



Auckland Health Research Ethics Committee (AHREC)

APPLICANTS' MANUAL

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1. INTRODUCTION

The Auckland Health Research Ethics Committee (AHREC) was established as an initiative of the Auckland Academic Health Alliance, the partnership between the Auckland District Health Board (Auckland DHB) and the University of Auckland (University) and initially provided ethical oversight and approval of health research carried out by staff and students of the two institutions which is not eligible for review by a Health and Disability Ethics Committee (HDEC) (see section 6.1 for further details). Since 2019, AHREC eligibility criteria have expanded to also review ethics application from staff of Counties Manukau District Health Board (CM Health).

1.1 Purpose of this document

This document is intended to provide guidance to researchers and ethics advisors on the conduct of their research projects, and on the process of applying for ethics approval from 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 Ethics Advisory Committee guidelines: http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research](http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research)
- *Standard Operating Procedures for Health and Disability Committees August 2014*, <http://ethics.health.govt.nz/operating-procedures>
- University of Auckland Guiding Principles for Conducting Research involving Human Participants
- University of Auckland Human Participants Ethics Committee (UAHPEC) Manual
- [Health Research Council \(HRC\) Guidelines for Approval of Ethics Committees](#)
- 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.

2. KEY PRINCIPLES

In line with international guidance on research ethics, the four key principles of ethical research that AHREC requires to be applied to the design, conduct and ethical review of

research are autonomy, beneficence, non-maleficence and justice. The value underlying these principles is respect for persons. Researchers should adhere to these principles when planning and undertaking their research.

These principles are outlined briefly below.

2.1 Autonomy

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

2.2 Beneficence

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

2.3 Non-maleficence

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

2.4 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.

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

3. AHREC TERMS OF REFERENCE AND GOVERNANCE

3.1 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 two institutions
- To promote awareness within the University and Auckland DHB community of ethical issues relating to research with human participants
- To provide an avenue for handling complaints or queries made by any interested person.

3.2 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 Director of Research, the Deputy Dean FMHS, and the Associate Dean Research 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).

4. 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 disciplines and expertise.

4.1 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 nominee 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 lay¹ 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
- 2 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.

¹ 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.

4.2 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 and Counties Manukau DHB Research Office. 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 2 referees, and to submit to an interview, as appropriate.

Appointments will be made by the AHREC Governance Board.

4.3 Term of membership

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

4.4 Decision-making process:

Decision-making will be by consensus.

4.5 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.

4.6 Responsibilities of members

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

4.7 Payment to Lay Members

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

4.8 Training for committee members

Members are provided with a folder of support documents, including the AHREC Applicants' Manual, the HRC Guidance Notes on Research Ethics (2014), Guidelines for Researchers on Health Research involving Māori (2010), Te Ara Tika - Guidelines for Māori Research Ethics, Te Ara Tika – Training Presentation, and Pacific Research Guidelines (2014). Members must attend an initial training session where review of ethics applications are discussed in light of the guidance from these documents. These initial training meetings will be followed up with at least one further session where the focus will be on the process of application review and writing a review report for the Committee meetings.

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.

5. ROLES AND RESPONSIBILITIES

5.1 Researchers' Responsibilities

Research by staff and students of the University of Auckland which involves human participants must be approved by UAHPEC, AHREC or an HDEC, depending on the nature of the research.

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.

5.2 AHREC Responsibilities

AHREC's ethical principles and procedures are consistent with the Health Research Council's ethics framework and with those of the National Ethics Advisory Committee (<http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research>).

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).

6. ETHICS APPROVAL REQUIREMENTS

6.1 Eligibility for AHREC review

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

- i. The study is **not** eligible for review for ethics approval by a Health and Disability Ethics Committee (HDEC)

The following studies require HDEC review:

- Any intervention study²
- Research involving participants or using identifiable health information without consent
- Research using human tissue in an identifiable form

² NEAC defines this as follows: 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. http://neac.health.govt.nz/system/files/documents/publications/ethical-guidelines-for-intervention-studies-2012v2_0.pdf

- Research involving vulnerable participants (which may include children and young people)
- Studies that withhold standard care.

The following studies may **not** require HDEC review³:

- Research wholly for the attainment of a qualification at masters level or below (unless it is for an intervention study)
- Using identifiable health information for audit or related activities
- Research using health information in a de-identified form

AND

- ii. The study involves recruiting human participants from within the geographic region served by the Auckland DHB and CMDHB and/or from within non-ADHB / CMDHB areas where the ADHB / CMDHB are clinical service providers in the area of practice for the research proposed.

AND

- iii. The study involves health research conducted by Auckland DHB or CMDHB employees, and/or employees and/or students of the University of Auckland.

For applications that meet the criteria listed in Recommendation 1 and additionally include participants recruited from any of the other New Zealand DHBs, applicants are to seek ethics approval from AHREC.

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.

AHREC uses the HDEC definition of health and disability research as “research that aims to generate knowledge for the purpose of improving health and independence outcomes.”

Research projects can commence only after AHREC approval has been given. There are no exceptions to this rule and AHREC does not grant retrospective approval.

6.2 Exemptions

The following studies will be exempt from approval by AHREC:

- 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/>).

³ The HDEC provides a summary flowchart for guidance about whether a research study requires HDEC review. See: <http://ethics.health.govt.nz/system/files/documents/pages/HDEC%20scope%20summary.pdf>

For fuller details of which studies require HDEC review, see <http://ethics.health.govt.nz/home>. Applicants are encouraged to submit a Scope of Review form to the HDEC ethics advisors for a determination of eligibility if there is uncertainty about which committee should review the study.

6.3 Transferring research

If a new staff member brings with them a research project from another institution, appropriate management approval is needed to continue the project. Unless the project has been approved by an HRC-approved ethics committee, the original ethics application and approval must be submitted to the appropriate local committee. The Chair may ratify the approval or refer the decision to the Committee. In either case, the researcher must obtain written approval prior to re-commencing the research.

6.4 Collaborations

Where research is conducted in collaboration with a researcher from another institution, the provisions outlined in section 6.3, above, apply: i.e., approval from any HRC-accredited ethics committee is acceptable, subject to institutional management approval. If the previous approval is not from an HRC-accredited committee, then the ratification/re-approval process outlined is required. Where research is conducted in collaboration with a researcher from an institution where ethics approval is not routinely required and it is within the scope for AHREC review, a full application for ethics approval must be made to AHREC.

6.5 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.

6.6 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.

6.7 Research conducted without ethical approval

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

Researchers who do not gain approval risk not being able to publish their research and, in the event of a complaint or legal suit, may not be covered by institutional indemnity insurance. If the researcher is a student, they may not be permitted to graduate.

7. EXTERNAL COMPLIANCE REQUIREMENTS

7.1 Compliance with Health Research Council requirements

AHREC must meet the HRC EC requirements in order to maintain its status as an HRC EC-approved ethics committee.

7.2 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's or University's policy on research and a professional code, the researcher should inform, and seek advice from, AHREC.

7.3 Requirements from other organisations

A research project may have requirements imposed upon it by an organisation outside the Auckland 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, the University, and/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 approved processes are requested by the organisation or during the process of locality approval, then these must be approved by AHREC.

7.4 Research eligible for UAHPEC review

UAHPEC will not usually review applications for studies eligible for AHREC review (single site). A research project should only be reviewed by a single HRC EC-approved committee, but management approval will usually be needed from each institution in which the research takes place.

7.5 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/>

8. APPLYING FOR ETHICS APPROVAL

8.1 Application process

The application process for AHREC ethics review will be administered by the University of Auckland Ethics Administrators, in cooperation with the Auckland DHB Research Office and the CM Health Research Office. 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: Contact the Manager, Auckland DHB Research Office at ResearchOffice@adhb.govt.nz (Tel 09 307 4949 ext 23854).

University staff and students: Contact the Ethics Administrators at humanethics@auckland.ac.nz or ahrec@auckland.ac.nz (Tel 09 373 7599 ext 83711).

CM Health staff: Contact the Research Coordinator, CM Health Research Office at researchoffice@middlemore.co.nz (Tel 021 574 928).

The application form, which outlines all documents required and provides templates for documents, are available at:

<https://www.staff.auckland.ac.nz/en/research/funding-and-ethics/applying-for-ethics-approval-and-ensuring-biological-safety/human-ethics.html>

Auckland DHB: <http://www.adhb.health.nz/health-professionals/research/>

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, seek advice from someone who can assist with grammar, syntax and spelling as necessary.

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

Only the PI can submit an application for ethics approval. For 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 HOD/HOS, as applicable.

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

8.2 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.

a. For research supported by funding from competitive internal (Auckland DHB or CM Health / 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.

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

The main supervisor may instead provide an explicit assessment of the research merit of the project, paying attention to the issues indicated above, 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 and doctoral student projects:

Applicants are required to provide an independent science review. This 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.

Scientific review should address the three issues listed in the guidelines for peer review in the *NEAC Ethical Guidelines for Interventional and Observational Studies (2012)* <http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research>:

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.

8.3 Māori responsiveness review process

Most research studies have impact on Māori. Researchers are encouraged to 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. 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.

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

Māori review services across all New Zealand DHBs now have the option to implement a standard criteria in the Māori locality assessment process. The criteria include a mechanism to make a decisions on the level of consultation for research projects. (Draft standard criteria, developed via a comprehensive national review process, in collaboration with those involved in Māori review in 20 DHBs, are currently being trialled at Capital and Coast DHB for six months.) AHREC will implement these standard criteria.

The different levels of consultation required for these types of research are given in the table below, as per the National Māori DHB Review Framework. The different types of Māori research have been described by Cunningham (2000) and utilised in the development of Te Ara Tika (Hudson et al., 2010) and in the HRC Guidelines for Health Research involving Māori (2010).

- *No expected involvement:* Although Māori have been excluded by the research design in the first level, this type of study is still of interest to tangata whenua as it is conducted in Aotearoa, and also represents research that has been funded at the expense of a project that could have addressed Māori issues (Cunningham 2000). The challenge here therefore is to identify opportunities within the project for Māori health development, such as health literacy improvement, resource sharing, or Māori researcher capacity development.
- *Possible involvement:* The second level of research includes the possible involvement of Māori as study participants (although minor), and/or junior research positions. A further consideration of the protection of Māori study participants comes into perspective here and more so with the third level of research.
- *Probable involvement:* Although the third level of research has been initiated by non-Māori, the expected Māori participation is considerable. It is likely to be an area of interest to Māori either where Māori may have high representation, or a health topic that has been prioritised by the DHB, mana whenua, or other Māori community groups. Depending on the design of the study it may be appropriate to use some Kaupapa Māori Research methods, and data should be analysed by ethnicity.
- *Definite involvement:* Māori-centred research (level 4) is that which is initiated by Māori and has a high involvement of Māori as participants and as senior researchers and advisors.
- *Significant involvement, possibly exclusive:* In Kaupapa Māori research (level 5) there is significant, and possibly exclusive, involvement of Māori, who have a governance role in the project. These two categories have clear aims on the contribution of the research to hauora Māori, and typically use Kaupapa Māori research methods and methodology.

While details of each type of research are provided (in the table below), they are not necessarily distinct categories, rather there is a continuum of the types of research from no Māori participation at all to full and exclusive participation. An individual research project will sit somewhere along this spectrum. The further along the spectrum, the greater the expected contribution of the study to Māori health development. To fulfil the obligation of contributing to reduction of inequities, and to the forward advancement of Māori health, all researchers should continually seek to orientate their research projects further along this continuum.

	Non-Māori focused research			Māori-centred	Kaupapa Māori
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	DHB Māori review	DHB Māori review	DHB Māori review and possible engagement with DHB 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	<ul style="list-style-type: none"> • Māori have not been included in the design of the project • There are still possibilities to contribute to Māori development 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Clear aims for the contribution of the research to Māori Health and equity • Māori knowledge produced, but non-Māori methods may be used 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Non-Māori and/or Māori • Ethnicity analysis • Equity analysis 	<ul style="list-style-type: none"> • Non-Māori and/or Māori • Ethnicity analysis 	Kaupapa Māori
Tools	Non-Māori	Non-Māori	<ul style="list-style-type: none"> • Non-Māori • Possibly some Kaupapa Māori Research methods 	<ul style="list-style-type: none"> • Non-Māori or Kaupapa Māori Research methods and Kaupapa Māori Epidemiology 	Kaupapa Māori Research methods and Kaupapa Māori Epidemiology

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

8.4 Documents to be included with the application form

Documents for participants may include Participant Information Sheet(s), Consent Form(s), advertisements, email invitations, questionnaire(s), list(s) of interview questions and confidentiality agreement(s). All documents intended for participants and/or third parties should be completed to a high standard of written English and must be submitted to 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
Reference number*

8.4.1 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 they 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, the management and protection of their rights to privacy and confidentiality, and their rights to their own or new personal information
- What will happen after the study, including how the results will be communicated and disseminated, and the storage, retention and destruction of data and samples
- The PIS should be offered to the participant to keep and therefore should be presented separately from questionnaires, consent forms or other material that will be returned to the researcher.

A link is provided in the application form to a PIS template from the HDEC website, however, the following information specific to AHREC needs to be added to the PIS:

- a. Contact details for Māori cultural support or to lodge a complaint:

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitemata District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

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 on [insert approval date] for three years. Reference number XXXXXX."

8.4.2 Consent Form (CF)

Typically, AHREC requires consent to be recorded 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, 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.

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

A link is provided in the application form to a CF template from the HDEC website, however, the AHREC approval wording needs to be added to the end of the CF:

"Approved by the Auckland Health Research Ethics Committee on [insert approval date]

8.4.3 Advertising material and email invitations

Any advertisements for recruiting participants, including email invitations and all other electronic invitations, 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 participate in the study.

The advertisement should include the source of research funding and contact details for the researcher(s), but does not need to 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 and/or the Auckland DHB'.

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 on [insert approval date] for three years. Reference number XXXXXX."

8.4.4 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 before using it.

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

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

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

If 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, 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.

8.4.5 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.

8.4.6 Confidentiality agreement(s)

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

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

- translating
- 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). 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.

Please refer to Appendix 2 for an example of a Confidentiality Agreement.

8.4.7 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 needs 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 need to be sent to the Ethics Administrators using the (ahrec@auckland.ac.nz) email address once available.

9. ETHICS REVIEW PROCESS

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

9.1 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 will 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 application form or given in Appendix 1.

Additional types of low-risk studies 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
- 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.

9.2 Full review

Any research not qualifying for an expedited review will be placed on the next AHREC agenda for review by the Committee. Each application will be reviewed 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 ratified at the following Committee meeting.

9.3 Committee decisions

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

9.3.1 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.

9.3.2 Approved with comment

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

9.3.3 Conditional approval

AHREC requires that amendments are made to the application or further documentation provided. The researcher must provide the requested revisions/modifications/clarifications/documents and highlight these in the text of the resubmitted documents using tracked changes. Each concern mentioned in the letter of outcome should be addressed in a covering memo with an explanation of the changes made. Amendments will be signed off by the Ethics Administrators, or if required, by Committee member(s) or the Chair. The researcher must wait for an approval letter from the Ethics Administrators before commencing their research. The application does not have ethics approval until the PI has submitted the amendments and received an approval letter.

9.3.4 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 that would allow the Committee to make a decision. Expedited applications cannot receive a pending outcome directly, but instead 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.

9.3.5 Empowered

In some cases, one or more Committee members are empowered by the Committee to work with applicants to resolve outstanding issues. The researcher must contact the nominated Committee member and arrange a meeting/exchange of correspondence with them in order to clarify the Committee's concerns. The researcher then makes the required changes and submits the revised documentation to the Committee member with the delegated authority to decide the outcome of the application. When the Committee member is satisfied with the changes, the researcher re-submits the amended application documentation to the Ethics Administrator and the reviewer informs the Ethics Administrator that the application is approvable. The Ethics Administrator will then issue an approval letter to the applicants. Once the researcher receives the letter of approval, the proposed research can commence and the approval will be noted on the Agenda of the next AHREC meeting.

9.3.6 Not required

Ethics approval is not required.

9.3.7 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 all research proposals up to the standard required for approval.

9.4 Period of ethics approval

Normally AHREC will approve an application for three years, but applicants can request a longer approval in their application.

An extension of approval for a further three years can be requested. A researcher who wishes to request an extension of approval should submit an amendment request at least one month before its expiry.

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

9.5 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>

10. CONDUCTING THE RESEARCH

10.1 Locality authorisation

AHREC approval and locality authorisation are separate processes

Locality review is the process by which a locality itself assesses its suitability for the safe and effective conduct of a 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 will have to pursue locality authorisation from each locality, such as a DHB, that will be involved in their study.

10.2 Annual Progress Reports

Normally AHREC does not require researchers to submit annual reports. In some cases, such as if the Committee feels that the study meets the [NEAC](#) criteria for an intervention study, the Committee may request as a condition of approval the submission of annual progress reports.

10.3 Changes to the research study

If changes need to be made during the course of the research, permission needs to be sought from AHREC. This can usually be done by either submitting an amendment request form via email (if the initial application was submitted prior to Ethics RM being implemented) or sending an amendment request via the Ethics RM system (if the initial application was submitted using Ethics RM), explaining the nature of the change(s) and providing relevant amended documents, such as the PIS and CF. 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, a new application for ethics approval may be required or the requests for change will be put on the next agenda for the Committee to consider.

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

10.4 Incidental findings and discovering illegal activity

Research occasionally gives rise to findings that are unexpected and unrelated to the original purpose of the research and which have implications for the well-being and interests of participants and the duties of researchers. Researchers should consider this in their research design and, where appropriate, discuss strategies for dealing with this situation in their application to AHREC.

10.5 Study completion

10.5.1 Dissemination of results

Whenever possible, the findings should be conveyed in a comprehensible form to those who participated in the research. The researcher must do this if they have undertaken to do so during study enrolment.

10.5.2 Final report

Once the study has concluded, the principal investigator must submit a final report to AHREC. The report must be submitted as an attachment to ahrec@auckland.ac.nz, with the AHREC reference number and "Final Report" in the email's subject line. The report 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 the Committee via the Expedited Review process. No further action will be necessary, unless the Committee wishes to discuss the report at a meeting.

11. ETHICAL CONSIDERATIONS IN RESEARCH DESIGN

11.1 Recruitment of research participants

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

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

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

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

It will usually not be appropriate for the researcher to recruit members of their own family or friends. As an exception to this general rule, small-scale and minimal-risk

research projects on topics that are not sensitive or controversial and conducted by students in the course of studying research methodology may involve the use of family and friends as participants, provided they are aged 16 years or above.

11.2 Clinicians recruiting patients within the Auckland DHB

The recruitment of DHB patients by researchers working within that institution is a long-standing practice and an integral part of clinical research. 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. 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 Auckland 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.

11.3 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 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.

11.4 Consent

11.4.1 General ethical issues about obtaining consent

The principle of autonomy 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. Researchers should explain how they have designed the consent process for a particular study, and why it is appropriate.

Consent to research must be voluntary, and participants can 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.

11.4.2 Documenting consent

Typically, AHREC requires consent to be recorded on a 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 completed written questionnaire as evidence of consent, provided that appropriate information has been provided about the research.

11.4.3 Storage of Consent Forms

Consent Forms should be retained in secure storage by the researcher (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 (see section 11.17.1).

11.5 Focus groups or interviews with more than one person

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

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

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

11.6 Institutional approval and documentation required

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

If researchers consider that it is not appropriate to seek institutional approval, they must justify this in the application and ensure that they address how, in these circumstances, the employer's interests would be protected. An example might be where individuals with specific expertise from a range of organisations will be recruited rather than research being conducted wholly or primarily within a single organisation.

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

11.7 The Privacy Act 1993

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

For further information about the Privacy Act 1993 and how it relates to research, please see: <http://www.legislation.govt.nz/act/public/1993/0028/latest/DLM296639.html>

In particular, Principle 10 states:

"An agency that holds personal information that was obtained in connection with one purpose shall 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 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.

11.8 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 maintained⁴.

11.8.1 Anonymity

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

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. Research where participants are personally interviewed by a researcher, or part of a focus group, is not anonymous.

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

Under normal circumstances, the anonymity of participants completing web-based surveys can be guaranteed, even when the IP address of the participant is known. The

⁴ Please see the information in the Glossary with definitions regarding identifiable data.

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 questionnaire is used, the preservation of anonymity may make it appropriate that those who have declined to participate return a blank questionnaire.

11.8.2 Confidentiality

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

Researchers need to have strategies in place to protect confidentiality and must outline these strategies in their ethics application. Consideration must be given to how data will be represented in research reports and to the management, storage and destruction of data. All data should be stored securely, and identifying materials (including key words or codenames) should be stored separately from coded data.

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

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

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

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

If potential participants cannot be guaranteed confidentiality, this should be clearly stated in the PIS. For example, 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 with 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 in CFs.

11.9 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 in the ethics application form and PIS anything that could be perceived as a conflict of interest, and explain what actions they propose taking to resolve, avoid or minimise the conflict.

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

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

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

To avoid conflicts of interest, or the appearance of conflicts of interest, researchers may not recruit their own children as participants if they are under the age of 16, except in exceptional circumstances that must be justified to 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 identified in the PIS or PIS/questionnaire and research reports.

11.10 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 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.

11.10.1 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. In the event of a physical injury as a result of participation in a research studies, 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':

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

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

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

11.11 Deception

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

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 after the data-gathering in which the deception is explained
- participants have the right to withdraw any data obtained from them by deception

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

11.12 Audio, video or other forms of electronic recording

11.12.1 Consent to being recorded

Some research studies requires electronic recording of participants. If the recording is essential to the research, participants cannot ask for the recording to be stopped. Therefore, the PIS should contain an explicit statement, 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*".

11.12.2 Transcription or translation

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

11.12.3 Review and editing of recordings and transcripts

The Committee recommends that participants are offered the opportunity to review and edit transcripts of recordings and when possible, also to review and edit the recordings. Editing of transcripts is not usually appropriate for focus groups (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 normally 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 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 from 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 situation, the recording device cannot be turned off during the discussion and, if you withdraw from the research, information you have contributed up to that point cannot be withdrawn.”

11.12.4 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.

11.13 Reimbursement and compensation

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

Researchers may reimburse research participants for reasonable expenses incurred as a result of participating in the research, such as bus or taxi fares. 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 inducements should be offered to participants who are under 16 years. Small gifts, or opportunities to participate in modest prize draws by way of thanks for participation, may be appropriate
- The reason for, and the level of, reimbursement, compensation or gifts should be clearly explained in the PIS
- 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."

11.14 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.

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

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

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

Where the research does not qualify for HDEC review, research studies involving human remains, tissue and bodily fluids should be submitted to AHREC for approval.

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

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

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

Further information is available in the Health Information Privacy Code 1994, see especially Rule 10 "Limits on the use of Health Information":

<https://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/HIPC-1994-incl.-amendments-revised-commentary-edit.pdf>

11.16 Secondary data analysis

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

Permission of the custodian of the data is required for access to secondary data which is not publicly available and researchers considering giving access to data sets should be aware of the requirements of the Privacy Act 1993, particularly Principles 10 and 11 (see Section 11.6).

Ethical approval will be required for the transfer of secondary data, if the data identifies individuals. If the personal information collected for a particular research project is to be used for statistical research purposes in a second project, and the information will not be published in a form that could identify the individual concerned, no further ethical approval is required.

11.17 Withdrawal

11.17.1 Withdrawal from participation in research

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

11.17.2 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.

11.18 Storage, retention and eventual destruction of data

11.18.1 Institutional requirements

The University's general requirements for the storage, retention and destruction of research data are set out in the University of Auckland's *Code of Conduct for Research*, section 5.4 Research Records (<https://cdn.auckland.ac.nz/assets/central/about/the-university/how-the-university-works/policy-and-administration/code-of-conduct-research.pdf>) which state that "*research data should preferably be kept indefinitely. At an absolute minimum, research data should be kept for at least six years*".

Auckland DHB requires data retention for a minimum of 10 years from completion of a study, though this appears to refer to clinical trials. Therefore, AHREC recommends research data retention for 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.

Clear indication should be given to both AHREC and participants regarding the secure storage and retention of data. If anonymised individual participant data will be made available to other researchers or publically accessible, the mechanism for this must be approved by AHREC.

11.18.2 Storage considerations

Information should be handled in a way that protects participants' confidentiality and ensures the authenticity, integrity and safe custody of the data. Take care to protect the privacy of individuals, institutions, communities and ethnic groups, as required by the Privacy Act 1993. Where research involves the use of audio, video or electronic recording, special attention is required to protect confidentiality and security of data.

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

Storage of data for posterity and future research that involves transfer to a public repository 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 such storage and the place and kind of access involved, and to include this in the PIS and CF for participants.

11.18.3 Contingency plan

The PI needs to have a contingency plan in the event that a researcher leaves the Auckland 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 electronic data as well).

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.

11.19 Hazards

11.19.1 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.

11.19.2 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.

11.19.3 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. 86714. Email: d.jenkins@auckland.ac.nz
- The University of Auckland Biological Safety Committee webpages on the staff intranet: <https://www.staff.auckland.ac.nz/en/research-gateway/research-support-gateway/manage-ethics-and-regulatory-obligations.html>

12. RESEARCH DESIGN – PARTICULAR TYPES OF RESEARCH

12.1 Telephone research

Where research is conducted by telephone interview, 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, and ask them whether they agree to participate in the research under the terms specified. Audio-record verbal consent if at all possible.
- Thank the participant, and provide a contact telephone number at the University in case of any complaints.

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

12.2 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, each employee has the right to decide whether to participate or not and to have their participation or non-participation kept confidential from their employers.
- Participants have the right to have the content of their participation kept confidential to themselves and the researcher.
- 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.

12.3 Audits

Audit investigations examine practice and outcomes in a particular time and place, and may compare the results with explicit predetermined standards. An audit is typically a retrospective analysis.

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

For a student-led audit study that contributes to obtaining a degree, AHREC approval must be obtained prior to commencing the audit.

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

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

1. **Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.
2. **Programme evaluation** is a type of audit where a whole programme is evaluated, rather than specific interventions.
3. **Evaluation studies** aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.
4. **Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.
5. **Outcome analyses** involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.
6. **Benchmarking** aims to improve practice through the comparison of two or more health and disability support services.
7. **Public health investigations** explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.

8. **Public health surveillance** involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.
9. **Pharmacovigilance** (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).
10. **Resource utilisation reviews** evaluate the use of resources in a particular health or disability service activity. For example by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.

Comparable activities to many of these occur in other areas, for example in educational practice, in commercial activities and in social and public policy. Where any such activities are combined with research aims or projects, AHREC review is required.

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

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

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

12.4 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. The characteristics 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 classified as 'low risk' and subject to the AHREC approval pathway that exists for low-risk review. However, in cases where practitioner applied research is designed to take place in practitioners' own workplaces, applicants for ethics approval must consider all the ethical concerns that this raises and how they intend to address them. This helps AHREC to make informed and timely decisions.

The following questions should be answered in the application:

1. 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.

12.5 Research involving Children

Before undertaking any study that involves child participants, the investigator must ensure that⁵:

- children will not be involved in a study that might be carried out equally well with adults
- a study that involves child participants must relate 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, see <https://ethics.health.govt.nz/> 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.

⁵ Taken from <https://ethics.health.govt.nz/guides-templates-forms-0/potentially-vulnerable-study-participants-%E2%80%93-guidance/children-and-young>

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.

13. Untoward events and complaints procedure

13.1 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.

13.2 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. Complaints forms should be submitted to the Ethics Administrators in the first instance.

13.2.1. 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:

A member of the University 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 or Auckland DHB 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 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.

13.2.2 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 and the Research Office. 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 project in which the alleged event is said to have occurred. The ethics administrator will ask the principal investigator to complete the Report Form for Untoward Events and Complaints and to submit this to the Chair 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, a response will be sought from the principal investigator. 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. At the end of an investigation where the matter is resolved, the Chair will advise parties of findings and will, where necessary, refer the findings to the appropriate person or agency for any consequential action.

i. Where the Chair's investigation determines that further action may be necessary, they will inform the AHREC Governance Board (see section 3.2 for details) who will determine what further steps are appropriate.

j. 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 Expedited Review

A. Risk of Harm				
	1.	Does the research involve situations in which the researcher may be at risk of harm?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	2.	Does the research involve the use of any method, whether anonymous or not, which might reasonably be expected to cause discomfort, pain, embarrassment, psychological or spiritual harm to the participants?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3.	Does the research involve processes that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person/group to discrimination?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	4.	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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	5.	Does the research involve any form of physically invasive procedure on participants, such as the collection of blood, body fluids, tissue samples, DNA, human tissue from a tissue bank, exercise or dietary regimes or physical examination?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	6.	Does the research involve any intervention administered to the participant, such as drugs, medicine (other than in the course of standard medical procedure), placebo, environmental conditions, food/drink?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	7.	Does the research involve processes that involve EEG, ECG, MRI, TMS, MRI, EMG, radiation, invasive or surface recordings?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	8.	Is the research considered a clinical trial?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	9.	Does the research involve physical pain beyond mild discomfort?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
B. Informed and Voluntary Consent				
	1.	Does the research involve participants giving oral consent rather than written consent? (If participants are anonymous, the response is "No").	<input type="checkbox"/> Yes	<input type="checkbox"/> No

	2.	Does the research involve participation of children under sixteen years of age?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3.	Does the research involve participants who are in a dependent situation, such as people with a disability, residents of a hospital, nursing home or prison, or patients highly dependent on medical care?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	4.	Does the research involve participants who are being asked to comment on employers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	5.	Does the research involve participants whose capacity to give informed consent is in doubt?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	6.	Does the research use previously collected information or biological samples for which there was no explicit consent? (Data collections with previous consent and accessed with authorisation are not included here)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
C. Privacy and confidentiality issues				
	1.	Does the research involve evaluation of University of Auckland or Auckland DHB services or organisational practices where information of a personal nature may be collected and where participants may be identified?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	2.	Does the research involve University of Auckland or Auckland DHB staff or students where information of a personal nature may be collected and where participants may be identified?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3.	Does the research involve matters of commercial sensitivity?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	4.	Does the research involve Focus Groups?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
D. Deception				
	1.	Does the research involve deception of the participants, including concealment or covert observations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
E. Conflict of interest				
	1.	Does the research involve a conflict of interest or the appearance of a conflict of interest for the researcher (for example, where the researcher is also the lecturer/teacher/treatment provider/colleague or employer of the participants, or where there is a power relationship between researcher and participants)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
F. Cultural sensitivity				
	1.	Does the research raise any specific ethnic or cultural issues?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

G.	Requirements imposed from outside The University of Auckland or Auckland DHB			
	1.	Does the research involve a requirement imposed by an organisation outside The University of Auckland or Auckland DHB?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

APPENDIX 2: EXAMPLE OF A CONFIDENTIALITY AGREEMENT



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

TRANSCRIBER CONFIDENTIALITY AGREEMENT

Project Title:

Researcher(s):

Supervisor:

Transcriber:

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

Name: _____

Signature: _____

Date: _____

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
LSRI	Large-Scale Research Institute (University of Auckland)
NEAC	National Ethics Advisory Committee
PI	Principal Investigator
PIS	Participant Information Sheet
SCOTT	Standing Committee on Therapeutic Trials
TEC	Tertiary Education Commission
UAHPEC	University of Auckland Human Participants Ethics Committee
UARC	University of Auckland Research 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.

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.

http://neac.health.govt.nz/system/files/documents/publications/ethical-guidelines-for-intervention-studies-2012v2_0.pdf

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. Most observational health research is epidemiological or health services research.

Participant Information Sheet (PIS)

The PIS is the document that informs the participant about the research and the nature of the involvement required and is retained by the participant. Generally, the PIS must be in a written format. However, in the case of telephone research, or in research in predominantly oral cultures, a researcher may make a case to present the information orally. In these cases a copy of the information to be presented orally must be submitted to 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.

Vulnerable people

The [NEAC Guidelines for Intervention Studies](#) defines vulnerable people as those who have restricted capability to make independent decisions about their participation in a study.

The definition also covers people who:

- may be unable to consent freely to participating in the study

- may be particularly susceptible to harm because of their health status, physical or mental capacity or employment status, or as a result of imprisonment.

Studies involving potentially vulnerable participants must be reviewed by the Health and Disability Ethics Committee (HDEC).

Further guidance about studies involving potentially vulnerable people is available from the HDEC website:

<https://ethics.health.govt.nz/guides-templates-forms-0/potentially-vulnerable-study-participants-%E2%80%93-guidance>