Human Ethics Guidelines

1. AIM

1.1 To provide broad guidelines and guidance on human ethics to ensure that research conducted by Wintec staff and students, or any other research Wintec has a role in, reflects the fundamental human rights and responsibilities related to research.

1.2 Any **research** that involves any form of human participation and/or the collection of personal data/information, and/or direct interaction with human participants, and is interventional and/or observational research, and/or is intended for publication, requires ethics approval.

1.3 **Research** is an "original independent" investigation undertaken to contribute to knowledge and understanding and, in the case of some disciplines, cultural innovation or aesthetic refinement,[1] which:

- Typically involves inquiry of an experimental or critical nature driven by hypotheses or intellectual positions capable of rigorous assessment by experts in a given discipline.
- Includes work of direct relevance to the specific needs of iwi, communities, government, industry and commerce.
- May be embodied in the form of artistic works, performances or designs that lead to new or substantially improved insights.
- May include:
  - contributions to the intellectual underpinning of subjects and disciplines (for example, dictionaries and scholarly editions), or
  - the use of existing knowledge in experimental development to produce new or substantially improved, materials, devices, products, or communications, or
  - he synthesis and analysis of previous research to the extent that it is new and creative.
- Is an independent, creative, cumulative and often long-term activity conducted by people with specialist knowledge about the theories, methods and information concerning their field of enquiry.
- Produces findings that must be open to scrutiny or formal evaluation by experts within the field, which may be achieved through various forms of dissemination including publication, manufacture, construction, public presentation, or provision of confidential reports.

1.4 Where more than minimal risk is identified, reasonable and proportionate independent ethical review must be carried out prior to research work commencing.

1.5 These guidelines are adapted from the Health Research Council (HRC) of New Zealand's Research Ethics Guidelines (2017), the Royal Society of New Zealand's Code of Professional Standards and Ethics in Science, Technology, and the Humanities, as well as the National Ethics Advisory Committee's Ethical Guidelines for Observational Studies (2012).[2]

1.6 They guide the protection of the rights and safety of human participants as well as to ensure that our researchers are well informed and protected in their conduct of research at Wintec.

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[1] Adapted from the University of Auckland website: https://www.auckland.ac.nz/en/about/the-university/how-university-works/policy-and-administration/research

[2] https://www.hrc.govt.nz/sites/default/files/2019-10/HRC%20Research%20Ethics%20Guidelines-%20December%202017.pdf
https://www.royalsociety.org.nz/who-we-are/our-rules-and-codes/code-of-professional-standards-and-ethics/code-of-professional-standards-and-ethics-in-science-technology-and-the-humanities/
https://www.moh.govt.nz/notebook/nbbooks.nsf/0/F21C6588D45EBA67CC257A600009C6C7/$file/ethical-guidelines-for-observational-studies-2012.pdf

2 PRINCIPLES OF RESEARCH INVOLVING HUMAN PARTICIPANTS

2.1 A number of principles guide research that involves human participants. These principles include, the following, which will be used by HERG to assess research proposals:

2.2 **Informed consent**

i. The ethical foundation of informed consent is **respect for persons**. Informed consent is required from participants involved in human research especially if the research constitutes a healthcare procedure. If informed consent cannot be obtained in writing, the circumstances under which consent was obtained should be recorded. If the participants themselves cannot provide informed consent, justification must be provided for using these participants within the research.

ii. HERG will be required to consider whether the circumstances are appropriate for the waiving of informed consent.

iii. Some of the basic criteria of informed consent to participate in research are:
- the participants are competent to understand the relevant issues prior to giving to their specific consent
- information about the proposed research, including any likely outcomes of participation in the research, is comprehensively, properly and appropriately given in lay terms
- the participants' consent is voluntary and not influenced by financial reward or by any form of duress, and the involvement of dependent or vulnerable groups must be appropriate with measures in place to ensure they are not exploited
- participants are able to withdraw from the research at any time without the loss of any rights and without giving reasons
- in the case of those who are unable to give their own consent, for example the mentally incapacitated or children, proxy consent is sought from a person with appropriate legal authority.

iv. It is not generally expected that deception will be used in research. In cases where deception is proposed, justification must be provided as well as a method of debriefing participants.

2.3 **The design and conduct of the study**

i. Lack of quality in a research project has ethical implications. Research with insufficient scientific merit will waste scarce resources, abuse the trust and commitment of participants, and may expose them to risk for no eventual benefit.

ii. HERG should verify that the scientific quality of proposed research has been assured through the researcher's Centre's internal peer review process and signed off by the Research Leader.

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2.4 **Risks and potential benefits**

i. The risks of the research should be reasonable in relation to the potential benefits. Risks can be physical, emotional, social, psychological, or financial.

ii. HERG should make sure that the proposed research poses minimal potential harm and negative impact to participants. HERG should also be aware that harm may occur at an individual, family or population level.

2.5 **Selection of study population and recruitment of research participants**

i. No group or class of persons should either bear more than its fair share of the burdens of participation in research or be deprived of its fair share of the benefits of research.

ii. HERG should consider whether the study population will benefit from participating in the research directly or benefit indirectly from the new knowledge derived from the research.

iii. Recruitment of research participants should be free from manipulation, coercion, deception, inducement or any other undue influence.

iv. Participants should be told the purpose of the research, the risks and benefits of participation and other relevant details that form the basis of informed consent.

2.6 **Payments for participation in research**

i. Any payment, koha or gift of money, goods or services to a research participant or to a body or organisation assisting in the recruitment of participants which constitutes an inducement to participate in the research is unacceptable. *(refer to Koha policy, OP-07/15 as a guide to the policy and procedures for giving koha)*.

ii. Reimbursement for participants' out-of-pocket expenses (e.g. taxi fares, meals, parking fees) or in compensation for inconvenience caused through their participation in the research may be made. Payments for inconvenience would typically be a nominal amount in recognition of the effort of the participant to attend the research event.

2.7 **Protection of research participants' privacy and confidentiality**

i. The privacy and confidentiality of research participants must be respected.

ii. Data must be stored securely to ensure confidentiality and retained in a manner that allows its credibility to be verified.

iii. Specific arrangements are needed to protect the physical security, collection, use, disclosure, storage and destruction of health information (refer to the Health Information Privacy Code, 1994[3] and Privacy Act, 1993.[4] Privacy Commissioner Te Mana Matapono Matatapu: available at Research Connections). www.privacy.org.nz

2.8 **Cultural responsiveness**

i. Often research is conducted within cultural settings that have evolved in a social and historical context. It is important that a researcher and their team reflect on the cultural perspectives of their organisations and workplaces, as these perspectives influence the attitudes and behaviors that are brought into the research environment.

ii. The researcher and their team need to identify how their own beliefs and value systems may differ from those of the participants in their research. This will require having clear processes and procedures in place to allow for the inclusion of different cultural values and beliefs and enable all cultural groups and their viewpoints to influence the way in which the research problem is defined and thus the way the research is designed, conducted, analysed and disseminated.

Such a process is more likely to lead to research that is responsive to the communities and/or populations involved which, in turn, should lead to benefits for these communities and populations.

iii. Within New Zealand, health research in particular is likely to have an impact upon Māori people and their communities. To this end, the researcher and their team should specifically identify how their research will support indigenous health gains and demonstrate a commitment to the principles of the Treaty of Waitangi.

[3] https://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Consolidated-HIPC-current-as-of-28-Sept-17.pdf
[4] http://www.legislation.govt.nz/act/public/1993/0028/latest/DLM296639.html

iv. HERG should ensure that all research involving human participants meets ethical standards that comply with international best practice. Best practice includes the expectation that researchers consult meaningfully with the participants of research about the study question(s), design and conduct of the research. As well as the HRC Research Ethics Guidelines, researchers should refer to the HRC Guidelines for Researchers on Health Research involving Māori (2010), and the Pacific Health Research Guidelines (2014).[5]

v. Additionally, all researchers conducting research involving Māori people or Māori artefacts need to be familiar with and follow the Wintec Policy Conducting Research in a Māori Context, AC-99/08 (A); AC-99/08 (B).

3 VULNERABLE PARTICIPANTS

3.1 A study is deemed to pose more than minimal risk where one or more participants are potentially vulnerable. Vulnerability is a broad category that includes people who:

- have limited capacity to make independent decisions about their participation in the study (i.e. who might be regarded as lacking the capacity to consent to participate)
- may lack the ability to consent freely or may be particularly susceptible to harm, either because of their health status, physical or mental capacity or employment status, or as a result of imprisonment.

3.2 Examples of potentially vulnerable people include:

- children and young people
- people with mental health issues
- people with serious intellectual disability
- people with English as a second language and/or a different cultural background to the Researcher (especially when the research details are primarily, or only, stated in English)
- people whose freedom to make independent choices is restricted (e.g. prisoners, ex-prisoners, employees or students of a researcher or a sponsoring industry partner).

3.3 It is important to note that, even if a group is identified as 'vulnerable', the label may not apply to all individuals in the group, and even where it does apply, it may do so only intermittently.

4 RESEARCH INVOLVING CHILDREN

4.1 Prior to undertaking research involving children the researcher must ensure that:

- children will not be involved in research that might be carried out equally well with adults.
- the purpose of the research is to obtain knowledge relevant to the needs of children.
- where possible, older children will be involved in preference to younger ones.
- the research is designed or supervised and carried out by people experienced in working with children.
- the number of children involved is limited to the number which is scientifically essential.

4.2 Research procedures or interventions that are intended to provide direct benefit to the child participants may be undertaken if:

- the risk is justified by the anticipated benefit to the child participants

[5] https://www.hrc.govt.nz/sites/default/files/2019-06/Resource%20Library%20PDF%20-%20Guidelines%20for%20Reseasrchers%20on%20Health%20Research%20involving%20Maori%20.pdf
https://gateway.hrc.govt.nz/funding/downloads/Pacific_health_research_guidelines.pdf

- the ratio of the anticipated benefit to the risk is at least as favorable to the child participant as any available alternative.

4.3 Research procedures which are not intended to be of direct benefit to the child participants, may be undertaken only if the risk presented by the interventions to the child participant is:
- minimal
- commensurate with the importance of the knowledge to be gained
- The interventions or procedures present experiences to the child participants which are reasonably commensurate with those inherent in their actual or expected medical, psychological, social or educational situations

4.4 When inviting children to participate in any research the researcher must ensure that the children, and where appropriate the children's parents, guardians or caregivers, have been fully informed about the research in a manner suited to their needs. This requires that:
- Each child be given full information about the research in a form that they can understand readily.
- Children are advised of their right to decline participation and their right to withdraw from the research at any time without giving a reason.
- The researcher gives the children an opportunity to ask questions and to have these answered to the child's satisfaction.
- A person giving proxy consent also has full information about the research and is advised of the child's right to decline participation or withdraw from the research at any time.
- A person giving proxy consent is given an opportunity to ask questions and have them answered to their satisfaction.

4.5 Before undertaking research with children the researcher must ensure that legally valid consent is sought on the basis of the information provided:
- A person of or above the age of 16 years may give consent to participate in their own right, provided they do not lack competence for reasons other than age.
- In the case of a child below the age of 16 years, or a person who lacks the necessary competence to give legally effective consent, proxy consent to the child's participation must be obtained and the child's assent must be obtained unless the child is unable to communicate. Refusal by a child to participate in research must be respected regardless of consent given by a proxy.

4.6 Consent and assent are dynamic, continuous processes and should be checked throughout the study to ensure they are maintained. Either consent and assent can be withdrawn at any time without penalty to the participant. If during the study a participant attains competence to give legally effective consent, their consent must be obtained and will replace the proxy consent.

4.7 Only one parent or legal guardian is required to give proxy consent. However, if there is more than one parent or guardian, and the research is not routine, there is an expectation that the person giving proxy consent will consult all of the other parents or legal guardians. The researcher is responsible for making the person giving proxy consent aware of their duty to consult and giving them sufficient time to do so.

4.8 If the researcher becomes aware that the person who gave proxy consent to the child's participation has been replaced, proxy consent should be obtained from the child's new legal guardian as soon as practicable.

4.9 Care must be taken to ensure that no pressure is placed upon a child to consent to

participate in research, especially if the procedures are not intended to be of direct benefit to the child participants.

4.10 The following points should be taken into consideration when consent or assent is withdrawn:

i. Withdrawal from the study should be managed in a responsible manner to avoid harm to the child.

ii. If the child gave either legally effective consent or assent to participate in the research, the child may withdraw their consent or assent at any time during the research without giving reasons and their wish to withdraw must be respected.

iii. A person giving proxy consent may withdraw consent at any time without giving reasons. The child must then be withdrawn from the study, unless the child has become competent to give legally effective consent and consents to continue to participate in the research.

4.11 Research data pertaining to child participants should be retained by the researcher for ten years after the child has attained the age of 16 years, with the proviso that children have the right to withdraw consent to the continued use or retention of personally identifiable research data once they attain the age of 16 years.

5 OBSERVATIONAL STUDIES

5.1 An observational study is either observational research or an audit or related activity.

5.2 Observational studies are distinguished from interventional or experimental studies as no intervention other than recording, classification, counting and analysis of data takes place.[6]

5.3 In observational studies, the researcher has no control over study variables and merely observes outcomes. However, some observational studies in social science research may include the observation of participants during an intervention.

5.4 The many types of audit and related activities are summarised as follows:

i. ***Audits*** involve the systematic evaluation of aspects of a system by considering measurable indicators of performance and/or quality.

ii. ***Programme evaluation*** is a type of audit in which a whole programme is evaluated, rather than specific interventions.

iii. ***Evaluation studies*** aim to determine the relevance, effectiveness and impact of activities in light of their objectives. There are several types of evaluation, including evaluation of the structure, process and outcome of an activity.

iv. ***Quality assurance*** activities aim to improve services by assessing the adequacy of existing practice against a standard.

v. ***Outcome analyses*** may involve the assessment of achievement of internally determined and planned outcomes without comparing them against a standard.

vi. ***Benchmarking*** aims to improve practice through the comparison of two or more services or systems.

[6] Whereas, in intervention or experimental studies, researchers may deliberately alter some feature of people's circumstances to study the effect of doing so.

vii. ***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.

viii. ***Resource utilisation*** reviews evaluate the use of resources in a particular system or activity.

5.5 The researcher should choose a method of approaching participants that meets ethical and scientific standards.

5.6 HERG's approval is required if health records or other forms of registry or records are to be obtained to identify and then approach participants for research.

5.7 When approaches to participants identified through such records involve visiting or telephoning them at their home, it is generally desirable that some advance notice be given (for example, through a letter). Additionally, the researcher or their field staff must provide their personal identification including a telephone number which the participant may call to establish their legitimacy. In some circumstances it may be appropriate to inform local police and other relevant authorities.

5.8 Interviewers should be properly trained and culturally sensitive, and should carry identification.

5.9 For communities in which collective decision-making is customary, communal leaders can express the collective will. However, the agreement or refusal of individuals to participate in a study has to be respected; a leader may express agreement or refusal on behalf of a community, but an individual's agreement or refusal of personal participation is binding.

5.10 Conversely, when an individual wishes to participate in a study that community leaders have objected to, individuals should be given information to this effect and the reasons that community leaders have declined to take part. Having considered this information, the individual then has the right to decide whether to participate.

5.11 Researchers who initiate a study within a whānau, hapū or iwi, when the researchers and participants are members of that same group, may prefer to provide, via a kaumātua or other person of authority in the group, a statement in the study proposal that group consent for participation was obtained from the representatives or participants in hui.

5.12 When a study is initiated from outside the whānau, hapū or iwi, or when the researchers do not have a representative from that group within their number, the usual procedures for informed consent to participate in the study are expected. In addition, a system of accountability of the researchers to the whānau, hapū or iwi concerned should be instituted after full discussion with and agreement by the participants and researchers. A group's right to decline to have a study proceed within their whānau, hapū or iwi if the study is unacceptable to them is paramount.

5.13 A representative of a community or group who will give consent on their behalf should be chosen according to the nature, traditions and political philosophy of the community or group. Approval given by a community representative should be consistent with general ethical principles.

5.14 When researchers work with communities, they must consider communal rights and protection as they would individual rights and protection.

6 THE COLLECTION AND USE OF RESEARCH PARTICIPANTS' INFORMATION

6.1 Two important definitions to note when handling information belonging to research participants are:

i. ***Privacy*** is the status of information about aspects of a person's life over which they claim control and which they may wish to exclude others from knowing. Privacy is a relative status and claims to it must be negotiated against countering claims, such as the rights of others or collective societal goods.

ii. ***Confidentiality*** is the respectful handling of information disclosed within relationships of trust, especially as regards further disclosure.

6.2 When a researcher proposes to collect information from a third party, this should be with the authority of the individual concerned, except in specific circumstances.

6.3 If the researcher proposes to collect personal information from a relative or other third party without the authority of the individual concerned, because that individual is deceased, untraceable or incapacitated, or for some other good reason, this approach should be justified to HERG on ethical and scientific grounds.

6.4 Access to medical or other records for the purposes of research should be restricted to appropriately qualified researchers and research associates responsible to them.

6.5 Researchers should be aware that access to health information is subject to the HIPC,[7] and that access to personal information is subject to the Privacy Act 1993.[8] Access to personal information may also be subject to the Official Information Act 1982.[9]

6.6 A named researcher to whom records are disclosed should give a written undertaking to ensure the confidentiality of the records.

6.7 Where a kaitiaki group has been established to act as guardian of information concerning Māori in the area of study, the kaitiaki group should be consulted. The purpose of kaitiaki groups is to give Māori control and protection of data concerning Māori and to ensure the data are used for the benefit of Māori, and that the aggregated data is not used in a way that affects Māori negatively.

6.8 The data used for research can be identified, potentially identifiable, partially de-identified, de-identified or anonymous. These terms are defined below.

i. ***Identified data*** allow a specific individual to be identified. Identifiers may include the individual's name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

ii. ***Potentially identifiable (key-coded, re-identifiable) data*** Key coding is the technique of separating personally identified data from substantive data, but maintaining a potential link by assigning an arbitrary code to each data-identifier pair before splitting them. Held securely and separately, the key allows the re-associating of the substantive data with the identifiers, under specified conditions, if that is ever necessary. Data can also be potentially identifiable if it is possible to infer an individual's identity from them.

iii. ***Partially de-identified data*** Data coded with abbreviated identifiers (for example, initials, date of birth, sex) are used for reporting HIV and some other conditions. This

[7] https://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Consolidated-HIPC-current-as-of-28-Sept-17.pdf
[8] http://www.legislation.govt.nz/act/public/1993/0028/latest/DLM296639.html
[9] http://www.legislation.govt.nz/act/public/1982/0156/latest/DLM64785.html

allows re-identification by the clinician reporting, but is anonymous to the recipient, although duplicates can be linked.

iv. ***De-identified (anonymized, anonymous, unlinked) data*** has had all identifiers removed permanently.

v. ***Anonymous data*** are collected without personal identifiers, and no personal identifier can be inferred from them.

6.9 Access to identifiable or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:

- the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study, or it is impossible in practice to obtain consent due to the quantity or age of the records
- there would be no disadvantage to the participants or their relatives or to any collectivities involved
- the public interest in the research outweighs the public interest in privacy.

6.10 A researcher who proposes not to seek informed consent for use of identified or potentially identifiable data for research must explain to HERG the reasons for not seeking consent, and how the study will be conducted in an ethical manner in the absence of consent.

6.11 The researcher must also demonstrate how safeguards will be maintained to protect confidentiality, and that the study has the goal of protecting or advancing societal interest.

6.12 When identified or potentially identifiable data are used in research, the information must not be used in a way that causes disadvantage to any participant.

6.13 Research may involve the collection and storage of personal information relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress.

6.14 Researchers should arrange to protect the confidentiality of such data by, for example, omitting information that might lead to the identification of individual participants, or limiting access to the data, or by other means.

6.15 Researchers are required to ensure the adequate physical and electronic security of data.

6.16 For studies involving the collection of information about illegal activities – for example, the use of illegal substances – potential participants should be made aware of whether researchers can or cannot ensure confidentiality.

6.17 Identified or potentially identifiable personal data should not be used when the study could be done without personal identification (for example, by key coding or unlinking the data).

6.18 When personal identifiers remain on records used for a research project, researchers should be able to justify this and ensure confidentiality will be protected.

6.19 A individuals' privacy and confidentiality of information need to be ensured unless there is an overriding ethical concern (for example, health or safety) justifying the release of such information or if such release is required by law.

6.20 If privacy or confidentiality must be breached, the researcher should first make a reasonable attempt to inform participants of such required infringements.

6.21 Research protocols should include provision for communicating results in a timely, understandable and responsible manner, so that benefit to the community is maximised and fairly distributed, noting that either premature release or unnecessarily delayed release of study results can be more harmful than beneficial to individuals and society.

6.22 Researchers have an ethical obligation to advocate the release of information that is in the public interest, even when the data is retained by governmental or commercial sponsors.

6.23 The publication of both positive and negative results of research is important, since it helps to prevent publication bias and allows for additional information to be gleaned through meta-analyses.

6.24 Researchers should strive to ensure that, the results of their research are interpreted and reported accurately. They should, wherever possible, anticipate and avoid misinterpretation of results which might cause harm.

6.25 The results of research must not be published in a form that permits the identification of individual participants (unless participants have consented to being identified) and must be published in a form that gives due regard to cultural and other sensitivities.

6.26 Conflict may arise for researchers between doing no harm and openly disclosing research results. Harm may be mitigated by presenting data in such a way that the interests of those at risk are protected and scientific integrity is maintained.

7 RESEARCHER'S RESPONSIBLITIES TO THEIR RESEARCH PARTICIPANTS

7.1 Researchers are obliged to promote and safeguard the health, safety, well-being and rights of participants involved in or affected by their research.

7.2 These include the obligation to:

- assess and minimise foreseeable hazards and safeguard the safety and health of research participants.
- only involve people as participants if the potential benefits sufficiently outweigh the risk of harm to those participants.
- design and perform their research in accordance with an accepted research protocol which conforms to widely applied good practice in their discipline, and which describes how the following ethical principles for human participants have been addressed:
    - disclosure of research aims
    - respect for personal autonomy through informed and voluntary consent
    - respect for the right to privacy and confidentiality
    - recognition of the vulnerability of some participants
    - minimisation of harm, including cultural harm
    - avoidance of conflicts of interest
    - respect for established property rights including intellectual, material, financial and
    - cultural rights
    - social and cultural responsibility.
- obtain approval of the proposed protocol involving human participants from HERG
- disclose the research aims to participants, normally in advance of the research, but at a later time if the HERG is satisfied that advance disclosure would adversely affect either data quality or the validity of the research method
- prioritise the welfare of participants, including ensuring that there are sufficient

protections (including, where relevant, insurance) for participants who suffer injury or are harmed as a result of participation in research
- disclose any vested interest in the research to HERG, and to participants; and refer the matter to HERG should any unexpected ethical issue arise and, if necessary, be prepared to stop the research and not restart it until HERG's approval to do so has been obtained
- avoid coercion, and inform potential participants v of their right to refuse participation without negative consequences and to withdraw from the research at any time

8 RESEARCHER'S RESPONSIBLITIES WHEN MANAGING DATA AND SAMPLES

8.1 Researcher are obliged to develop, and implement as far as they are reasonably able, a management plan to ensure the integrity, secure storage and appropriate use of data and samples gathered and/or developed as part of their research.

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8.2 In the development and implementation of their management plan, researchers are obliged to:

- recognise the different types of data and samples, including personal and community data
- identify situations in which both individual and community permissions are required
- recognise the mana that Māori, iwi and hapū have over data and samples collected from and about them, their communities, cultural knowledge and resources, including respecting any rights to ownership, governance and control of use of the data or samples
- recognise and disclose the intellectual property that may exist in any data or samples
- ensure that the established rights of the intellectual property owner are recognised and observed
- ensure that all conditions under which consent has been given, including any limitations on future use of the data and samples, are recorded and those records securely linked to the data or samples
- ensure or require that all conditions of consent are complied with whenever the data and samples are used, collated, interpreted or presented
- ensure that if data or samples collected for one restricted purpose are proposed to be used for another, all practicable steps are taken to extend existing consents or obtain new consents
- ensure that all data and samples have clear labelling and annotations to enable their accurate interpretation by others
- endeavour to safeguard the privacy of individuals when data sets are collated or aggregated with other data
- ensure that samples of any newly discovered flora and fauna are lodged in recognised national collections or with appropriate authorities.

9 RESEARCHER'S RESPONSIBLITIES TO ENSURE THE SUSTAINABILITY AND GUARDIANSHIP OF THE ENVIRONMENT

9.1 Researchers are obliged to recognise the need for the sustainable management of resources and minimise any foreseeable adverse environmental impacts arising during or resulting from their research activities

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9.2 Consistent with with this principle, researchers are obliged to:

- endeavour to utilise all resources efficiently
- minimise the generation of waste and, where applicable, encourage the environmentally sound re-use, recycling and disposal of waste
- observe the principles and practices of sustainable management

- identify and assess the impacts of their activities on the environment, and take steps to avoid or mitigate any adverse effects
- inform decision makers, mana whenua and others likely to be affected by any environmental impacts of their research, and engage such stakeholders with regard to any foreseeable consequences arising from this
- not impair the ongoing conservation of unique or valued features, components and systems within the Aotearoa New Zealand natural environment
- not impair the ongoing protection and conservation of artefacts, places or areas of cultural or historical significance; and where practicable, endeavour to partner with Māori as kaitiaki in activities likely to affect taonga species, or flora and fauna indigenous to Aotearoa New Zealand significantly.

GLOSSARY

Iwi	Tribe, nation, people, community
Te reo Māori	Māori language
Tikanga Māori	Māori method or custom. Encompassing things or ways pertinent to an authentic Māori view or lifestyle
Rangahau	Research underpinned by Māori principles
Koha	Gift, present, offering, donation, contribution - especially one maintaining social relationships, with connotations of reciprocity
Whānau	Extended family, family group - the primary economic unit of traditional Māori society
Hapū	Kinship group, subtribe - the primary political unit in traditional Māori society
Kaumātua	Elderly man or woman, - a person of status and authority within the whānau
Hui	Gathering, meeting, assembly, seminar, conference
Mana whenua	Trusteeship of land, authority over land or territory, jurisdiction over land or territory
Kaitiaki	Trustee, custodian, guardian, steward
Taonga	Treasure, anything prized - applied to anything considered to be of value

WINTEC'S HUMAN ETHICS IN RESEARCH STRUCTURE AND PROCESSES

The Human Ethics in Research Group (HERG)

Wintec's Human Ethics in Research Group (HERG) is accredited to the Health Research Council (HRC). Its terms of reference are developed and applied in alignment with HRC requirements in order to maintain this accreditation.

HERG is the Committee that receives and makes decisions on all research ethics applications, with the aim of protecting the rights and safety of human participants, as well as processes and products arising from research.

HERG members shall adhere to the following Terms of Reference:

- The Committee will receive, review, and make decisions on research ethics applications submitted to them.
- HERG will communicate each decision to the applicant in writing. HERG may offer appropriate advice to the researcher/s involved should clarification be required.
- The minutes of each meeting and an annual report will be forwarded to the Research Committee.
- Standard Local Body Act protocols will apply to the disclosure of these minutes and all information received is confidential.
- Members of the Committee will be required to declare any conflicts of interest related to specific applications.
- New members will be appointed to the HERG by the Research Committee of the Academic Board.

Members appointed to the HERG are expected to collectively possess experience and expertise in the following areas in order to maintain HRC accreditation:

- a recognised awareness of te reo Māori and understanding of tikanga Māori, and Rangahau (research underpinned by Māori principles);
- ethical and moral reasoning;
- law;
- the perspectives of the wider community (e.g. the perspectives of consumers of health and disability services, iwi);
- the design and conduct of intervention studies;
- the design and conduct of observational studies;
- the provision of health and disability services;
- reviewing qualitative and quantitative research.

Gender balance of an Ethics Committee should be as close to half male and half female as practicable.

The composition of the HERG should adhere to the following:

- One Non-staff Member (Chair)
- One Non-staff Māori Representative
- Research and Development Director (or delegate)
- Māori Achievement Manager (or delegate)
- One Non-staff Representative

- Eight Wintec Researchers, i.e. Staff members actively involved in research, of whom:
  - Two are registered health professionals (one clinically trained, one in active practice)
  - One has a background in science
- One Student Representative
- Research Coordinator or delegate (Executive Officer non-voting)

The constitution of HERG shall be as follows:

- A quorum will be 50% plus one. In order to review health-related applications at least one internal health professional member needs to be present.
- The Committee should meet monthly or as required.
- The term of office for members will be three years from the date of appointment. Members may complete two consecutive terms and may be reappointed for a further two terms after a three-year stand-down period.

The recruitment of new internal and external members shall adhere to the following process:

- This process will be led by the Research Office through an open invitation for nominations at Wintec
- All applications (with CV) will be taken to HERG for review and feedback
- Applications that align with the composition, and meet the expertise and experience requirement of the HRC, will be submitted to the Research Committee of the Academic Board for ratification
- All HERG members are to be appointed by the Research Committee.

Procedures for Ethical Scrutiny

The role of the HERG is to ensure that ethical standards for all research undertaken by Wintec staff or students or on behalf of Wintec are met. This includes scrutiny of all stages of a research project, i.e. planning, implementation, analysis and dissemination.

Prior to submitting a research proposal for approval, a researcher will address all ethical considerations, including the relevant professional codes. This will be done in consultation with their mentor/s, research supervisor, and research leader who collectively are expected to possess recognised expertise and experience in the relevant research processes and content areas.

The first step in the research approval process is for the researcher to complete the Screening Questionnaire to determine whether their project requires Low Risk or Full Ethics approval.

Low risk research applications are reviewed and approved by the HERG Chairperson, in consultation with the Research Office, with details of the approved applications kept on record by the Research Office.

Low risk applications that are not approved are returned to the researcher for necessary revisions in order to gain such approval.

Research designated as needing Full Ethics approval requires review by the HERG at its monthly meeting. Possible outcomes of the ethical review process are:

- approved as is,
- provisionally approved subject to meeting stated requirements,
- approval deferred, or
- declined.

All researchers will be notified in writing of the HERG's decision.

If the research is approved, researchers must fulfil their stated obligations as identified by HERG during all stages of the research being conducted, with any changes to these obligations to be included in the interim and final reports.

If approval is deferred, the research must not proceed until the issues raised by the HERG have been addressed and resubmitted to the full satisfaction of HERG.

If approval is declined, the researcher may not proceed with their research. The notification to the researcher will include the full justification for declining the research, as well as a notice of the right to appeal to the Academic Board or to seek a second opinion from the University of Waikato's Ethics Committee.

Procedures for Appeal

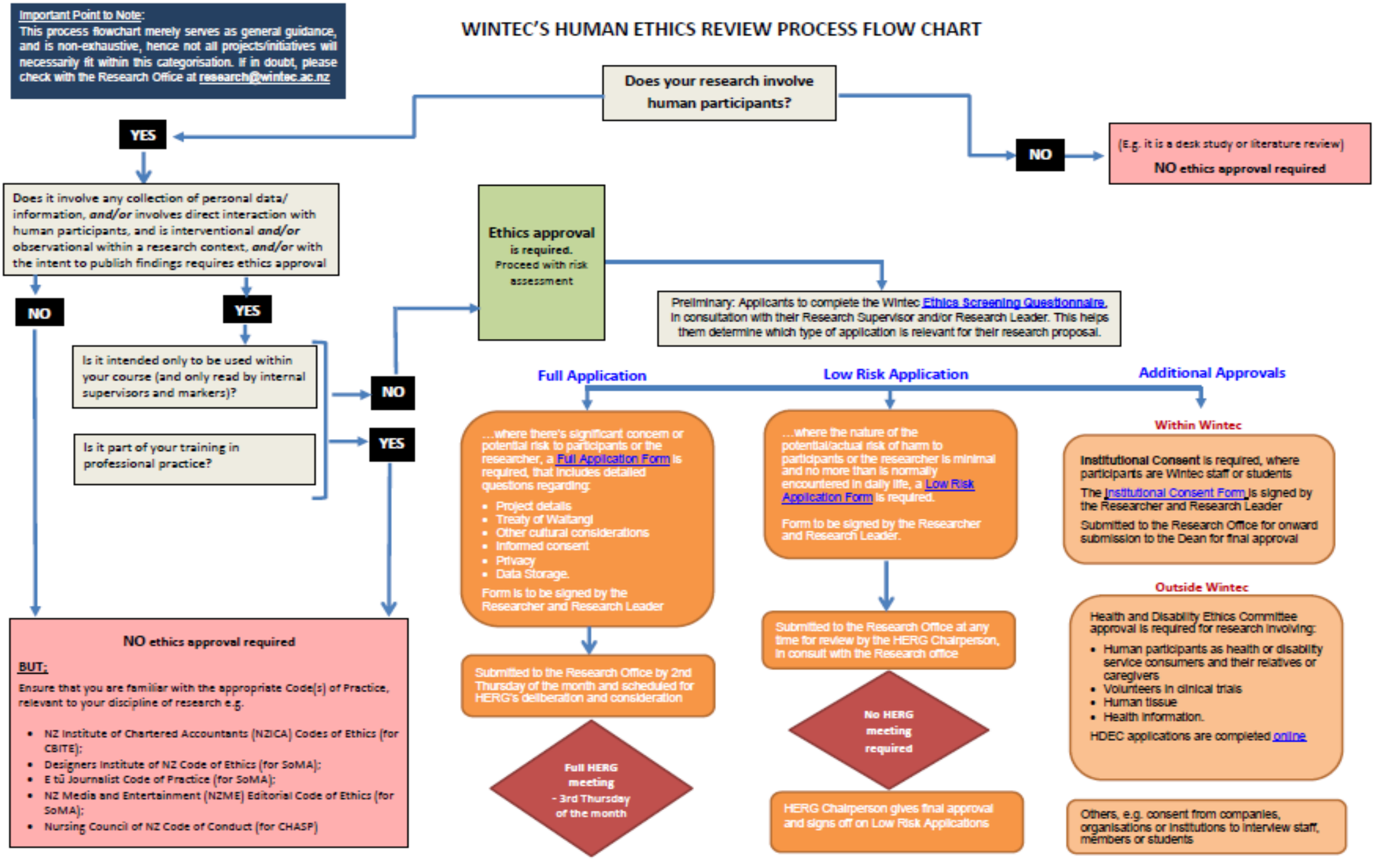
Complaints about the administration and/or a decision of the Human Ethics in Research Group (HERG) must be made to the HERG Chairperson or the Research Office, in the first instance. It is expected that many issues will be able to be resolved through this process.

If the outcome of the complaint process is not satisfactory, a second opinion may be sought from the University of Waikato's Ethics Committee.

The University of Waikato's Ethics Committee will consider the application and forward its opinion to HERG.

However, if HERG does not agree with the opinion of the University of Waikato's Ethics Committee, it will provide a rationale to the researcher. The final decision remains with HERG.

Appendix 2


Important Point to Note:
This process flowchart merely serves as general guidance, and is non-exhaustive, hence not all projects/initiatives will necessarily fit within this categorisation. If in doubt, please check with the Research Office at research@wintec.ac.nz
WINTEC'S HUMAN ETHICS REVIEW PROCESS FLOW CHART
Does your research involve human participants?
YES
NO
(E.g. it is a desk study or literature review)
NO ethics approval required
Does it involve any collection of personal data/ information, and/or involves direct interaction with human participants, and is interventional and/or observational within a research context, and/or with the intent to publish findings requires ethics approval
NO
YES
Is it intended only to be used within your course (and only read by internal supervisors and markers)?
Is it part of your training in professional practice?
NO
YES
Ethics approval is required. Proceed with risk assessment
Preliminary: Applicants to complete the Wintec Ethics Screening Questionnaire, in consultation with their Research Supervisor and/or Research Leader. This helps them determine which type of application is relevant for their research proposal.
Full Application
Low Risk Application
Additional Approvals
...where there's significant concern or potential risk to participants or the researcher, a Full Application Form is required, that includes detailed questions regarding:
Project details
Treaty of Waitangi
Other cultural considerations
Informed consent
Privacy
Data Storage.
Form is to be signed by the Researcher and Research Leader
Submitted to the Research Office by 2nd Thursday of the month and scheduled for HERG's deliberation and consideration
Full HERG meeting - 3rd Thursday of the month
...where the nature of the potential/actual risk of harm to participants or the researcher is minimal and no more than is normally encountered in daily life, a Low Risk Application Form is required.
Form to be signed by the Researcher and Research Leader.
Submitted to the Research Office at any time for review by the HERG Chairperson, in consult with the Research office
No HERG meeting required
HERG Chairperson gives final approval and signs off on Low Risk Applications
Within Wintec
Institutional Consent is required, where participants are Wintec staff or students
The Institutional Consent Form is signed by the Researcher and Research Leader
Submitted to the Research Office for onward submission to the Dean for final approval
Outside Wintec
Health and Disability Ethics Committee approval is required for research involving:
Human participants as health or disability service consumers and their relatives or caregivers
Volunteers in clinical trials
Human tissue
Health information.
HDEC applications are completed online
Others, e.g. consent from companies, organisations or institutions to interview staff, members or students
NO ethics approval required
BUT:
Ensure that you are familiar with the appropriate Code(s) of Practice, relevant to your discipline of research e.g.
NZ Institute of Chartered Accountants (NZICA) Codes of Ethics (for CBITE);
Designers Institute of NZ Code of Ethics (for SoMA);
E tū Journalist Code of Practice (for SoMA);
NZ Media and Entertainment (NZME) Editorial Code of Ethics (for SoMA);
Nursing Council of NZ Code of Conduct (for CHASP)