Auckland Health Research Ethics Committee

(AHREC)

APPLICANTS' MANUAL

June 2022

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Contents

1. INTRODUCTION

The Auckland Health Research Ethics Committee (AHREC) was established in 2017 as an initiative of the Auckland Academic Health Alliance, the partnership between the Auckland District Health Board (Auckland DHB) and Waipapa Taumata Rau | the University of Auckland (University). AHREC provides ethical oversight and approval of health research which is not eligible for review by a Health and Disability Ethics Committee (HDEC) (see Section 4.1 for further details). In 2019, AHREC eligibility criteria were broadened to review ethics applications from staff of Counties Manukau District Health Board (CM Health), and in 2022, to review applications from Waitematā DHB.

1.1 Purpose of this document

This document is intended to provide guidance to researchers and ethics advisors on their research projects, and on the process of applying for ethics approval from AHREC. The manual highlights issues to which particular attention needs to be paid during the design and conduct of research. Where a specific issue or situation is not addressed herein, the following sources should be consulted for guidance:

- National Ethical Standards for Health and Disability Research and Quality Improvement, National Ethics Advisory Committee (NEAC), 2019: National Ethical Standards for Health and Disability Research and Quality Improvement | National Ethics Advisory Committee
- Health Research Council (HRC) Research Ethics Guidelines (2021)

Auckland DHB applicants:

- Board Policy – Clinical Research, available from the Auckland DHB Policies and Guidelines Library.

CM Health applicants:

- Research Policy and a Clinical Audit Policy, available from the CM Health 'Research' Paanui webpage, or by contacting researchoffice@middlemore.co.nz

Waitematā DHB applicants:

- Interventional and observational research, audit and evaluation policy available on StaffNet under Research and Knowledge Centre/Resources or by contacting research@waitematadhb.govt.nz

University of Auckland applicants:

- University of Auckland Guiding Principles for Conducting Research involving Human Participants
- 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

1.2 Aims

The aims of this manual are to:

- Provide a clear statement of the ethical principles and standards by which AHREC is guided
- Draw attention to ethical issues that might arise in the course of a research project and suggest strategies for responding to them
- Provide examples of appropriate wording in the application form and research documents
- Provide information about further resources which may be helpful to the researcher.
- Provide guidance about the procedures and process of submitting and review of AHREC applications.

2. KEY PRINCIPLES

The National Ethical Standards for Health and Disability Research and Quality Improvement (hereafter, the National Ethical Standards), published by the National Ethics Advisory Committee (NEAC) in 2019 sets out two sets of principles for ethical health research: Te Ara Tika Principles and Bioethics Principles. While these are differently framed, their primary focus can be seen to be on relationships of respect and care. How these principles apply to different kinds and instances of human interactions is a matter of judgement, often involving weighing different and possibly competing sets of interests (individual, community, privacy and well-being). They underpin more detailed requirements and guidelines for the conduct of ethical research.

Careful consideration of how these principles may apply is a primary responsibility for all who are planning research involving other people as participants, partners, or sources of information, as well as for the Committees charged with the ethical review and approval of research proposals. For more detailed discussion, see Section 2 of the National Ethical Standards.

2.1 Te Ara Tika Principles[1]

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]

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

[2] NEAC National Ethical Standards for Health and Disability Research and Quality Improvement (2019)

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.[2]

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]

2.2 Bioethics Principles

The following principles are well recognised within bioethics and health research. The primary values underlying these principles are respect and care for persons. Researchers should adhere to these principles when planning and undertaking their research. These principles are widely accepted as key principles that guide the conduct of ethical 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.

i. Respect for people

This principle is frequently phrased as respect for autonomy, but is wider in that it 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 of groups 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 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, including greater societal harm. Researchers 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.

3. ROLES AND RESPONSIBILITIES

3.1 Researchers' Responsibilities

Research by staff and students at the University of Auckland which involves human participants must be approved by UAHPEC, AHREC or an HDEC, depending on the nature of the research. Auckland DHB, CM Health and Waitematā DHB have regulations regarding when research which is not eligible for HDEC review needs to be submitted to AHREC.

The primary responsibility for maintaining ethical standards in research rests with the research team and, in particular, with the Principal Investigator (PI). 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. AHREC 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.

3.2 AHREC Responsibilities

AHREC's ethical principles and procedures are consistent with the Health Research Council's ethical framework and with those of NEAC as outlined in the National Ethical Standards.

In reviewing applications, AHREC reserves the right to seek expert opinions from individual experts or 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), the University of Auckland Human Participants Ethics Committee (UAHPEC) and the Health and Disability Ethics Committees (HDECs).

4. ETHICS APPROVAL REQUIREMENTS

4.1 Eligibility for AHREC review

AHREC undertakes the review of health and disability research studies that fulfil both of the following criteria:

1. *The study is not eligible for ethics approval review by a Health and Disability Ethics Committee; AND*
2. *The study involves health research conducted and/or led by any of the following: an Auckland DHB, CM Health or Waitematā DHB employee, or staff or students of the University of Auckland.*

AHREC approval should also be sought when a staff member of Auckland DHB, Waitematā DHB or CM Health, or staff and students of the University will be recruiting participants from other New Zealand DHBs or health providers.

For those multi-site applications, it remains the responsibility of the applicant(s) to obtain locality governance approvals for the other DHB(s) or other health providers.

Researchers are advised to contact the Research Office(s) of the DHB(s) where the research will take place to determine the specific locality approval requirements of the relevant DHB(s). Contact details for DHBs are available from the Ministry of Health website:

https://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards/district-health-board-websites

AHREC uses the NEAC definition of health and disability research as outlined in the National ethical Standards (p.28): "health and disability research is any social science; kaupapa Māori methodology; or biomedical, behavioural or epidemiological activity that involves systematically collecting or analysing data to generate new knowledge, in which a human being is exposed to manipulation, intervention, observation or other interaction with researchers either directly or by changing their environment, or that involves collecting, preparing or using biological material or medical or other data to generate new knowledge about health and disability."

Quality improvement or audits that do not fall under an exemption category may also be eligible for AHREC review, for example in cases where they use methodologies that may have ethical implications, have a clear research aim, or where they are intended to meet requirements to attain a degree.

Research projects can commence only after AHREC approval has been given and application to conduct the research at a given locality site has been approved by that locality (refer to section 8.1). There are no exceptions to this rule and AHREC does not grant retrospective approval.

4.2 Exemptions

The following general exemptions from AHREC approval apply:

- 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 approved by an HDEC
- Research that is approved by the Ethics Committee on Assisted Reproductive Technology (http://www.ecart.health.govt.nz/).

For University staff and students, additional exemptions are listed in the Guiding Principles for Conducting Research with Human Participants, Section 3.1.1.

Should further guidance be required about studies requiring ethical approval and institutionally specific exemptions at the Auckland DHB, Waitematā DHB and CM Health, this can be sought from the respective Research Offices.

4.3 Research collaboration and transferring research

A research project should only be reviewed by a single HRC EC approved committee, but in some situations of research collaboration it may be necessary to obtain ratification by AHREC of the approval given by another ethics committee. Management approval will usually be needed from each institution in which the research takes place.

Previously obtained ethics approval:

Where a new staff member of the University brings with them a health research project from another institution or where health research is conducted in collaboration with a researcher from another institution, unless the project has been approved by one of the HDECs, the original ethics application and approval must be submitted to AHREC for ratification. (See Section 4.5). If the transfer of research involves adding participants or data from DHBs not previously included, locality authorisation will be required (see Section 8.1) and a new application to AHREC may be required.

All research by students for University qualifications requires an application for approval by either AHREC or UAHPEC.

For new CM Health researchers transferring projects, CM Health locality authorisation will be required, but no additional ethical review will be required if the original approval remains valid.

For new Auckland DHB researchers transferring projects, locality authorisation will be required only if the research transfer has resource implications for Auckland DHB or involves adding Auckland DHB staff, patients, or data to a previously approved project. Requests for Auckland DHB locality authorisation will also involve application to AHREC for ethical approval.

For new Waitematā DHB researchers transferring projects, Waitematā DHB locality authorisation will be required, but no additional ethical review will be required if the original approval remains valid

Where research is conducted with ongoing consultation with cultural groups, individuals and/or organisations, an amendment request must be requested if there is any deviation from the previously approved ethics application.

If no ethics approval was previously obtained:

A new application needs to be submitted to AHREC or an HDEC. Where research is conducted in collaboration with a researcher from another institution where ethics approval has not been obtained, a full application for ethics approval must be made to AHREC or an HDEC.

4.4 International projects

Where a University staff member is the Primary Investigator (PI) for a health research project involving international collaboration, application for ethics approval should be made to AHREC as normal, unless the project is eligible for HDEC. If ethics approval has been obtained previously from another institutional ethics committee, application will need to be made for ratification of that approval (see Section 4.5).

Where a University staff member is part of the research team for an international health research project which has been given ethical approval by an ethics committee in another country, application needs to be made to the Chair of AHREC for ratification of that approval (see Section 4.5).

Where a researcher from the University, Auckland DHB, CM Health or Waitematā DHB is part of an international health research project which requires local (New Zealand) ethics approval for part of the project, then an application should be made to AHREC (or HDEC if eligible) for that approval. A clear statement of the protocol with respect to the New Zealand arm should be provided with the application, as well as a copy of the International protocol together with any approvals already received from other (international) committees.

Researchers engaged in international projects should note that AHREC may request alterations to meet New Zealand expectations or regulations where the research involves New Zealand participants or data. Particular attention may need to be paid to meeting New Zealand requirements with respect to collection of demographic data, as well as ensuring security of data storage.

4.5 Ratification

To seek ratification from AHREC of ethical approval given by another University / Institution, the applicant will need to provide the following documentation, written in English, to ahrec@auckland.ac.nz:

- Approval letter (and any approval for subsequent amendments).
- Approved application (including relevant supporting documentation and any documents for participants).

For AHREC ratification to be considered, the following conditions will need to be met:

- The original ethics approval is from a committee whose governing principles and processes are similar to those of AHREC.
- The University, or DHB staff member(s) seeking ratification is/are named on the original approved application (or an approved amendment).
- Any intended research site in New Zealand is included in the original approval or an approved amendment.

- The staff member seeking ratification confirmed that participants will only be those mentioned in the originally approved application. If the application does include new participants, then a new application will need to be submitted for approval.

Once received at ahrec@auckland.ac.nz, the approval letter and approved application will be sent to the AHREC Chair. The Chair has delegation to review and ratify such applications, but can also refer the ratification request to the full Committee for review, or require that a new application be submitted to AHREC. The research can only start in New Zealand once the applicant has received an AHREC approval letter. It is the responsibility of the research team to abide by the conditions of the approved application, for example, to note the expiry date of the initial approval. The AHREC ratification date does not change the approval period of the initial approval.

Ratification may be given with conditions appropriate to undertaking the research in New Zealand.

Ratifications are noted at the AHREC meetings.

If an amendment request has been made to the approved application of another University / Institution, then the amendment(s) requested and approval also needs to be submitted for ratification by AHREC.

If a University student is involved such that the project will be used to meet the research requirements for a programme in which they are enrolled, then a new application is required through AHREC.

4.6 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 ethical approval. A new application will be required for the subsequent full study.

Requesting a small number of peers or experts to check the suitability of research instruments is not considered a pilot study. Trialling an instrument or methodology with a small group of prospective research participants is a pilot study.

4.7 Projects with multiple parts

If a project has multiple parts, this should be clearly indicated in the application. Separate applications for individual parts of a study may be required by AHREC.

4.8 Research conducted without ethical approval

Failure to obtain AHREC ethics approval when it is required, and failure to comply with the policies and guidelines of the University, Auckland DHB, CM Health or Waitematā DHB may constitute research misconduct and may give rise to disciplinary action according to standard procedures at the Auckland DHB, CM Health, Waitematā DHB or the University.

5. EXTERNAL COMPLIANCE REQUIREMENTS

5.1 Compliance with Health Research Council Ethics Committee (HRC EC) requirements

AHREC is an HRC EC approved ethics committee and as such, must meet the HRC EC requirements in order to maintain this status.

5.2 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 Auckland DHB, CM Health, Waitematā DHB or University policy on research and a professional code, the researcher should inform, and seek advice from AHREC.

5.3 Requirements from other organisations

A research project may have requirements imposed upon it by an organisation outside a partner DHB or the University, such as a funding organisation. 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 Auckland DHB, CM Health, Waitematā DHB, the University, or the outside organisation. Researchers should detail such requirements in their ethics application and explain how these will be met within the guidelines and requirements of AHREC.

If any changes to an approved application are requested by the organisation or during the process of locality approval, then these must be approved as an AHREC amendment before implementation.

5.4 Research eligible for review by the University Of Auckland Human Participants Ethics Committee (UAHPEC)

UAHPEC reviews applications for research studies of staff and students of the University only where the studies do not involve human health research or use and collection of human tissue.

All University coursework applications should be submitted to UAHPEC.

5.5 Ethics Committee on Assisted Reproductive Technology (ECART) review

Research that creates or uses a human gamete, human embryo or hybrid embryo (i.e., "human reproductive research") requires approval by the Ethics Committee on Assisted Reproductive Technology. See: http://www.ecart.health.govt.nz/

6. APPLYING FOR ETHICS APPROVAL

6.1 Application process

The application process for AHREC ethics review is administered by the University Ethics and Integrity team, in cooperation with the Auckland DHB, Waitematā DHB and CM

Health Research Offices. Completed applications with supporting documents are submitted using the Infonetica Ethics RM software (https://apply.ethics.research.auckland.ac.nz/).

Support available:

- Auckland DHB staff: https://www.adhb.health.nz/health-professionals/research/approval-process/
- Starship Child Health staff: the Research & Innovation Office, Starship, at StarshipResearch@adhb.govt.nz (Tel 021 220 6953)
- Support for CM Health staff is available from the Research Coordinator, CM Health Research Office at researchoffice@middlemore.co.nz (Tel 021 574 928)
- Support for University of Auckland staff and students is available from the Ethics Administrator, Ethics and Integrity team, at ahrec@auckland.ac.nz (Tel 09 373 7599 ext 83711)
- Support for Waitematā DHB staff is available from Research and Knowledge Centre email research@waitematadhb.govt.nz

A Word template of the application for preparing a draft application prior to pasting into relevant parts of the online form (e.g., where this is required for a student to receive supervisor feedback) is available at: https://www.auckland.ac.nz/en/research/about-our-research/human-ethics.html

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

The ethics approval process requires disclosure of all known relevant information about the proposed research to AHREC. The 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 must submit an application for ethics approval. For student (including Doctoral, Masters and Honours) research, applications should be submitted by the primary supervisor who will be named as the PI.

All correspondence regarding individual ethics applications will be addressed to the PI, and also copied to the co-investigator(s), student researcher(s) and the academic head, as applicable.

6.2 Scientific reviews

For research to be ethically sound, it must be of scientific merit. AHREC's requirement for a scientific review is based on the guidance from NEAC in order to ensure all research studies approved are of scientific merit. This guidance is described in the National Ethical Standards and requires peer review of the relative merit, the design and methods, and the feasibility of the research study, as outlined below. The summary below was taken

from Section 9 of the National Ethical Standards, and researchers should read that section in full.

Scientific reviews should be provided by an independent person with appropriate expertise. The document should be signed and include a clear statement of the name and academic or clinical position of the reviewer.

a. For research supported by funding from competitive internal (Auckland DHB, Waitematā DHB, CM Health or University of Auckland) or external funding sources:

Proof of a peer-reviewed funding award will be sufficient. However, the award must be from a funding source where the award was judged on scientific content.

Award of a scholarship must be accompanied by a clear statement from the PI that the award has been based on an evaluation/scientific review of the specific project planned.

If the grant award process does not include an evaluation/scientific review, then an independent scientific review is required (see below).

b. For applications concerning student projects at or below Masters level:

The main supervisor may provide an explicit assessment of the research merit of the project, paying attention to the relative merit, the design and methods, and the feasibility of the research study as outlined below, but recognising that benefits for student learning may be part of the justification for a project and properly balanced against such things as scope and significance of health outcomes of the proposed research.

c. For unfunded projects, including unfunded doctoral student projects, and funding where an evaluation/scientific review is not part of the grant allocation process:

Applicants are required to provide an independent science review. This peer review should address the importance of the scientific question, the appropriateness of the methodology, study power, feasibility, the track record of the applicant(s), and a global assessment of the study's scientific merit, as outlined below.

NEAC areas of focus during peer review

Peer review can be tailored to deliver opinions on a variety of matters relating to a health and disability research proposal. In order to determine scientific validity, the following factors should specifically be determined and the person providing the scientific review must provide brief comments on each:

- **The relative merit of the research:** A key consideration is whether the proposed work is important, worthwhile and justifiable. The research should address a health issue that is important for health and/or society. The aims, research questions and hypotheses will build on and address gaps in existing knowledge.
- **The design and methods:** The quality of study design and methods should be reviewed to assess its robustness. This might include study methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) and proposed methods of data analysis. Indication of timelines for the research should be included.

- **The feasibility of the research:** This includes assessing:
    - whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project
    - whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions
    - Whether the research will be achievable within the specified timeframe and the research team has the appropriate experience and expertise to undertake the research.

6.3 Responsiveness to Māori

All research in New Zealand is of interest to Māori, and researchers must explain to AHREC how their research study can contribute to improving Māori health outcomes.

Researchers are encouraged to read Section 3 of the National Ethical Standards particularly to understand the importance of using a partnership approach when developing and executing their research proposal. This approach is even more important when a particular whānau, hapū, iwi, Māori community or Māori organisation will be participating in the study.

Additional resources:

- Reid et al, 2017. *Aotearoa: strengthening responsiveness to Māori in health research.* New Zealand Medical Journal *130*:1465. Retrieved from https://journal.nzma.org.nz/journal

- Simmonds, S. (2015). A Framework for Māori Review of Research in District Health Boards: A joint research project between Auckland and Waitematā District Health Board and Capital and Coast District Health Board. Retrieved from www.ccdhb.org.nz.

- Hudson, M., Milne, M., Reynolds, P., et al (2010). *Te Ara Tika: Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members*. Auckland: Health Research Council on behalf of the Pūtaiora Writing Group.

- Stats NZ (2020). Ngā Tikanga Paihere: a framework guiding ethical and culturally appropriate data use. Retrieved from www.data.govt.nz

The level of consultation will vary depending on whether there is no Māori involvement, if Māori participants are involved in non-Māori initiated research or whether it is Kaupapa Māori research. Researchers should determine the level of consultation with Māori appropriate to their project in line with the criteria specified by Table 1 below prior to submitting their application. These consultation guidelines were adapted from Simmonds (2015).

Applications will be assessed by AHREC to ensure the appropriate level of consultation has been explained by researchers. AHREC membership will include at least two Māori representatives, at least one of whom will be Ngāti Whātua.

Table 1 Types of research and levels of Māori involvement in a research project

	Non-Māori initiated research			Māori-centred research	Kaupapa Māori Research
Level of Māori involvement: **• as participants**	(1) no expected involvement	(2) possible involvement	(3) probable involvement	(4) definite involvement	(5) significant involvement, possibly exclusive
• on research team	No expected involvement	Possible involvement as junior researcher positions	Probable involvement as researchers and/or advisors	Definite involvement as researchers, senior researchers and advisors	Significant involvement, possibly exclusively Māori researchers and advisors
Type of consultation recommended	Institutional Māori review	Institutional Māori review	Institutional Māori review and possible engagement with Institutional Māori reviewers (face to face meeting)	Full and on-going engagement and collaboration with appropriate Māori community group(s)	Full and on-going engagement and collaboration with appropriate Māori community group(s), Māori are kaitiaki of project
Description of research	• Māori have not been included in the design of the project • There are still possibilities to contribute to Māori development	• The research topic is not designed to be analysed by ethnicity • Not a topic of particular relevance for Māori. • There are still possibilities to contribute to Māori development	• the contribution of the research to Māori health and equity is detailed • an area of health that Māori have high representation • a topic of particular relevance for Māori (nationally or locally)	• Clear aims for the contribution of the research to Māori Health and equity • Māori knowledge produced, but non-Māori methods may be used	• Clear aims for the contribution of the research to Māori health and equity • Māori analysis is undertaken and Māori knowledge produced
Control	Non-Māori	Non-Māori	Non-Māori	Non-Māori and/or Māori	Māori
Analysis	Non-Māori	Non-Māori	• Non-Māori and/or Māori • Ethnicity analysis • Equity analysis	• Non-Māori and/or Māori • Ethnicity analysis	Kaupapa Māori
Tools	Non-Māori	Non-Māori	• Non-Māori • Possibly some Kaupapa Māori Research methods	• Non-Māori • or Kaupapa Māori Research methods and Kaupapa Māori Epidemiology	Kaupapa Māori Research methods and Kaupapa Māori Epidemiology

6.4 Recruitment documents to be included with the application form

Documents for participants may include the following:

- participant information sheet(s)
- consent and assent form(s)
- advertisement(s)
- email invitation(s)
- questionnaire(s)
- interview / focus group questions
- 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 AHREC in final format on institutional letterhead. All documents that will be given to participants should clearly state that the research study was approved by AHREC, as follows:

Approved by the Auckland Health Research Ethics Committee for three years on [insert approval date] Reference number …….

6.4.1 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 participants have to do and the purpose of what has to be done
- Potential benefits and risks and how these 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 while participating or withdrawal of their data after participation, the management and protection of participants 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 and any possible future use of data and samples
- The PIS must 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.

A PIS template is available from the Ethics RM application submission system. Within the black ribbon on the top of the screen in Ethics RM, click Help, then select Templates. If the more general PIS available from the HDEC website is used, the following information specific to AHREC needs to be added to the PIS:

a. Contact details for Māori cultural support or other cultural support as appropriate.

For example, for Auckland and Waitematā DHB studies, this should be: If you require Māori cultural support, talk to your whānau in the first instance, or contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324.

b. AHREC Chair contact details:

AHREC Chair contact details: For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

c. AHREC approval wording (at the end of the document):

Approved by the Auckland Health Research Ethics Committee for three years on [insert approval date]. Reference number XXXXXX.

6.4.2 Consent Form (CF)

Typically, AHREC requires consent to be recorded in written format on Consent Forms (CFs). The CF must similarly be written on institutional letterhead that includes the full postal address together with telephone and email contact details.

If alternative methods of consent, such as verbal consent or recording consent electronically, are sought, this must be clearly explained and justified in the application. In such instances, the research process must include a procedure for documenting and/or recording that consent has been obtained, and include information about how these consent documentations will be stored.

Where questionnaires are anonymous, AHREC accepts a completed written and submitted questionnaire as evidence of consent, provided that appropriate information has been provided about the research. This advice should typically be in the form of a PIS that can be printed or downloaded for future reference.

A CF template is available from the Ethics RM application submission system. Within the black ribbon on the top of the screen in Ethics RM, click Help, then select Templates. If the more general Consent or Assent Form templates available from the HDEC website is used, the AHREC approval wording needs to be added to the end of the CF:

Approved by the Auckland Health Research Ethics Committee for three years on [insert approval date]. Reference number XXXXXX.

6.4.3 Advertising material and email invitations

Any advertisements for recruiting participants, including email invitations, other electronic invitations or postings on social media, must be submitted to AHREC 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 receive further information about the study.

The advertisement should include the source of research funding and contact details for the researcher(s), but does not need to have a 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', 'Waitematā DHB', 'CM Health' or 'the Auckland DHB', unless the research is being conducted on behalf of the institution named.

All advertising material, including flyers, advertisements, invitation emails, and all other electronic invitations must include the AHREC approval wording:

Approved by the Auckland Health Research Ethics Committee for three years on [insert approval date]. Reference number XXXXXX.

6.4.4 Questionnaires

A questionnaire is a specifically designed set of questions that a participant completes independently and returns to the researcher. Questionnaires should be submitted to AHREC 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 AHREC as an amendment request before using it.

Forms provided to participants for the completion of demographic information are considered to be questionnaires.

If an invitation email is used to recruit participants, the email should preferably contain a link to the PIS rather than a link directly to the questionnaire.

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

If the email contains a link directly to the online questionnaire, the online questionnaire must include a complete PIS with all the relevant information about the study, including any funding information. For these online questionnaires, researchers must ensure that participants are able to print and/or save the PIS section of the questionnaire for future reference.

These PISs must contain similar information to PISs that are provided directly, including contact details for the researchers and the AHREC Chair, as well as the AHREC approval wording. For University studies, the contact information for the relevant Academic Head is also required.

If the questionnaire is anonymous, it should be clearly explained within the PIS that submission constitutes consent to participating in the research.

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 participants will be invited to leave their contact details for a prize draw or to receive compensation, to receive a summary of results or to indicate willingness to be invited to participate in some further aspect of the research, researchers must use an online tool that allows collecting this information separately from the questionnaire content.

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

6.4.5 Interview and focus group 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.

6.4.6 Confidentiality agreement(s)

Any researcher who will be accessing patient records must have signed an appropriate institutional confidentiality document, unless they have the appropriate confidentiality clause in their employment agreement.

Individuals not part of the research team and who will conduct specific research tasks, such as transcribing or editing data for the project, must sign a confidentiality agreement.

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

- translating
- transcribing
- interpreting
- recording
- recording or editing sound or image data
- entering data
- destruction of data

The PI must provide AHREC with a copy of the proposed confidentiality agreement(s) specific to the research project. 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.

A Confidentiality Agreement template is available from the Ethics RM application submission system. Within the black ribbon on the top of the screen in Ethics RM, click Help, then select Templates.

6.4.7 Translated 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.

AHREC approval is based on the documents submitted in English; it is the researcher's responsibility to ensure that translations are accurate. AHREC recommends using the services of a professional translation service. AHREC also recommends that translations be completed after AHREC approval, as amendments to the documents may be required during the review process.

Copies of the translated document must be sent to the Ethics Administrators using the Correspondence facility in Ethics RM after ethics approval has been provided. Documents that will be provided to participants in te reo Māori will need to be first provided to AHREC in English.

7. ETHICS REVIEW PROCESS

There are two pathways for review of AHREC ethics applications: expedited review and full review.

7.1 Expedited review

A research project in which there is deemed to be a low risk of physical harm, psychological harm, exploitation or other potential adverse effect may be reviewed via an expedited review process. Applicants can determine if an application is eligible for review in the expedited pathway by completing the questions on the checklist at the end of the Word application form or given in Appendix 1 of this Manual. The decision as to whether an application is eligible for expedited review lies with the Committee.

Examples of studies which normally receive expedited review are those that:

- require access to health information only, where the person accessing the data is involved in the clinical service provision in that clinical area
- involve administration of low risk procedures (e.g., surveys, questionnaires, etc.) not as part of clinical care and not involving vulnerable participants
- involve observation only of clinical processes by members of the clinical team.

Expedited applications will be reviewed by two Committee members, including the Chair. Applicants should be aware that during the expedited ethical review, reviewers may recommend that the application is referred to the Committee for full review.

7.2 Full review

Any research not qualifying for an expedited review will be placed on the next AHREC meeting agenda. Each application will be reviewed independently by two Committee members prior to the meeting, and an outcome determined after Committee discussion of the application. Researchers are not expected to attend meetings, but may request to be present and will be given a specific time during the meeting when their application will be reviewed. After each AHREC meeting the Ethics Administrators will inform PIs of the Committee decision within five working days of the Committee meeting. The turnaround time for applications is usually about four weeks from the time of submission of the application.

In exceptional circumstances, applications may be reviewed between meetings. Requests for such a review must be made in writing by the PI to the AHREC Chair (via the Ethics Administrators, using ahrec@auckland.ac.nz). An application accepted by the Chair for out-of-meeting-cycle review will be reviewed by four Committee members, including the Chair. Decisions will then be reported for noting at the following Committee meeting.

7.3 Committee decisions

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

7.3.1 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.

7.3.2 Approved with comment

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

7.3.3 Conditional approval

When an application is conditionally approved, AHREC requires further amendments to the application or further documentation provided before the study can commence. The researcher must provide the requested revisions / modifications / clarifications / documents and highlight any made in the text of the resubmitted documents by using tracked changes. Changes to the application form will show up as tracked when re-submitted.

Each concern mentioned in the letter of outcome should be addressed in a covering memo with an explanation of how these concerns were addressed. These amendments will be signed off by the Ethics Advisers, or if required, by Committee member(s) or the Chair, and does not require further Committee review (unless required by the Chair). The researcher must receive an approval letter from the Ethics Advisers before commencing their research.

A conditionally approved application does not have ethics approval until the PI has submitted the amendments and received the approval letter.

7.3.4 Pending resubmission

In this instance, AHREC has not granted approval. This is usually because there are substantive ethical issues that still need to be addressed or are unresolved, or insufficient information provided to allow the Committee to make a decision. Applicants must make the changes required by the Committee and resubmit the application for review at a next Committee meeting. The Committee will review the application to determine if all outstanding ethical issues have been resolved, and may require further changes.

Expedited applications do not receive a pending outcome, but if the reviewers consider that a study presents more than minimal risk, the application will be referred for review by the full Committee. Changes made to the application documentation should be listed in a covering memo and changes to the documents clearly indicated by tracked changes.

Expedited applications where the study does not present more than minimal risk but further information or changes are required before approval can be given may be returned to applicants to make further changes or provide additional information.

7.3.5 Empowered

In some cases, one or more Committee members can be empowered by the Committee to work with applicants to resolve outstanding issues until the application can be approved. The researcher must contact the nominated Committee member(s) and arrange a meeting/exchange of correspondence with them in order to clarify the Committee's concerns. Once the Committee member(s) are satisfied that all the required changes have been made, the application will be approved and the proposed research can commence. The approval will be noted on the Agenda of the next AHREC meeting.

7.3.6 Not required

Ethics approval is not required.

7.3.7 Declined

The application cannot be approved and the project cannot proceed. It is rare that an application is declined, and the Committee aims to facilitate researchers in bringing their research proposals up to the standard required for approval or to resolve ethical issues.

7.4 Period of ethics approval

Normally AHREC will approve an application for three years and approval for a further three years can be granted upon request.

In exceptional cases, applicants can request a longer initial approval period in their application with an explanation why a longer approval period is required. AHREC is unlikely to approve an initial period of longer than six years unless there are exceptional reasons for a longer approval.

A researcher who wishes to request extension of the approval should submit an amendment request at least one month before the expiry of that approval. A request must be sent through the Correspondence facility in Ethics RM for the application form to be unlocked. A new copy of the application and documents will then be available to document the extension request.

If ethics approval is still required for a project after a six-year period, a new application must be submitted.

7.5 AHREC meetings and deadlines

AHREC meets monthly from February to December. The agenda closes two and a half weeks prior to a meeting to allow for compliance checking of the initial application, for initial revisions to be made as a result of this check, 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.

The AHREC meeting dates and the deadlines for submitting applications for review are available online at: https://www.auckland.ac.nz/en/research/about-our-research/human-ethics/ahrec.html

8. CONDUCTING THE RESEARCH

8.1 Locality authorisation

Locality review is the process by which a locality itself assesses its suitability for the safe and effective conduct of a study, and the resources required from that site to complete the study. If a locality is satisfied that this is the case, it authorises the study.

A locality is an organisation responsible for a hospital, health centre, surgery or other establishment or facility in New Zealand at or from which the procedures outlined in the protocol of a study are to be conducted. Localities for studies within the New Zealand public health system will usually be DHBs. Examples of localities outside the public health system may include academic institutions (such as universities), private companies (such as clinical trial units), private hospitals or clinical practices.

Researchers need to pursue locality authorisation from each locality, such as a DHB, that will be involved in their study. For student research, it is expected that the PI/Supervisor will assist the student in this process and in seeking any necessary clinical support.

For those multi-site applications, it remains the responsibility of the applicant(s) to obtain locality governance authorisation from the DHB(s) or other health providers. Researchers are advised to contact the Research Office(s) of the DHB(s) where the research will take place to determine the specific locality approval requirements of the relevant DHB(s). Contact details for DHBs are available from the Ministry of Health website:

https://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards/district-health-board-websites

8.1.1 Locality authorisation from Auckland DHB, including Starship Child Health

For research projects recruiting staff or patients from the Auckland DHB, locality authorisation will be provided by the Auckland DHB Research Review Committee. Applicants must provide the AHREC application plus all supporting documents to the Auckland DHB Research Office, ideally at the same time as submission to AHREC is made, so that any locality specific issues may be dealt with in parallel. Locality authorisation will be granted once all issues have been resolved and AHREC approval awarded.

For research projects recruiting patients, staff or accessing patient data at Starship Child Health, and where the application is low risk or expedited review, locality authorisation will be provided by the Starship Research & Innovation Office (SRIO). The study documents and AHREC application may be submitted to SRIO ahead of receipt of the authorisation letter for governance review StarshipResearch@adhb.govt.nz. The locality authorisation letter will be issued on receipt of the AHRC approval letter.

Researchers working with Auckland DHB must contact the appropriate Departments early in the study development process to discuss the study requirements and identify the appropriate departmental head so that the departmental sign-off process can be facilitated. Departmental approval must be finally requested via the online Ethics RM system.

8.1.2 Locality authorisation from CM Health

For studies involving staff, patients or data from CM Health, researchers must register their study directly with CM Health for locality authorisation. Auckland DHB and University researchers will need to engage with a CM Health-based associate to represent them and access the online CM Health Research Registry on their behalf. The study will be processed through the CM Health locality authorisation process in parallel with the AHREC ethics approval process. Queries can be directed to: researchoffice@middlemore.co.nz

8.1.3 Locality authorisation from University of Auckland

Locality authorisation is obtained by requesting Academic Head sign off when the application is ready for submission.

8.1.4 Locality authorisation from Waitematā DHB

For studies involving staff, patients, facilities and/or data from Waitematā DHB, researchers must register their study directly with the Waitematā DHB Research and Knowledge Centre by completing the locality application form and submitting it together with any supporting documents to research@waitematadhb.govt.nz

Link to the process for Research Locality | Waitematā District Health Board (WDHB) (waitematadhb.govt.nz) and to access the Locality Application Form - research and audit activity at WDHB (waitematadhb.govt.nz)

8.2 Changes to the approved application

If any changes need to be made to the approved application during the course of the research, permission needs to be sought from AHREC. (Please note this requirement differs from the approval process for an HDEC-approved ethics applications where minor amendments do not require prior approval).

An amendment request must be submitted in the Ethics RM system by modifying the initially approved ethics application. The change(s) must be added to the initially approved application form and any relevant amended documents, such as the PIS and CF provided. To start the amendment process, a request is sent through the Correspondence facility in Ethics RM for the application form to be unlocked. A new copy of the application and documents will then be available to document the changes requested. When a previously attached document requires amending, the initial copy provided needs to be deleted and a new version attached (The initial copy will still be available in Ethics RM). All changes to documents need to be highlighted by using tracked changes.

Minor changes (e.g., that do not increase the demands on participants or affect risk) are dealt with under delegation by the Chair. If the change(s) is substantial, the requests for

change will be put on the next agenda for the Committee to consider and approve. The Committee may also determine that a new application must be submitted.

Failure to notify significant changes to a research project risks jeopardising that project's approval. Unapproved changes constitute unapproved research.

8.3 Annual Progress Reports

Normally AHREC does not require researchers to submit annual reports. In some cases, such as if the Committee considers that the study meets the NEAC criteria for an intervention study (see Section 10 of National Ethical Standards), the Committee may request the submission of annual progress reports as a condition of approval.

8.4 Incidental findings and illegal activities

8.4.1 Incidental findings

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. Researchers should consider this in their research design and, where appropriate, discuss strategies for dealing with this situation in their application to AHREC.

8.4.2 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. The foremost consideration of researchers is the principle of avoiding harm to participants and third parties and to act within the law at all times.

Private citizens have no legal obligation to report illegal activities to the relevant authorities. While the legal obligations of a researcher are the same as private citizens, academic staff and students have additional obligations under the academic freedom provisions of the *Education and Training Act 2020* to act in a manner consistent with "*the highest ethical standards"* - Section 267(2)(a).

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 illicit crops or breaches of health and safety legislation. It is up to the property owner to take any subsequent action required.

The PIS and CF for studies involving illegal activities must include and acknowledge that if the researcher uncovers any illegal activity that poses a serious threat to the health and safety of an individual or the public, the researcher is required to 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 confidentiality, but that such communications are not protected in the same way that

those with a lawyer or priest acting in their professional capacity are. While confidentiality 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.

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. 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 (dia.govt.nz) 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.

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 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.

8.5 Study completion

8.5.1 Dissemination of results

Whenever possible, the findings should be conveyed in a comprehensible form to those who participated in the research. The researcher must complete dissemination of the results in the way they have undertaken to do during study enrolment (if applicable).

8.5.2 Final report

Once the study has concluded, the PI must submit a final report to AHREC. The report must be submitted as an amendment request in Ethics RM, indicating in the summary section that the study has concluded and with a final report attached. The report form is available on the AHREC webpage at https://www.auckland.ac.nz/en/research/about-our-research/human-ethics/ahrec.html

The report will be reviewed by a Committee member and on the basis of this review, the Chair will accept the report and notify the Committee or refer the report to the Committee for discussion at a meeting. The Chair or Committee may request a revised report should this be considered necessary.

9. ETHICAL CONSIDERATIONS IN RESEARCH DESIGN

9.1 Recruitment of research participants

In the application, the researcher must describe in detail how they 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 electoral role, 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 2020, it is not acceptable for them to recruit participants on the basis of this access. In such a case, the researcher should seek a form of indirect contact, e.g., 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 they are aged 16 years or above.

9.2 Clinicians recruiting patients within the metro Auckland DHBs

The recruitment of DHB patients by researchers working within those institutions is a long-standing practice and an integral part of clinical research. In determining who should approach potential participants, researchers may need to balance considerations of who best understands the project with the risks of explicit or implicit pressure to participate which might be felt by someone approached by a researcher involved in their clinical care. The latter may be mitigated by providing information on the basis of which those interested in possible participation may contact researchers. The following bullet-points describe some of the scenarios that may arise, and the currently acceptable practices.

- *Ascertainment of patient potential eligibility from health records*. Ideally, the health records accessed for ascertainment of eligibility should be provided in de-identified format to the researchers, or a member of the clinical team caring for those patients should identify potentially eligible patients for the research team. If neither of these options is feasible, the researchers must take care to explain in their application how they will minimise risks of loss of patient privacy or confidentiality.

- *Contact of potential participants by telephone, letter or email*. Ideally a member of the clinical service team caring for the patients, rather than the researchers, would make the contact on behalf of the researchers. If the researchers are part of the clinical service team the contact should be made by a team member that does not provide direct

care to the patient. Initial contact by an administrative staff member might be considered, and a letter or email may be preferable to phone contact. The reasons why the patient is being introduced to the study should be made in quite general terms and avoid reference to sensitive health information that might inadvertently be made known to third parties.

- *Contact via colleagues.* Researchers may use clinician colleagues to notify their potentially eligible patients of a study for which they might qualify. Interested patients may be given researchers' contact details or patients may give permission for a clinician to provide their contact details to the study team.

- *Direct approach to patients.* Researchers may contact potential participants directly at DHB clinics or wards with the permission of the individual or team caring for that patient. If a clinician is caring for a patient who might be eligible for a study that clinician is involved in, then it is appropriate for the clinician to mention the possibility of the study to the patient, along with the other management options they have. If the patient expresses interest, then other members of the research team should take responsibility for obtaining fully informed consent.

- *Recruitment of colleagues.* Researchers may directly contact their own colleagues to request their participation in research providing there is not a power imbalance between researcher and participant. For instance, researchers should not recruit staff reporting to them. If there may be a power imbalance between researchers and potential participants, a research associate should make the initial approach to staff to notify them of the study and obtain informed consent.

9.3 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, AHREC requires that indirect recruitment is 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. The Privacy Act 2020 prevents the use of contact details collected for a purpose by a third party for other than the stated purpose. However, AHREC 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.

AHREC 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.

9.4 Consent

9.4.1 General ethical issues about obtaining consent

The principle of respect for persons requires that research participants' capacity for self-determination is treated with respect.

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 and proposed participant group. Researchers should explain how they have designed the consent process for a particular study, and why it is appropriate.

Consent to participate in a research study must be voluntary, and participants have a right to withdraw from research participation at any time. 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.

Researchers are recommended to consider Section 6 Ethical management of vulnerability, and Section 7 Informed Consent, of the National Ethical Standards for more detailed discussion of the issues concerning informed consent.

9.4.2 Participants requiring special consideration with respect to consent

(i) Children

While recognising that some persons under 16 years old may have the capacity to give informed consent to certain kinds of research, AHREC normally requires that parental consent be obtained for the participation of children under 16 years old in research. In addition, the child participant should be provided with age-appropriate information on the basis of which they can assent (agree) or not to their own participation. Even where parental consent has been obtained, the assent of the child is usually required for participation in research. An age-appropriate assent form can be used for recording child consent, or it may be combined with parental consent.

(ii) People requiring assistance or support to enable them to give informed consent

An individual's capacity or ability to make informed decisions may be affected by context and the complexity of the decision, as well as by physical and mental states which lead to diminished capacity. In many situations people with diminished capacity may be able to make an informed decision with appropriate support.

Where potential participants have a disability of some kind which makes it difficult for them to comprehend the information required for informed consent, researchers should consider appropriate alternative modes of providing that information and the use of assistance from support persons who may be able to ensure that the required information is available to the person as a basis for making an informed decision.

Where potential participants are able to comprehend information and have the capacity to decide whether or not they wish to participate in the research, but are not able to record their decision, this may be recorded by someone else on their behalf, but the person recording this must be clearly identified and recorded.

Clause (2) Right 7 of the Code of Health and Disability Services Consumers' Rights 1996 (Right to make an informed choice and give informed consent) states that 'Every consumer of health and disability services must be presumed competent unless there are reasonable grounds for believing that they are not competent'. Where researchers consider that some potential participants may not have the capacity to give consent, or where they wish to exclude participants with diminished capacity from participation, the research protocol should include a method for determining a person's capacity to give consent.

(iii) People not able to give consent on their own behalf.

Ethical justification for involvement in research of someone unable to give consent is very difficult. It may be possible, in accordance with the Code of Health and Disability Services Consumers' Rights, where participation is clearly in the best interests of that individual and where 'reasonable steps have been taken to ascertain the views' of the person. However it is rarely the case that a research study will clearly benefit an individual participant.

In some situations, another person may be able to give substituted consent on behalf of someone who is not able to give their own consent. However in general, a person cannot give consent for another adult unless authorised by a Power of Attorney. These matters are legally complex, particularly in the area of participation in research ("medical experiments"). Researchers planning studies which may involve such participants are advised to seek expert advice about the possibility of using substituted consent.

9.4.3 "Opt-out" or passive consent

"Opt out" (or passive) consent is taken to mean situations where people will be considered to be consenting participants in some project or activity unless they state explicitly that they do not wish to be participants. It is not clear that such situations meet either ethical or legal requirements in New Zealand for informed consent to participate in research. Researchers wishing to use such "consent" will need to justify its use to AHREC including: reasons why this is considered ethically preferable to standard consent requirements in the particular context; how the risk of including non-willing participants will be mitigated; how it will be ensured that all participants have sufficient information for an informed choice to participate or not and that all participants have easy access to and knowledge of how to inform the researchers that they do not wish to be included.

9.4.4 Waiver of consent (secondary re-use of identifiable health data)

Gaining informed consent to use previously collected identifiable data (including data-linking) should always be the default starting point. Where researchers propose to use identifiable data without specific consent for a research study project (e.g., where data was collected for care, or the proposed data use is not consistent with the scope of the original research consent), they must (in addition to satisfying national data standards and local data governance requirements), justify to AHREC that the nature, degree and

likelihood of possible benefits (including to participant and/or individuals and the value of the research to the public) outweigh the nature, degree and likelihood of possible harms (including to any participant and/or individual, other individuals, whānau, hapū, iwi, Māori communities and any other groups or communities).

In determining whether to grant a waiver of consent, AHREC may also consider whether there are scientific, practical, or ethical reasons why consent cannot be obtained.

When considering a waiver, researchers should identify if there is any known or likely reason to expect that the participant and/or individual(s) would not have consented if they had been asked.

9.4.5 Consent for future use of data

Researchers sometimes have in mind possible future projects for which data they are planning to collect prospectively might be useful, and sometimes they wish to request consent for future use of this data without any specific future project in mind. Where consent is being sought for future use of data, what this use might be should be made as clear as possible in the information for prospective participants, including a clear statement as to whether the data for such use would be de-identified or not. Consent for this should be given explicitly and separately on the consent form; it should not be subsumed under the general consent to participate.

Researchers need to identify and inform the Committee of procedures to ensure that any data that does not have consent for reuse is not included with data that does have this consent in future projects. Proposals to obtain consent for future use of data without some indication of the kind of use or research area, or clear information about conditions of access to the data would be approved only in exceptional circumstances.

9.4.6 Documenting consent

Typically, AHREC requires consent to be recorded on a consent form. Although written consent remains preferable, consent forms may be electronic. The research process must include a procedure for storage of both these types of consent forms.

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, AHREC accepts a submitted written questionnaire as evidence of consent, provided that appropriate information about this form of consenting has been provided to participants in the Participant Information Sheet outlining the research.

9.4.7 Storage of Consent Forms

Consent Forms should be retained in secure storage by the PI (in the case of students, through the primary supervisor) for a period of six years, or longer if research data is to be retained for a longer period in other than in de-identified format (see Section 9.17.1). To ensure confidentiality, such storage should be separate from research data.

9.5 Focus groups or interviews with more than one person

Focus groups and interviews with two or more participants present specific ethical considerations (these must be made clear to participants in the Participant Information Sheet and consented to in the consent form):

- It is not possible to guarantee confidentiality to participants in a focus group.
- Participants should be asked in the PIS not to discuss what was said in the focus groups with others, and the focus group facilitator should actively encourage participants to maintain the confidentiality of information shared under such conditions.
- Withdrawing information contributed by a participant is generally not possible, because it 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 the focus group discussion will be recorded and that they cannot ask for the recorder to be turned off. They can however, choose to not answer any question (that is, they can stay silent) or they can leave the room. On the consent form, a bullet point must be included where participants can acknowledge their understanding that the focus group will be recorded.
- The presence of a support person who is not contributing data to the interview does not constitute an interview with more than one person.

9.6 Institutional approval and documentation required

When conducting research within an institution or organisation (e.g., a school, medical practice or business), researchers should determine what forms of institutional authority to enable the research to take place are needed prior to recruitment of participants. Typically, executive officers or managers must consent for the research to proceed in their organisation, but only the participants themselves can give consent for their own participation. Section 8.1 addresses the need for location approval from institutions such as DHBs.

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.

In the application, indicate the proposed process for gaining permission to access other institutions.

9.7 The Privacy Act 2020

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.

The Privacy Act 2020 regulates the collection, holding, retention, use and disclosure of information about identifiable individuals. Most, and in some cases all, of the Privacy Principles in Part 6 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.

For further information about the Privacy Act 2020 and how it relates to research, please see: https://www.legislation.govt.nz/act/public/2020/0031/latest/LMS23223.html

In particular, Principle 10 states:

> *"An agency that holds personal information that was obtained in connection with one purpose may not use the information for any other purpose unless the agency believes, on reasonable grounds,-*
> *that the information—*
> *(i) is used in a form in which the individual concerned is not identified; or*
> *(ii) is to be used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the individual concerned"*

Principle 11 makes similar provision regarding the *disclosure* of such information.

Link to Privacy Principles (Section 22 of the Act):
https://www.legislation.govt.nz/act/public/2020/0031/latest/LMS23342.html

Health researchers also need to be aware of and comply with the Health Information Privacy Code 2020 as it may apply to their research.

9.8 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 AHREC committee members to consider how the privacy of research participants is protected and the confidentiality of data maintained[3].

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.

9.8.1 Anonymity

In the context of research, 'anonymity' means more than the removal of a participant's name.

[3] Please see the information in the Glossary with definitions regarding identifiable data.

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

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

A common practice in research projects is to assign codes to participants. However, a research study is not anonymous if the researcher assigns codes to participants. In these circumstances, 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.

If a list connecting research codes to participants' identity is kept, then the data is re-identifiable. To preserve anonymity, the list containing participant identities should be stored by the third party. In any event, researchers are required to keep such lists securely and separate from research data.

In describing how data will be stored, it is preferable to use terms such as 'de-identified' or 're-identifiable' for greater clarity and accuracy.

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.

If potential participants cannot be guaranteed anonymity, they must be informed about 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 nurses in a Department, it may be possible to identify respondents in the research report if sufficient details are given of age, gender, or ethnicity, even if the nurses 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 hard copy questionnaire is used, the preservation of anonymity may make it appropriate that those who have declined to participate return a blank questionnaire.

9.8.2 Confidentiality

Confidentiality in research means that information is private to the researcher and participant; that is, the (identifiable) 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.

To re-assure participants that their identities will be kept confidential, appropriate phrasing for the PIS might be:

> "If the information you provide is reported/published, this will be done in such a way that its source cannot be identified";
>
> or
>
> "When the data will be published, your identity will not be disclosed."

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

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 could therefore be included in a stated guarantee of confidentiality in studies where this may be relevant, 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, 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.

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. Also, the PIS should state who will see the data and why, and how the confidentiality of the participant will be maintained. Any confidentiality agreement template for transcribers or translators must be submitted with the application to AHREC.

Where there is a possibility that the researcher may be given information that reveals a reasonable likelihood that the life or health of any person may be at 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 explicitly in the consent form.

9.9 Conflicts of interest

The researcher must address potential conflicts of interest, for example, a conflict of interest between their activities as a researcher and their professional and/or personal interests. The researcher must declare their conflict of interest in the ethics application form and PIS, and also 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
- their patients
- their colleagues
- those who are (or may perceive themselves to be) dependent on the researcher
- family members (not recommended)
- friends (not recommended)

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 the child is under the age of 16, other than in exceptional circumstances which must be justified to AHREC.

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 declared in the PIS or PIS/questionnaire and research reports.

9.10 Minimising harm

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 any 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 AHREC the experience available in the research team to deal with such

potential harm. Generally, a list of relevant cost-free resources available to participants if needed after the study, should be included in the PIS.

In studies where researchers are visiting participants at their homes, a basic safety plan outlining how others will be made aware of the researcher's movements must be included in the application form.

9.10.1 Compensation for participants as a result of any harm

Information must be provided to participants about compensation available to them if they are harmed as a result of participating in a study.

Where ethics approval is being sought for a clinical study that 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 any intervention or device in respect of which the research is carried out.

a. For research studies not conducted principally for the benefit of the manufacturer or distributor of the intervention in respect of which the research is carried out:

In the event of a physical injury resulting from participation in a research study, participants may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and all cases are assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001.

Participants should also be advised to check whether participation in a particular study would affect any indemnity cover they have or are considering, such as medical insurance, life insurance and superannuation.

The following wording could be included in the PIS under the heading 'Compensation':

> *If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.*
>
> *If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.*

b. If the research study is a clinical trial conducted principally for the benefit of the manufacturer or distributor of the intervention in respect of which the trial is carried out:

New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of the injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

Evidence of the insurance cover must be provided to AHREC in the form of the insurer certificate, and the following information should be included in the PIS under the heading 'Compensation':

"As this research study is for the principal benefit of its commercial sponsor [insert name], if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, [insert name] has satisfied the AHREC that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study. "

9.11 Deception

Some research studies 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.

It is never appropriate to deceive participants about the procedures they will have to follow, or the length of time the procedures will take.

AHREC will comprehensively review 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, and also provide documentation that will be provided to participants as part of debriefing.

AHREC 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 in which the deception is explained as soon as possible after the data-gathering
- Participants have the right to withdraw any data obtained from them by the deception

9.12 Audio, video or other forms of electronic recording

9.12.1 Consent to being recorded

Some research studies requires electronic recording of participants, and the PIS should explain whether the recording is essential to the study, or optional.

If the recording is essential to the research, participants cannot ask for the recording to be stopped. Therefore, the CF should contain an explicit statement, such as *"I understand that I will be recorded"*.

If the recording is optional, the participant may choose to have the recorder turned off at any time, and the CF could offer an option such as *"I agree/do not agree to be recorded"*. The PIS should also state that *"Even if you agree to being recorded, you may*

choose to have the recorder turned off at any time, without needing to provide a reason".

9.12.2 Transcription or translation

The PIS should explain who will transcribe and/or translate recordings and how confidentiality of information will be preserved. If someone other than a member of the research team is going to transcribe/translate a recording, the transcriber and/or translator must sign a confidentiality agreement.

9.12.3 Review and editing of recordings and transcripts

The Committee recommends that participants are offered the opportunity to review and edit transcripts of their recordings. Editing of transcripts is not usually appropriate for focus groups (see below).

Only people who have been recorded should be given the opportunity to review their own recordings or transcripts. CEOs or managers, for example, should not be given access to recordings made of their employees or staff or to transcripts of the recordings. If such access is proposed, this must be justified to the Committee and 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.

Focus group recordings: Participants can withdraw during focus groups, but recording devices cannot be turned off during the discussion or information cannot be subsequently withdrawn. The following wording may be used on the PIS:

> "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 discussion, 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."

9.12.4 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.

9.13 Koha, gifts, compensation and reimbursement of expenses

Koha may be provided to participants in culturally acceptable forms as part of establishing or recognising a relationship of reciprocity between researchers and participants.

Participants can be reimbursed for costs they may have incurred in participation, such as bus or taxi fares. Gifts, including small sums of money (usually as vouchers) or inclusion in a prize draw, may be offered in recognition of the contributions of participants to a

research project. 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. When there is evidence for actual costs, reimbursement should be processed through normal institutional reimbursement procedures.

It is 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 compensation 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
- The reason for, and the level of, reimbursement, compensation or gifts should be clearly explained in the PIS
- Any vouchers or prizes should be of a kind which could be expected to be useful for any participant (e.g., not all participants may use petrol or smart devices)

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. 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, 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."*

Researchers should make clear in information for participants if withdrawing from the research will have an impact on any recompense.

9.14 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.

For guidance specifically on research with Pacific Peoples, please refer to Section 4 of the National Ethical Standards:

9.15 Use of human remains, tissue and bodily fluids in research

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

Applications for research involving human tissue can only be reviewed by AHREC when the sample(s) are given with informed consent and when the tissue will not be made available to researchers in a form that could reasonably be expected to identify the individual(s) concerned (HDEC Standard Operating Procedures for Health and Disability Ethics Committees, 2019).

For studies that meet the requirements for AHREC review, researchers are encouraged to discuss collection of tissue samples with the Auckland Regional Biobank | Te Ira Kāwai.

The HDEC SOPs consider a tissue bank to be a collection of human tissue samples stored for potential use in research beyond the life of a specific research project, and the establishment and management of a tissue bank as not research. Applications for the establishment of a human tissue bank must be reviewed by an HDEC.

Research involving human remains, tissue 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. In general terms, samples collected for one purpose must not be used for another without the consent of the donor.

In all cases of research 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 AHREC.

Further information is available in the Health Information Privacy Code 2020, see especially Rule 10 "Limits on the use of Health Information":

9.16 Withdrawal

9.16.1 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 in the consent process.

9.16.2 Withdrawal of data from the 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 explained in the PIS and specifically consented to by the participant.

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

Where information cannot be traced to an individual (e.g., when provided anonymously) it cannot be withdrawn and this should be clearly stated in the information for participants.

9.17 Secondary data analysis or Re-use of existing data

Some research studies make use of existing data collected originally for a purpose other than the proposed research study, e.g., census data, data from earlier research, administrative data, or clinical records, to explore questions formulated after the collection of the data. Data use may also occur through databanks (Data Registries). Any re-use of data can raise ethical concerns, primarily with respect to issues of consent, privacy and potential for harm.

As well as respect for the persons who have provided data, researchers wishing to make use of existing data sets should be conscious of cultural significance of data and of Māori Data Sovereignty principles (see Section 12, National Ethical Standards).

Research projects using data which are publicly available do not require approval by AHREC. Permission of the custodian of data (e.g., a DHB for clinical records) will be required for access to data or data sets which are not publicly available, and custodians of data may require ethical approval of planned research projects prior to providing access to data. Access to existing health data for research purposes is governed by principles articulated in the Health Information Privacy Code 2020, particularly Principles 10, 11, and 12. Researchers considering giving access to their own data sets which include health data should also be aware of these requirements.

In general, access to de-identified data raises fewer ethical concerns than access to identified data. In storing data, or proposing to access existing data, researchers should be aware of the increasing possibilities of re-identification of de-identified data and pay careful attention to mitigation of these. Identifiability of data is well-discussed in Section 12, Health Data, of the National Ethical Standards.

9.17.1 Re-use of identifiable data

Research projects which involve researchers accessing identifiable data require ethical approval. 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. AHREC pays particular attention to the question of whether the persons who may be identified from the data gave or will give consent to the proposed re-use. Where researchers consider consent was given previously, they should provide evidence of this to AHREC. Where researchers request a waiver of such consent, they will need to provide reasons which justify not obtaining consent and a case for significant general benefit from the proposed research. Researchers must also be able to give reasonable assurance that publishing the results of their research will not enable identification of those whom the data concerns.

Identifiable data may be sent overseas for the purposes of research if the person from whom the data was collected has consented to it or if a waiver of consent is granted.

9.17.2 De-identified data

The major ethical issues with respect to re-use of de-identified data are in the areas of possible re-identification and the possibility of harms (to individuals or groups) from the proposed access or research.

If personal information collected for a particular research project or other purpose will be provided to researchers for another project in an already de-identified form, no further ethical approval is required. Researchers must treat the data with care for its security and to mitigate any possibilities of re-identification. Ethical approval may be applied for if it is needed for some purpose such as publication or for approval of access to data.

Researchers making use of large datasets, even when de-identified, need to be conscious of the increasing possibilities of identification through data linking.

9.17.3 Databanks and registries

Databanks have different forms and purposes and are an increasingly common and potentially highly valuable feature of the health research landscape. Their establishment and use raise issues of dignity, autonomy, privacy, confidentiality and discrimination. Researchers should address these issues in accordance with the following general principles:

- Research using databanks should benefit society, particularly in terms of public health objectives.
- Researchers have ethical and legal obligations to respect the dignity, autonomy, privacy and confidentiality of individuals when using data from databanks.

Additionally, international databanks raise issues about data protection across different jurisdictions, about which researchers need to be cognisant if proposing to submit data.

In considering proposals to establish or contribute to a health data registry, AHREC is particularly concerned about:

- The informed consent of patients/clients with respect to this use of their data (a proposal for "opt out" or form of consent other than would be required for research participation would need strong justification).
- Clear information for patients/clients as to whether, and if so, how they may obtain access, check and possibly withdraw their own data from the databank.
- In what form the data is to be held (re-identifiable, de-identified, anonymous), electronic or hard copy, and where (e.g., a DHB server, local New Zealand server, cloud server, overseas, etc.)
- The governance structure of the database (including control of and conditions for access for research).

Sources of helpful information on establishing registries include: https://registries.ncats.nih.gov; www.slideshare.net/ifpri/setting-up-a-data-repository-what-does-it-entail.

9.18 Storage, retention and eventual destruction of data

As noted in the National Ethical Standards (Section 12) "In the New Zealand context, data is seen as taonga (something sacred, precious, or significant)" and as such, "should be actively cared for in a manner that preserves its integrity and value." Researchers have a responsibility to ensure ethical standards not only in collection and use of data, but through all stages of the data life-cycle (collection, use, analysis publication, storage, curation and destruction).

Researchers must prepare a robust plan for the management of data and its governance at all stages of its life-cycle, with clear consideration to the nature and duration of storage and control of access, during and after completion of the project. If anonymised individual participant data will be made available to other researchers or publicly accessible, the mechanism for this must be approved by AHREC. Clear information about proposed retention, secure storage and destruction of data must be provided in information for potential participants.

High quality and transparent data governance and management are particularly important where the consent requirement for data use has been waived, where there is data linkage, or where unspecified future use is intended. Māori control of Māori data is the primary goal for Māori data sovereignty by improving Māori/iwi access to data for governance decision-making and ensuring Māori/iwi involvement in governance of data. (Māori data refers to data produced by Māori or that describes Māori and the environments they have relationships with.)

Research data management and governance plans should be reported to AHREC through the application form and in attached documents, and should include:

- The purposes of the data collection, and how data will be collected and by whom, including any training required for data collectors
- the proposed uses of health data, including any future uses, linking and other analytics that may result in harm to the participant and/or individuals or others, such as their families, whānau, communities and groups
- Details of the form (i.e., identifiable, de-identified or anonymised) in which health data will be collected, accessed, used and stored during the data life cycle and measures proposed to remove identifying details
- Plans for how consent will be sought for data collection and use, including secondary use. If data collection and use are unconsented, plans for seeking a waiver of consent from organisational data governance committee or an ethics committee
- Who will be able to access the health data and under what conditions
- How Māori rights and interests in relation to data will be recognised, and how Māori will be involved in the governance of Māori data
- The length of time health data will be retained
- How the privacy and confidentiality of health data will be protected, including any circumstances in which it may not be possible to protect it, and any circumstances that may result in unauthorised disclosure of such data
- Procedures compliant with organisational policies and procedures for dealing with any breaches of privacy and confidentiality, including unauthorised disclosure of health data; measures that will be taken to notify those affected by the disclosure; and measures that will be taken to mitigate any harm caused by unauthorised disclosure
- Named accountability for complying with requirements regarding the privacy and confidentiality of health data

- Transparent plans for any foreseen commercial use of health data and proposals for benefit sharing, including intellectual property issues
- Whether health data will be transferred to other countries, and whether, in those countries, it will be subject to laws providing comparable safeguards to those available in New Zealand and whether there will be New Zealand representation on overseas governance committees
- Whether health data will be transferred to other institutions such as databanks and registries, and in that context, who will access it, how it will be used (e.g. future uses and linking) and how privacy and confidentiality will be protected and whether there will be New Zealand representation on overseas governance committees
- Participant and/or individuals' rights to correct their data
- Procedures for withdrawing participant and/or individuals' data
- Details of proposed approaches for community engagement
- What measures will be adopted to ensure transparency across all aspects of the data life cycle.

Note: Many of these considerations are included as questions in the AHREC application form, but prior consideration in the overall context of data responsibilities will aid in the completion of the ethics application.

9.18.1 National and Institutional requirements

Researchers' plans for data governance and management should complement organisational governance and management structures, but do not supersede those requirements. Plans must comply with current relevant standards for data governance and security (see: Health information standards | Ministry of Health NZ). At present, these include (1) the "Digital, data and technology services – minimum requirements"; (2) "HISO 10029: 2015 Health Information Security Framework"; and (3) "HISO 10064:2017 Health Information Governance Guidelines", the last of which highlights some key elements of data quality, privacy, privacy breach, and secondary use of data.

The University's general requirements for the storage, retention and destruction of research data are set out in the University *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)

For further advice about management of research data at CM Health, please contact researchoffice@middlemore.co.nz.

For further advice about management of research data at Waitematā DHB please contact research@waitematadhb.govt.nz

9.18.2 Storage considerations

Data may be stored in analogue or digital form. The following are things which researchers should consider:

i. Security of storage

In whatever form, data should be stored securely and so as to meet any assurances to participants of confidentiality, to protect privacy and to ensure the authenticity, integrity and safe custody of the data. Secure storage options may be: locked cabinets in locked rooms, password protected databases, password protected computers.

Personal storage devices are not in general as secure as institutional storage and may not offer possibilities of appropriate later access.

Where research data includes audio, video or electronic recording, special attention is required to protect confidentiality and security of data.

ii. Where data is to be stored, especially if it is in electronic format.

Some kinds of storage may have particular security issues (e.g., storage on servers outside New Zealand may not meet the privacy protections, required by New Zealand law, or data sovereignty considerations). Researchers should consider if it is possible, appropriate and practical to seek consent to store data overseas, and if seeking consent, should ensure that participants understand that privacy protections in other countries may be different to those offered in New Zealand and that there may be no New Zealand representation on overseas bodies making decisions about data use.

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 AHREC in their application of their intention to use a public repository for storage and the place and kind of access involved, and to include this in the PIS and CF for participants.

iii. The format in which the data are stored.

The software will need to be something stable and widely accessible, otherwise it may not be possible to access stored data in a few years' time. Removable media such as USB sticks are easily lost and corrupted, and use of these is not recommended.

iv. Identifiability

Researchers should weigh the benefits and risks of keeping identifiers, or links to identifiers, on stored data. This may be warranted in some cases, e.g., to maintain participant safety or to re-use data, but obviously increases risks of loss of privacy and possible accompanying harms. Researchers must identify and assess risks related to re-identification in the case of stored data, and implement measures to mitigate those risks though de-identification of data and obfuscation. Data analysis involving data integration and linking may heighten risks of re-identification. Such a risk is greater if the study relates to a population in a small geographical area, or to individuals with unique characteristics, where a large number of variables relate to an individual.

v. Length of storage

Data should not be stored longer than is required for the purposes for which it may lawfully be used, however there are some requirements with respect to minimum periods of storage. The minimum period required by New Zealand law for health data related to an identifiable individual, is 10 years (from completion of the study). Fully de-identified or anonymous data is not restricted to this limit. The University advises that "*research data should preferably be kept indefinitely. At an absolute minimum, research data should be kept for at least six years".*

While research imperatives may indicate keeping data for as long as possible, this should be weighed against risks, possibly increasing, of breaches of security. AHREC recommends research data retention for at least 6 years, unless new clinical data have been collected as part of the study, in which case both clinical and research data should be retained for 10 years. Researchers should keep research data on child participants for at least 10 years after the child has reached the age of 16 years.

Information for participants must include a clear statement of the intended time for storage of data, either a fixed term in years (not 'at least' n years) or indefinitely, as well as how and where data will be stored.

vi. A contingency plan

Researchers should give consideration to what should happen in the event that a researcher leaves the DHB or 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 both electronic and hard copy data). Data will remain the property of the host institution and become the responsibility of the academic unit or department involved. Individuals leaving the institutions may negotiate to take copies of the data.

9.18.3 Data destruction

Researchers need to consider and plan for secure destruction of research data, particularly if this is potentially identifiable. Thought should be given also to ensuring removal and destruction of any data used during the research process which is not being stored (e.g., data which may be on devices of individual researchers or research assistants).

Clear information should be provided to AHREC and to research 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 of retaining them.

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

9.18.4 Managing breaches of privacy or data security

Should it become apparent that, for whatever reason, the privacy or security of collected data has not been maintained, the PI/supervisor should follow the University or relevant DHB's process to manage the potential breach, and PIs must also report the incident to AHREC as soon as possible via the ahrec@auckland.ac.nz email. Following this process will ensure that the University/DHB meet any legal obligations that may arise, and that the circumstances leading to the breach can be addressed as soon as possible.

University of Auckland: If the breach involves personally identifiable information, the Privacy Breach Reporting Form in the Privacy Centre should be used.

If the breach involves a computer system, the Cyber Security Incident Reporting Standard should be followed.

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. AHREC 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. Research or other activity involving the administration of any radioactive substance or exposure to ionising radiation, must comply with National Radiation Laboratory requirements.

9.19.3 Biological safety

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

University staff and students can use the following links to obtain more information:

- 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. 89466. Email: francesca.casu@auckland.ac.nz
- The University of Auckland Biological Safety Committee webpages on the staff intranet: https://www.staff.auckland.ac.nz/en/research-gateway/research-support-gateway/manage-ethics-and-regulatory-obligations.html

10. RESEARCH DESIGN – PARTICULAR TYPES OF RESEARCH

10.1 Telephone research

Where research is conducted by telephone interview or includes a telephone screening component, the researcher should:

- Provide AHREC 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, ask them whether they agree to participate in the research under the terms specified and 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 or queries.

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.

10.2 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, an 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.
- 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.

10.3 Quality assurance, audit and related activities

Audit and quality assurance or improvement investigations are an essential component of the responsibilities of health care institutions and professionals, and should be conducted ethically within the codes and principles governing those institutions and professions. The primary aim of such activities is informing and improving the delivery and management of a service rather than seeking new knowledge. For these reasons,

these activities do not always require ethical review and approval. However, it may be necessary or desirable to seek review from AHREC in certain contexts:

(i) Where a clinical audit is to be conducted (wholly or in part) by an enrolled student with the additional purpose of meeting research requirements of the programme for which they are enrolled, then it must be reviewed as research by an appropriate Ethics Committee. In the case of University of Auckland students, this is AHREC.

(ii) Where those conducting the audit consider that they may wish to publish results or procedures for the benefit of other institutions/professionals, then it is desirable to obtain ethical approval because publishers may require this, and ethical approval cannot be obtained retrospectively.

(iii) Where audit or quality improvement procedures will involve interviewing or otherwise engaging directly with patients, it is desirable that these be approved by an Ethics Committee. Such review and approval may provide protection for both participants and staff conducting such activities.

While quality assurance and improvement activities may be identifiable from their purpose, the borderline between these, other audit-related activities, and research is not always clear cut. In general, if a project is intended to provide new knowledge about some condition, then it is likely to be research. For example, some audit-like activities are really research (e.g., reviewing records of patients with a particular condition to find the frequency of a possibly related condition, event or medication) and hence require ethical review. However, the National Ethical Standards (Section 18) indicate that outcome analysis, while not the same as clinical audit, is not research because it is "conducted on activities already being undertaken and does not provide new knowledge for an intervention where no knowledge exists in that area". Researchers should seek advice from an ethics advisor or the Chair of AHREC if they are unsure whether their project requires AHREC approval.

Section 1 of the National Ethical Standards discusses quality assurance and improvement, and ways in which these differ from research. Section 18 has further discussion and comments on a range of quality improvement tools.

AHREC requires that applications for projects which include audit of existing records must contain details of how permission for, and access to, audit data will be achieved, how audit data will be used in the study and how it will be stored. It is preferable that the data be provided to the research team in de-identified format. If researchers will have access to identifiable data, they will need to meet or observe appropriate confidentiality requirements. They will also need to state in the application form when they will de-identify the research data, if they will keep a coded list for possible re-identification (and if so, why re-identification would be necessary), or if they propose not to identify the data.

Researchers should note that even where they may have access to health data in a role as a health professional, they may need to obtain permission for use of such data for research purposes. 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 AHREC approval is obtained before they will release any clinical records.

10.4 Case Reports for publication

Clinicians sometimes wish to publish information about particular individual cases they have dealt with. Where it is a single case intended to be published as a case report, ethical review and approval is not required. However informed consent should be obtained from the person that the case relates to, preferably in writing, in addition to any verbal discussion.

In obtaining informed consent for the publication of case reports, clinicians should make clear the extent to which the person might be identifiable from the information they wish to publish.

Where information from a series of cases will be gathered from clinical records, collated and compared, the project should be treated as secondary data analysis (that is, it is analysing for research purposes data which was collected for a different purpose). Ethical review will therefore be required as outlined in Section 9.17. Where a new case is compared to others for which information is accessed only from previously published reports, ethical approval is not required.

10.5 Practitioner applied research

Practitioner applied research (particularly in one's own work setting) is a discrete field of methodological action with discrete ethical demands, and raises particular issues with regard to ethical approval. It is allied to but distinct from audit or clinical audit, and is specifically undertaken within, and for the purposes of improving, the practitioner's own practice. Some features of applied practitioner research that may distinguish it from other forms of research are:

- The growing frequency of 'reflective practice' means that research is already an element of practice and already features in interactions between researcher and participants. Many health professions are subject to a formal expectation that they will research their practice.
- 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.
- Many professional practitioners work to professional codes of practice that include guidelines on ethical action. These may or may not include the specifics of research ethics, but they have particular implications for them.
- Sometimes practitioner research falls within existing collegial relationships and mutual obligation, such that pro forma procedures (requiring signatures, no-prejudice undertakings and third-party mediation) may be considered inappropriate.
- It is appropriate to assume that 'leadership' (such as a health team leader) corresponds with 'hierarchy' and that voluntary decision-making about research participation will be constrained if 'leaders' recruit participants.

Practitioner applied research may be 'low risk' but the interconnection of practice and research components can raise issues with respect to ethical requirements of research, such as the informed consent of participants free from any sense of pressure or coercion. The conduct or practitioner applied research in the practitioners' own workplace, can raise issues also of protection of confidentiality and of potential consequences for other parties such as colleagues, employees and employers. Applicants for ethics approval must consider such ethical concerns and make clear in their application how they intend to address these matters.

For example:

1. Given possible ethical concerns, why does this research need to be carried out in your own setting (as distinct from a setting from which you are more independent)?

2. 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?

3. 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?

4. What are the potential or possible risks to the participants?

5. How, particularly in settings with small numbers of participants, will you retain confidentiality and/or anonymity?

6. How will you ensure that participation is voluntary and that potential participants do not feel under any pressure to participate?

7. 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 and other colleagues?

8. 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.

10.6 Research involving Children

Research involving children and young people, while necessary, requires particular care with respect to the protection of child participant from harm and appropriate information and consent processes. The following points are based largely on HRC guidelines (Research involving children | Health Research Council of New Zealand (hrc.govt.nz)) and Section 6 of the National Ethical Standards. Other assistance in this area may be found at Ethical Research Involving Children, ERIC, Child Ethics.

Before undertaking any study that involves child participants, the investigator must ensure that:

- Children will not be involved in a study that might be carried out equally well with adults
- The purpose of the research is to obtain knowledge relevant to the health needs of children
- Where a study involves children, it should involve the least vulnerable children

- If a choice of age groups is possible, older children should be involved in preference to younger ones
- The study is designed or supervised and carried out by people experienced in working with children
- The number of children involved is limited to the number that is scientifically and clinically essential.

AHREC usually requires parental consent to be obtained for participants under the age of 16 years, but it has some flexibility in this regard depending on the nature of the research proposal.

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.

As potential participants under the age of 16 years may be vulnerable, AHREC usually requires that a legal guardian consents to the participation of a child in research. The informed *assent* of the child is also required if he or she is of an age to understand the project. HDEC requires that this takes the form of a simply-written age-appropriate Assent Form. 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.

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 (e.g., 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, AHREC 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, AHREC 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.
- In occasional circumstances, e.g., in non-treatment studies involving samples for biomarker research, where a child's and/or parental competence is compromised by serious illness or distress, it may be acceptable to store samples taken as standard of care procedures at the site, until it is more appropriate to obtain informed consent and/or assent prior to utilising/sending the samples for research.
- 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.

There must be parental consent in any research where children are video-recorded.

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

11. Untoward events and complaints procedure

11.1 Untoward Events

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.

Serious negative events or effects are 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 a negative event, 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 a negative event affects researchers, then appropriate institutional health and safety reporting procedures should be followed.

AHREC wishes to be notified of all negative events or unanticipated problems 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, AHREC 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 AHREC will seek further advice.

To report an untoward event to AHREC, the PI must complete a Report Form for Adverse Events and Complaints. The form can be requested from the Ethics Administrators using ahrec@auckland.ac.nz, and the completed form submitted to the Ethics and Integrity Manager at the same email address.

11.2 Complaints procedure

An important part of AHREC'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 AHREC may do so in writing to the AHREC Chair. The complaint should be submitted to the Ethics and Integrity Manager in the first instance.

11.2.1. Lodging a complaint

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 AHREC may do so in writing to the AHREC Chair, by contacting the Ethics and Integrity Manager (the Manager) in the first place via email (ahrec@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, Auckland DHB, Waitematā DHB or CM Health:

A member of the University, Auckland DHB, Waitematā DHB or CM Health wishing to raise a matter of concern or a complaint about research approved by AHREC and relating to ethical standards of research on human participants conducted by members of the University, Auckland DHB Waitematā DHB or CM Health, must complete a Report Form for Adverse Events and Complaints. The form can be requested from the Ethics Administrators using ahrec@auckland.ac.nz, and the completed form submitted to the Ethics and Integrity Manager at the same email address.

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

11.2.2 Investigation procedures

The complaint or expression of concern about an untoward research event should be set out in sufficient detail to enable the Chair to identify both the research and the issue of concern.

a. In consultation with the Deputy Chair, the Chair will determine if the matter will be investigated and, if so, the process to be followed.

b. To protect the privacy of the informant/complainant, the researchers and research participants, all information about an alleged untoward event will initially be treated as confidential to the Chair, the Deputy Chair and the Ethics and Integrity Manager. The Chair, in consultation with the Deputy Chair, will determine the appropriate levels of confidentiality throughout the proceedings. 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. If the Chair, in consultation with the Deputy 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.

c. 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 study in which the alleged event is said to have occurred. The Manager will ask the Principal Investigator to complete the Report Form for Untoward Events and Complaints and to submit this to the Chair, using

ahrec@auckland.ac.nz, within 15 working days of receipt (if that was not already completed).

d. The Chair will ask the subject of the complaint for a written response. In all cases, if the reported alleged research event or other matter of complaint is of a serious nature and an investigation needs to be conducted urgently, the Chair and Deputy Chair will take whatever steps they consider necessary.

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

f. If the Chair, in consultation with the Deputy Chair, comes to the view that there has been a breach of the conditions set by AHREC or there is evidence of possible misconduct in research, the matter will be referred to the University, Auckland DHB, Waitematā DHB or CM Health, depending on where the PI is employed, for any consequential action, together with recommendations of remedy to the study or participants. Informants/complainants should be kept informed about the progress of the investigation.

g. 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.

h. Where the Chair's investigation determines that further action may be necessary, they will inform the AHREC Governance Board (see Appendix 2 for details of the composition of the Governance Board) who will determine what further steps are appropriate.

i. AHREC will be informed of the outcome of the investigation. Normally the Committee will only be informed of the identity of the researcher and the research project if it can be established that an untoward research event did indeed occur.

APPENDIX 1: AHREC CHECKLIST FOR EXPEDITED REVIEWS

AHREC Checklist for Determining the Review Pathway (Expedited or Full Review)

A research project where there is a low risk of physical/psychological harm to the participants, of exploitation, or of other potential adverse effects will normally be reviewed via the expedited review pathway.

The review pathway determination is based on the answers to the questions below. An application will initially be processed by expedited review if **all** of the questions below are answered "No".

NOTE: In all cases, it is the Committee's decision whether an application is low risk or that it qualifies for expedited review.

Please select **Yes** or **No** for each of the following questions:

Q#	Risk of Harm		
F3a	Is it possible the research will involve any risk of harm to the researchers?	☐ Yes	☐ No
F3b	Is the research likely to cause any possible harm to the participants, such as physical pain beyond mild discomfort, embarrassment, psychological or spiritual harm?	☐ Yes	☐ No
F3c	Does the research involve processes that are potentially disadvantageous to a person or group, such as the collection of information which may lead to discrimination?	☐ Yes	☐ No
F3d	Does the research involve collection of information about illegal behaviour(s) which could place the researcher or participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships?	☐ Yes	☐ No
F4i	Will the identifiers be stored to enable re-identification of individuals?	☐ Yes	☐ No
E1	Will human tissue be collected and/or used in this study?	☐ Yes	☐ No
F3i	Does the research involve any intervention administered to the participant, such as drugs, medicine (other than in the course of standard medical procedure), a placebo, nutritional supplements, environmental conditions, food/drink?	☐ Yes	☐ No
F3j	Is the research considered a clinical trial?	☐ Yes	☐ No
F5c	Will the study involve the administration of ionising radiation that is not needed for participants' normal clinical management?	☐ Yes	☐ No
F5	Does the research involve EEG, ECG, MRI, TMS, MRI, EMG, invasive or surface recordings?	☐ Yes	☐ No
F15	Might the study adversely impact on the provision of health and disability services to participants?	☐ Yes	☐ No
	Informed and Voluntary Consent		
C9dii	Does the research involve participation of children under sixteen years of age?	☐ Yes	☐ No

C9div	Does the research involve participants who are in a dependent situation, such as people with a disability, residents of a hospital or Residential Aged Care facility or prison, or patients highly dependent on medical care?	☐Yes	☐ No
C9diii	Does the research involve participants whose capacity to give informed consent (other than children) is compromised?	☐ Yes	☐ No
C9dv	Does the research involve participants who may be vulnerable for some other reasons, such as older people, persons who have suffered abuse, persons who are not competent in English, or newly arrived immigrants?	☐ Yes	☐ No
G4	Will all participants in the study give their informed consent to participate? (Only applicable to the response to question G.4, and not applicable for audit chart review studies or anonymous questionnaires)	☐ Yes	☐ No
	Privacy and confidentiality		
F3f	Does the research involve matters of commercial sensitivity?	☐ Yes	☐ No
F3g	Does the research involve University of Auckland or DHB staff or students as participants where information of a personal nature may be collected and where the participants may be identified in study reports?	☐ Yes	☐ No
	Deception		
G6	Does your study involve deliberately withholding or concealing information from participants?	☐ Yes	☐ No
	Conflict of interest		
F14a	Will the Principal Investigator or any Co-Investigator also be the usual health or disability support service provider directly involved in the healthcare for one or more participants in your study?	☐ Yes	☐ No
F14c	Does the research involve any other conflict of interest or the appearance of a conflict of interest for the researcher?	☐ Yes	☐ No
I1D	Does the Principal Investigator, any Co-investigator, or any direct member of their families have any commercial interest (such as potential commercialisation) in the research or any financial relationship to the study sponsor or funder(s)?	☐ Yes	☐ No
	Requirements imposed from outside the University of Auckland or DHBs		
C11	Has an organisation outside the University of Auckland, Auckland DHB, Waitematā DHB or CM Health contributed to the study design?	☐ Yes	☐ No

APPENDIX 2: AHREC TERMS OF REFERENCE, GOVERNANCE AND COMPOSITION

Terms of reference

The terms of reference for AHREC are as follows:

- 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 AHREC partner institutions
- To provide an avenue for handling complaints or queries made by any interested person.

Governance

All aspects of the governance of AHREC will be the responsibility of a Governance Board of four members, two appointed by the Auckland DHB CEO and two by the Dean of the Faculty of Medical and Health Sciences (FMHS) of the University. Usually the nominees would be the Auckland DHB Chief Medical Officer, the Auckland DHB Manager of Research, the Deputy Dean of the Faculty of Medical and Health Sciences (FMHS), and the Associate Dean (Research) of FMHS. The Chair will provide an annual report of AHREC's activities to the Governance Board. The Governance Board, in turn will report to the Auckland DHB CEO and to the University Council via the Deputy Vice-Chancellor (Research).

Composition of AHREC

The Committee membership meets the requirements for Health Research Council Ethics Committee (HRC EC) approval. As far as possible, the Committee aims to include the representatives specified below. 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 clinical, research and other expertise.

Membership

AHREC membership includes:

- At least two nominees of the University of Auckland – nominated by the Dean of the Faculty of Medical and Health Sciences
- At least one nominees from each DHB (more if required to be approximately in proportion to applications)
- At least two Māori members, one of whom represents Ngāti Whātua – nominated jointly by the Chief Advisor Tikanga and the Tumuaki
- At least one non-medical health professional
- Where practicable, one or more early career researchers.

The HRC Ethics Committee additionally requires the following:

- A lay[4] Chair
- A non-lay Deputy Chair
- Individuals with experience and expertise in:
  ethical and moral reasoning; law; the perspectives of wider community (e.g., the perspectives of consumers of health and disability services, ethnic communities); the design, conduct and reviewing of research; the provision of health and disability services; the perspectives of the student community
- Two appropriately qualified health professionals, one clinically trained and one in active practice.

It would be beneficial for the balance of AHREC's cultural expertise to take into account the cultural composition of Auckland's patient population.

Recruitment/Appointment of members

Recruitment of the Chair, Deputy Chair and members will be managed by the University Ethics team in consultation with the Auckland DHB, Waitematā DHB and CM Health Research Offices. Methods of recruitment may include public or institutional advertisements, self-nomination, nomination by third parties, and direct approaches to possible candidates. Prospective members may be asked to provide a CV, names of up to two referees, and to submit to an interview, as appropriate.

Appointments of lay members will be made by the AHREC Governance Board.

Term of membership

The term of membership shall be two years, which is renewable. No member shall serve for more than four consecutive terms.

Decision-making process

Decision-making will be by consensus.

Quorum

At least half of the appointed members (including the Chair or acting Chair).

If a meeting is inquorate, absent committee members can be asked to provide input by correspondence as long as the Chair believes this has allowed an adequate assessment of the application.

Responsibilities of members

Members are expected to provide an impartial ethical appraisal of proposals irrespective of their route of appointment or other responsibilities.

[4] A layperson is a person who (1) has no affiliation to the institution that sponsors, funds, or conducts research reviewed by that committee, and (2) is not a registered health practitioner, and has not been a registered health practitioner at any time during the five years preceding in the date of their appointment, and (3) is not involved in conducting health or disability research, or employed by an organisation whose primary purpose relates to health and disability research, and (4) may not otherwise be construed by virtue of employment, profession, relationship or otherwise to have a potential conflict or bias with the work of the committee.

Payment to Lay Members

Lay members will receive an attendance fee, calculated on the basis of each half-day attendance. The fee is the same amount provided to members of the University Council committee members, and is regulated by the Ministry of Education (Tertiary Education Commission). The attendance fee is approved annually by the University Governance Committee. Costs of transport are paid, and parking can also be arranged.

Training for Committee members

Members are provided with support documents, including the following:

- AHREC Applicants' Manual
- HRC Research Ethics Guidelines (2021)
- Guidelines for Researchers on Health Research involving Māori (2010)
- Te Ara Tika Guidelines for Māori Research Ethics
- Te Ara Tika – Training Presentation
- Te Mata Ira - Genome Research Guidelines
- He Tangata Kei Tua - Biobanking Guidelines
- Pacific Health Research Guidelines (2014)
- NEAC National Ethical Standards for Health and Disability Research and Quality Improvement (2019).

New members are provided with a previously approved AHREC application so they can provide a review as part of their training. The review is sent to the Chair for comment. New members also have access to online training modules covering the main ethical issues in research projects.

On-going training will be provided in the form of workshops where topical issues can be addressed in detail. These workshops will be held at least annually.

APPENDIX 3: ABBREVIATIONS

ACC	Accident Compensation Corporation
AHREC	Auckland Health Research Ethics Committee
CEO	Chief Executive Officer
CF	Consent Form
DHB	District Health Board
ECART	Ethics Committee on Assisted Reproductive Technology
FMHS	Faculty of Medical and Health Sciences
GTAC	Gene Technology Advisory Committee
HDEC	Health and Disability Ethics Committee
HOD	Head of Department
HOS	Head of School
HRC	Health Research Council
HRC EC	Health Research Council Ethics Committee
NEAC	National Ethics Advisory Committee
PI	Principal Investigator
PIS	Participant Information Sheet
SCOTT	Standing Committee on Therapeutic Trials
UAHPEC	University of Auckland Human Participants Ethics Committee

APPENDIX 4: GLOSSARY

Adverse events in research

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

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

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

AHREC regards a child or young person as being someone aged under 16 years.

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 over time. *[NIH National Cancer Institute]*

Examples of different types of studies are available to provide further clarity about the type of studies / projects that are regarded as being clinical research for the purposes of ethics approval. Please click here to access the examples.

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 (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. AHREC 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 / 5 years following publication of the data.

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, but is not limited to, names, initial, 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 is a study in which the investigator 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).

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 AHREC 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. 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 means 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).

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 AHREC 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 AHREC. Approval 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 approval.

Questionnaire

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

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.

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 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 Section 6 of the National Ethical Standards.