collection of human tissue samples stored for potential use in research beyond the life of a specific research project".

For further information see:

- Human Tissue Act 2008: http://www.health.govt.nz/search/results/human%20tissue%20act
- Guidelines for the use of human tissue for future unspecified research purposes (Ministry of Heath): https://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0
- Standard Operating Procedures for Health and Disability Ethics Committees: https://ethics.health.govt.nz/operating-procedures
- HRC Specific considerations: Collection and use of human materials: https://www.hrc.govt.nz/resources/collection-and-use-human-materials
- Te Ira Kāwai – Auckland Regional Biobank (ARB)http://www.aaha.org.nz/en/aaha-in-action/artb-te-ira-kawai.html

5.13 Incidental findings and discovering illegal activity

Research occasionally gives rise to findings that are unexpected and unrelated to the original purpose of the research, but which may have implications for the wellbeing and interests of participants. Examples of incidental findings are discovery of a previously unknown medical condition in a participant, or when a participant reveals in the course of the study that they are party to illegal activity.

The Committees consider that if a contingency is more likely to arise due to participation in the study than it would in everyday life outside of the study, then it should be identified and considered as a possible incidental finding.

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

In the case of discovering illegal activities, what should happen will depend on the specific circumstances of the study. The Committees require the researchers to give consideration

to this issue for research where this may be a concern. The researcher/s must explain to the reviewing Committee (and participants where necessary) how they intend to manage such revelations.

When there are incidental findings, researchers are expected to advise participants within the limits of their expertise and put participants in contact with appropriate assistance. Nothing in regard to incidental findings should normally compromise participant confidentiality or privacy. However, researchers may have an obligation to breach confidentiality where they consider that appropriate disclosure is necessary to prevent or lessen a serious threat to life or health of an individual (participant or non-participant). There may be legal requirements or professional obligations to report certain kinds of discoveries, and it is the researchers' responsibility to be aware of these.

5.14 Unexpected harm

An important part of the Committees' responsibilities is the evaluation of events in which research participants have been unexpectedly harmed.

In order to fulfill their responsibility to protect all research participants, to the extent that it is possible to do so, the Committees require written reports to be submitted in all cases of unexpected harm. It is the responsibility of researchers (in the case of students, through their primary supervisor) to report these unexpected events using a form for reporting adverse events or unanticipated problems involving participants (available from the Ethics Administrators).

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

Where there is an adverse or serious unexpected event, the first priority is that the researcher ensures that any affected participant immediately receives care and assistance appropriate to the event or outcome.

If an adverse event affects researchers, then the University Health and Safety reporting procedures should be followed. Where researchers are not members of the University, reporting procedures of their employing institution should be followed.

5.15 Storage, security, destruction and retention of data

All data collected by research participants, including personal information, must be stored or disposed of securely in accordance with the University's policies, including the Privacy Framework, IT Security Policy and the Research Code of Conduct Policy.

- The Code of Conduct for Research can be found at: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/conduct/code-of-conduct-policy.html
- The University's Privacy statement is available from: https://www.auckland.ac.nz/en/privacy.html
- The IT Security Policy is available from: https://www.auckland.ac.nz/n/about/the-

university/how-university-works/policy-and-administration/computing/security/security-1.html

Clear indication should be given to the reviewing Committee 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 in the case of students).

Identifiable personal information about research participants should be retained for no longer than the researcher, or the University, has a lawful purpose to use it. Data may be retained for longer periods where it has been meaningfully de-identified.

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

If data are to be disposed of or destroyed, this must be done securely. Clear indication should be given to the reviewing Committee and to participants regarding the timing and manner of data destruction. If data are not to be destroyed, this must be indicated to participants along with the purpose for retaining them.

In considering storage or disclosure of data, researchers should consider whether material is subject to copyright provisions and ensure compliance with the University's Copyright Materials Policy. Participants should be informed in the PIS of any copyright conditions that may affect their contribution to the research.

The University requires Consent Forms to be retained in secure storage by the researcher (in the case of student research, by the primary supervisor) for a period of six years, or as long as identifiable or re-identifiable data is stored, separately from the project data. Information relating to the timeframe for storage must be shown at the top of the Consent Form.

5.16 Dissemination of results

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

5.17 Complaints procedure

A person wishing to raise an unexpected event, a matter of concern or a complaint about research approved by either UAHPEC or AHREC, and relating to the ethical standards of research on human participants conducted by members of the University, may do so in writing to the Ethics and Integrity Manager, or to the Chair of the Committee who will convey the complaint to the Ethics and Integrity Manager. The complaints procedure will encompass an investigation of the unexpected event or complaint by the Ethics and Integrity Manager and the relevant Committee Chair, taking into account written statements from both the complainant and the researcher of the study. The complaint

procedure is set out in full in Appendix 1.

6. APPLYING FOR ETHICS APPROVAL

6.1 Overview

Any member of the University who conducts research of any nature with human participants must apply for ethics approval unless an exemption applies. Exemptions from obtaining UAHPEC or AHREC approval are listed in section 3.1.1 and also in their respective Applicants' Reference Manuals.

The ethics approval process requires disclosure of all relevant information about the proposed research study to the reviewing Committee. The Principal Investigator (PI) needs to consider whether a particular piece of information is relevant to the ethics approval process even if the Guiding Principles do not specifically request provision of that particular piece of information.

Failure to obtain ethics approval when it is required, failure to adhere to an approved research study, and failure to comply with the policies of the University may constitute research misconduct and may occasion disciplinary action following standard University procedures. See section 6.8 for further guidance.

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

6.2 Research with ethics approval from other ethics committees

a. Where research is to be conducted in collaboration with a researcher from another institution and an ethics committee other than an HDEC has approved the research, the researcher must submit the ethics application and evidence of ethics approval to either UAHPEC or AHREC, depending on the nature of the research. That Committee may either ratify the approval or require a new ethics application.

b. Where research is to be conducted in collaboration with a researcher from an institution where ethics approval was not required or obtained, a new application for ethics approval must be made to UAHPEC, AHREC or the HDECs, as appropriate.

When a new staff member brings a research project to the University from another institution, unless the project has been approved by one of the HDECs, the original ethics application and approval should be submitted to the relevant Committee Chair. After considering evidence of how closely the approval process matches that of UAHPEC or AHREC, and whether the approval covered the research proposed to be conducted at the University, Auckland DHB or CM Health (or other DHBs that might be part of AHREC in the future), the Chair will decide whether or not it should be submitted to UAHPEC or AHREC for ratification. It is the researchers' responsibility to obtain the required locality approvals to conduct the proposed research.

Ratification is delegated to the Chairs of the relevant Committee who may refer the decision to a committee meeting for review. The researcher must obtain written approval from the Chair prior to engaging in the research activities.

6.3 Overseas research

Where research is conducted involving participants in overseas localities, the PI must demonstrate that they have taken into account ethical considerations appropriate to the area in which the research will take place and also considered the safety of the participants, the participants' data and the research team. They must pay attention to contextual issues and show how they have addressed these.

The Committees also require that local ethics approval is obtained if required or appropriate, and that local laws are complied with. A researcher is obliged to be familiar with local law, including in relation to the protection of privacy and data, and must assure the reviewing Committee in their ethics application that they will abide by any local laws relating to research privacy and data collection.

6.4. Secondary data analysis

Some research studies use secondary data from human participants, 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.

Ethics approval may be required for the use of secondary data. If the data is identifiable or re-identifiable, or if the data was acquired with participant consent which did not include use for the purpose of the proposed secondary analysis, then ethics approval must be sought.

Ethics approval may also be required by custodians of data prior to providing access to the data.

Permission of the custodian of the data is required for access to secondary data which is not publicly available. Researchers must ensure that the agency that is hosting the research or allowing access to data it has collected has a lawful basis to share that information and has ensured the participants are aware of the ways in which they might use or share the data. Researchers considering giving access to data sets should be aware of the requirements of the University's Privacy Framework.

The University's Privacy statement is available from:
https://www.auckland.ac.nz/en/privacy.html

6.5 Student research

Research activities involving human participants that are to be undertaken by University students as researchers require ethics approval unless an exemption applies.

6.5.1 Thesis and Dissertations

Ethics applications for student thesis projects for credit of 90 points or more must be submitted as individual research applications to either UAHPEC, or AHREC (for human health research), if the research does not fall within scope for review by an HDEC.

Dissertations and smaller student research projects (less than 90 points credit) may be submitted for ethics approval as individual applications. However, UAHPEC may consider approval of dissertations and smaller student research projects (less than 90 points credit) in an enrolment-based group application. Such projects can be submitted as a coursework application by the Course Director as PI, instead of requiring an individual application from each student. Coursework applications can be submitted only to UAHPEC,

not AHREC.

To be considered in this way, the student projects must have a common set of research questions and procedures, or a specified range of research questions and procedures within which students may choose their project. Student projects outside the specified choices, or which raise substantive ethical concerns (such as using child or vulnerable participants, presenting a risk of more than minimal harm to participants), must be submitted for ethics approval as an individual research application.

The Course Director or designated responsible academic is responsible for ensuring that students understand and observe ethical principles and work within the constraints and requirements of the ethics approval.

6.5.2 Course-related research

The University recognises that as well as supervised independent research projects for a thesis or dissertation, a range of research, research-like and research training activities regulated under the Health Practitioners Competence Assurance Act may be undertaken by students as part of coursework (course-based research). These may include, for example, testing or taking measurements of other students as part of learning research skills, or undertaking interviews. Such course-based research also requires ethics approval, using a 'Coursework Application' submitted by the Course Director to UAHPEC.

AHREC does not consider coursework applications.

Course-based research is typically restricted to activities which:

- pose no greater than minimal risk to participants,
- do not involve partial disclosure or deception,
- do not include participants who are vulnerable such as children, institutionalised elderly, cognitively impaired individuals, or persons who are not able to legally consent to participate in the research.

Research and research training activities carried out by students within courses which meet the following conditions are regarded as course-based research requiring ethics approval for the course from UAHPEC[4]:

- The objective of the project/data collection is for the student to acquire skills involved with conducting academic and scholarly research in a rigorous manner
- The approved course syllabus includes an objective which deals with the need for the student to acquire research skills
- Results may be shared with classmates or teaching staff and are intended to generate generalisable (and new) knowledge from which others might benefit even if this does not actually occur
- Typically, the activities are characterised as research in the course syllabus, evaluation scheme/rubric, and descriptions
- Evaluation criteria include an assessment of the quality of the research conducted
- While pedagogical in nature, results intend to reflect scholarly or academic traditions and customary approaches used in the discipline
- Processes used are systematic, rigorous, and intended to generate knowledge according to scholarly or academic traditions within the discipline
- Participants are typically drawn from populations outside of the University

[4] Coursework definition and criteria adapted from Waterloo University, Canada – sourced from the online research pages: Definition of course-based research | Research | University of Waterloo (uwaterloo.ca)

- Findings and results are typically not disseminated beyond the classroom or academic unit but are of sufficient quality for dissemination via posters, seminar presentations, or journal articles.

Course-based research activities typically use methods involving:

- Structured or semi-structured interviews with key informants working in a particular area/field (e.g., academic experts, not-for-profit organisations, employers)
- Surveys with family/friends/other students/members of the general public
- Focus groups/group interviews with employees or members of an organisation or group.

Course-based research typically does not involve**:**

- Schools or school boards
- Hospitals or clinics or other health-based institutions
- Controlled acts as outlined by the Health Practitioners Competency Assurance
- Procedures or equipment for the collection of physiological or biometric data
- Secondary data analysis of health or personal data or the linking of data sets.

Course-based research does not include research papers/projects designated as "thesis" or "dissertation".

6.5.3 Course activities which do not require approval by UAHPEC

Teaching and learning exercises where some students may act as model patients/clients for others within the teaching of clinical skills or disciplinary technical skills do not constitute research and do not require UAHPEC or AHREC approval. Clinical skills include a wide variety of skills that are useful in any clinical setting, such as physical examination skills, use of technological apparatus, practical procedure, communication skills, and management. Technical skills may be taught using other students as models or exemplars in a number of disciplinary areas.

Course activities do not require ethics review if students are:

- using information-gathering procedures and practices for educational purposes outside the context of a research framework, AND
- the acquisition of research skills is NOT an objective of the exercise.

All course activities, whether requiring ethical approval or not, must:

- meet University health and safety requirements AND
- align with the appropriate University and faculty standards and review procedures for course content and conduct AND
- conform to ethical standards within the profession.

6.5.4 Staff research in class time

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

It is University policy that research in class time is only permissible under the following three conditions:

- the research is directly related to course content, AND
- the express written consent of the course coordinator is given to conduct the research in class time, AND

- the course coordinator is satisfied that the students will be debriefed as to the aims, hypotheses and, where possible, results of the research. Such assurances should be included in the ethics application.

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

6.6 Funded research

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

Research involving human participants conducted at the University that is supported by US Federal funding, or where University researchers are part of a multi-centre study with NIH funding, is subject to special requirements. In order to fulfill the terms of the Federal-wide Assurance that the University holds with the US Office of Human Research Protections, researchers should contact the Ethics Administrators, ext. 83711, for advice prior to taking up the research grant.

6.7 Liability and indemnity insurance

The University maintains a liability insurance programme that extends to the performance of clinical trials. The policy conditions include the requirement to obtain ethics approval when applicable and to adhere strictly to the approved protocol.

In the event of a complaint or legal suit, researchers who did not obtain ethics approval for their research involving human participants when required may not be covered by the University's indemnity insurance. Failing to obtain the required ethics approval could also put researchers at risk of not being able to publish their research in reputable journals and other possible consequences.

For more information about insurance cover for research involving human participants, please contact the Risk Management and Audit team (risk@auckland.ac.nz).

6.8 Misconduct in research

When describing its purpose, the Research Code of Conduct Policy states: This code of conduct seeks to ensure that researchers at the University maintain the highest standards of professional conduct when undertaking and supervising research by outlining the guiding principles and responsibilities along with relevant examples. Breaches of the code may constitute "Misconduct in Research". The Education and Training Act 2020 protects the academic freedom of academic staff and students to undertake research, but this academic freedom is predicated on the need to maintain the highest ethical standards; the need to permit public scrutiny to ensure maintenance of those standards; and the need for accountability and the proper use of resources.

All researchers at the University are expected to adhere to this Code.

Failure to obtain ethics approval when it is required, failure to adhere to or deviating from an approved research study, and failure to comply with the policies established by the University, may constitute research misconduct and may occasion disciplinary action following standard University procedures.

For further information, refer to the following University documents:

- Ethics Review of Research Involving Human Participants Policy https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/ethics/ethics-review-of-research-involving-human-participants-policy-.html

- Code of Conduct for Research policy: Research Code of Conduct Policy - The University of Auckland

- Staff Research Misconduct Policy: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/conduct/staff-research-misconduct-policy.html

- Statute and Guidelines for the Degree of Doctor of Philosophy (PhD): https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/teaching-and-learning/postgraduate-research/previous-statutes/2020-phd-statute.html

- Student Charter: https://www.auckland.ac.nz/en/students/forms-policies-and-guidelines/student-policies-and-guidelines/student-charter.html

- Student Academic Conduct Statute: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/teaching-and-learning/students/student-academic-conduct-statute--2020-.html

- Statue for Student Discipline: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/teaching-and-learning/students/statute-student-discipline.htmlatute for Student Discipline - The University of Auckland

7. REFERENCES

Ethics Committee on Assisted Reproductive Technology, available from: http://www.ecart.health.govt.nz

General Data Protection Regulation (GDPR) Compliance Guidelines, available from: https://gdpr.eu/

Guidelines for the use of human tissue for future unspecified research purposes (Ministry of Health), available from: https://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0

Health and Disability Ethics Committees Standard Operating Procedures, available from: https://ethics.health.govt.nz/operating-procedures

Health Information Privacy Code 2020, see especially Rule 10 "Limits on the use of Health Information" available from: https://privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/

Health Research Council (2012). *HRC Guidelines for Approval of Ethics Committees (Approval Guidelines)*. Wellington: Health Research Council of New Zealand, available from: https://www.hrc.govt.nz/resources/hrc-guidelines-approval-ethics-committees

Health Research Council: Collection and use of human materials, available from: https://www.hrc.govt.nz/resources/collection-and-use-human-materials

Health Research Council Research Ethics Guidelines (2021), available from: https://gateway.hrc.govt.nz/funding/downloads/HRC_research_ethics_guidelines.pdf

Health Research Council Pacific Health Research Guidelines (2014), available from: https://gateway.hrc.govt.nz/funding/downloads/Pacific_health_research_guidelines.pdf

Human Tissue Act 2008, available from: http://www.legislation.govt.nz

National Oral History Association of New Zealand Code of Ethics & Technical Practice, available from:http://www.oralhistory.org.nz/index.php/ethics-and-practice/

NEAC National Ethical Standards for Health and Disability Research and Quality Improvement, available from: https://neac.health.govt.nz/node/107

Privacy at the University of Auckland, available from: https://www.auckland.ac.nz/en/admin/footer-links/privacy.html

Privacy Act 2020, available from: http://www.legislation.govt.nz

Taumata Teitei, Vision 2030 and Strategic plan 2025, available from: https://www.auckland.ac.nz/en/about-us/about-the-university/the-university/official-publications/strategic-plan.html

Te Ara Tika Guidelines for Māori research ethics: A framework for researchers and ethics committee members, available from:https://www.hrc.govt.nz/resources/te-ara-tika-guidelines-maori-research-ethics-0

The University of Auckland Copyright policy, available from: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/university-organisation-and-governance/records-management.html

The University of Auckland Ethics Review of Proposals Involving Human Participants Policy, available from: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research/ethics/ethics-review-of-research-involving-human-participants-policy-.html

The University of Auckland (2003). University of Auckland Charter, available from: https://www.auckland.ac.nz/en/about-us/about-the-university/the-university/official-publications/university-of-auckland-charter-2003.html

The University of Auckland (2012). University of Auckland Code of Conduct for Research, available from: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/teaching-and-learning/students/statute-student-discipline.html

The University of Auckland. Student Charter, available from: https://www.auckland.ac.nz/en/students/forms-policies-and-guidelines/student-policies-and-guidelines/student-charter.html

The UAHPEC Applicants' Reference Manual, available from: http://www.auckland.ac.nz/uoa/re-uahpec

The AHREC Applicants' Manual, available form: https://www.auckland.ac.nz/en/research/about-our-research/human-ethics/ahrec.html

The UAHPEC Terms of Reference, available from: https://www.auckland.ac.nz/en/about-us/about-the-university/the-university/governance-and-committees/committees/a-z-committees/human-participation-ethics-committee.html

8. GLOSSARY

Adverse events in research

Adverse events can arise in both biomedical, social and behavioural research.

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

Anonymity

Research participants are anonymous when neither the researcher(s) nor other participants are aware of who is participating. Research data, or a participant's responses,are anonymous when the researcher gathering or analysing these is unable to trace them to any individual participant. A questionnaire is not anonymous if it is coded in such a way that the researcher can trace it to the participant. It is preferable to use more precise descriptions when referring to identifiability of data (see below).

Assent

Assent is the agreement to participate in research offered by someone who is able to understand what is required but not of an age (under the age of 16) or ability to give hisor her consent. Assent may be given orally, and the researcher should record the oral assent where possible and store the recording in the same way as written consent.

Child/Young person

UAHPEC regards a child or young persons as being someone aged under 16.

Human Health Research

Human Health Research is research in which people, or data or samples of tissue from people, are studied to understand health and disease. Clinical research helps find new and better ways to detect, diagnose, treat, and prevent disease. Types of clinical research include clinical trials, which test new treatments for a disease, and natural history studies, which collect health information to understand how a disease develops and progresses overtime." *[NIH National Cancer Institute]*

Clinical trials

UAHPEC and AHREC adopt the definition of clinical trials from the World Health Organisation and the 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 Health and Disability Ethics Committees (HDECs) have Standard Operating Procedures (SOPs) that define rules and guidance on the health and disability research that they review as well as the role and review process of HDECs. The SOPs can be found at: http://ethics.health.govt.nz/operating-procedures

Confidentiality

Research participation may be described as confidential when the participant's identity is known to the researcher but will not be disclosed to third parties or in any discussion or report of the research. This means that any report or discussion of the information given by the participant will be done in a way that does not identify, or allow identification of, the participant as the source of the information. Information provided by a participant should not be described as confidential if it may be shared, reported or published, even when the informant will not be identified. Instead the way in which it will be stored, reported or shared (for example, non-identifiable, or coded) should be clearly stated. Personal information about participants may be described as confidential if it will not be reported.

Conflict of interest

A situation in which professional judgement concerning one interest, such as a person's health or the validity of research, could be influenced by another interest, such as meeting recruitment targets, personal relationship, financial gain or impact on future career.

Consent Form

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

Legal Guardian of a child

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

Identifiable Data

- **Identifiable data** is data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the research. Identifying information includes, butis not limited to, names, addresses, birth dates, phone numbers, email addresses, identifying numbers (for example, National Health Index number or Inland Revenue number), employment details and photos.
- To de-identify data is to remove from it all identifying information. It should be made clear to the Committee and participants whether this has been done in a way which allows re-identification or not.
- **Re-identifiable data** is data from which researchers have removed identifiable information and assigned a code, but it remains possible to re-identify a specific

individual, for example, using a code-key or linking different data sets.

- **Non-identifiable data** is data that has never been labelled with individual identifiers or from which identifiers have been permanently removed, and for which there is no reasonable basis to believe that a specific individual can be identified. A subset of non-identifiable data is the data that can be linked with other data so it can be known that the two sources are about the same data participant, although the person's identity remains unknown.

Intervention study

An intervention study in which the researcher controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s) The term 'intervention study' is often used interchangeably with 'experimental study'. Many intervention studies are clinical trials and most will require HDEC approval. (National Ethical Standards, Section 10).

Non-health related interventions include, but are not limited to, changes to educational practices.

Koha

Koha is an unconditional gift where the recipient has neither stipulated that it be given, nor has an expectation of receiving it. It is distinct from expenditure for services supplied. The giving of koha is an integral part of Māori culture.

Member of the University

A member of the University includes:

- anyone employed under a University or Auckland UniServices Limited employment agreement or as an independent contractor, and
- any student enrolled at the University, and
- anyone else who is undertaking, piloting or supporting research in association or affiliation with the University, including anyone subject to the Honorary and Adjunct Appointment Policy and Procedures or holding a University title such as Emeritus Professor.

Observational study

In health research, observational studies are distinguished from intervention or experimental studies as those where no intervention other than recording, classifying, counting and analysing of data takes place. The investigator has no control over study variables and merely observes outcomes. The prospective collection of data – such as from blood samples, imaging or questionnaires – does not change the status of a study from observational to interventional. Observational studies are not automatically of minimal risk. Some may involve an invasive or high-risk mean as of collecting data from participants. Many may pose a risk of privacy harm, particularly where data collected or accessed may be sensitive. (National Ethical Standards, Section 10).

In Social Sciences and some other disciplines, observation is a particular research methodology which may be included alongside other research activities.

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 topresent the information orally. In these cases a copy of the information to be presented orally must be submitted to the reviewing ethics committee.

For online questionnaires, the PIS can be the first page of the questionnaire, and in those cases, applicants must ensure that the PIS can be downloaded by participants to keep for future reference.

Questionnaire

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

Research

The University adopts the definition of research issued by the Tertiary Education Commission (TEC) as part of the assessment of the research performance of staff.

The February 2021 PBRF definition of research is taken from the TEC's guidelines for tertiary education organisations planning to participate in the 2025 Quality Evaluation:

For the purposes of the PBRF, research is original investigation undertaken in order to contribute to knowledge and understanding and, in the case of some disciplines, cultural innovation or aesthetic refinement (the term 'independent' does not exclude collaborative work).

Research typically involves inquiry of an experimental or critical nature driven by hypotheses or intellectual positions capable of rigorous assessment by experts in a givendiscipline. 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.

Research includes work of direct relevance to the specific needs of iwi, communities, government, industry and commerce. Research includes:

- contributions to the intellectual infrastructure of subjects and disciplines (for example, dictionaries and scholarly editions); the term 'scholarly' is defined as the creation, development and maintenance of the intellectual infrastructure of subjectsand disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research database).
- 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.

Research findings must be open to scrutiny or formal evaluation by others in the field, and this may be achieved through publication or public presentation. In some disciplines, the investigation and its results may be embodied in the form of artistic works, designs or performances.

Research participant

A research participant is a person about whom a researcher obtains with 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.

Vulnerability

In the context of research involving human participants, 'vulnerability' refers to a 'substantial incapacity to protect one's own interests owing to impediments such as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group' (National Ethical Standards, section 6). Vulnerability may vary in degree, over time as well as context or situation and may affect both individuals and groups. It needs to be considered and addressed by researchers in the contexts of both of securing informed consent to participate and of possible harms and benefits from the research.

Further guidance on research involving participants who may be vulnerable can be found in the National Ethical Standards.

9. APPENDIX 1: COMPLAINTS PROCEDURE

An important responsibility of UAHPEC and AHREC is the investigation of complaints received as well as the evaluation of other events in which research participants have been unexpectedly harmed or approved processes were not followed.

1. Lodging complaints:

a. Complaints made by members of the public or participants:

A member of the public wishing to raise a matter of concern or a complaint about research approved by UAHPEC or AHREC may do so in writing to the relevant Committee's Chair by contacting the Ethics and Integrity Manager (the Manager) in the first place via email (humanethics@auckland.ac.nz).

The complaint, or expression of concern, should be set out in sufficient detail to enable the Chair to understand both the research study and the issues of concern.

b. Complaints made by a member of the University:

A member of the University wishing to raise a matter of concern or a complaint about research approved by UAHPEC or AHREC must complete a Report Form for adverse event and complaints. The form can be requested from the Ethics Administrators and the completed form submitted to the Manager using humanethics@auckland.ac.nz

c. If the complaint is about the Chair, or if the complainant/informant is dissatisfied with the Chair's response, the complainant/informant should, in the first instance, write to the Manager who will then direct the complaint or concern to the DVCR.

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

2. Investigation process:

a. If the complaint or matter of concern is relating to ethical standards of research on human participants conducted by staff or students of the University, the matter will be investigated as outlined below according to the policies of the University.

b. When the complaint or matter of concern is relating to the ethical standards of research on human participants conducted by a member of the DHBs using AHREC for ethics review, the complaint will be investigated according to the processes and polices of the relevant DHB.

c. When the matter of concern or a complaint is relating to ethical standards of research on human participants conducted by a researcher in an honorary or adjunct academic position at the University, the complaint will be investigated at the organisation of the researcher's primary employment. If the researcher is not employed at another institution, the complaint will be investigated according to the policies of the University.

d. The University's investigation process:

i. The Manager will co-ordinate the investigation in consultation with the Chair.

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

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

iv. If the Manager, in consultation with the Chair, considers there are good reasons to protect the identity of the complainant or informant, and the investigation can still proceed in a procedurally fair manner, the identity of the complainant or informant may initially remain confidential.

v. Procedural fairness will normally require that details of the complaint or concern and sufficient information about the source of the complaint or concern will be made available to those about whom the complaint is made.

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

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

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

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

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

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

3. After conclusion of the investigation:

a. 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.

b. Where the investigation determines that there may be a breach of the University's Research Code of Conduct Policy, the Manager, in consultation with the Chair, will refer the matter to the DVCR. In such circumstances, the Chair will inform the complainant or informant and the subject of the complaint or concern accordingly.

c. Where the matter is not resolved through this investigation, the Manager will inform the DVCR and advise the complainant/informant and the Principal Investigator accordingly.

The DVCR shall determine if further steps are to be taken within the University to address the matters raised by the complainant/informant.

d. Where the complaint remains unresolved at the University level, the complainant/informant may refer it to the HRC EC for an independent opinion.

e. The relevant Ethics Committee will be informed of the outcome of the investigation, and the identity of the researcher and the research project will only be disclosed where the complaint (or parts thereof) is upheld, or if it can be established that an adverse research event did indeed occur.

f. The Chair will provide non-identifying advice to the UAHPEC annually with respect to the number and nature of complaints or reports of adverse events.

g. The Chair will report the number and nature of complaints or adverse events in a non-identifying manner to the HRC EC annually. This report will also be provided to the AHREC and UAHPEC as well as the Auckland DHB and CM Health.