

# **Ethical Guidelines for Observational Studies**

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**Observational research, audits  
and related activities:  
Revised edition**

**July 2012**

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## Foreword to the 2012 edition

These *Guidelines* were first released in 2006; the current document is a revision. The Health Committee's inquiry into improving New Zealand's environment to support innovation through clinical trials (June 2011) resulted in significant changes to the ethics review process, as reflected in the revised *Standard Operating Procedures* (SOPs) for Health and Disability Ethics Committees.

This 2012 revision aims to provide consistency with the SOPs. These *Guidelines* have been updated to remove process guidance, and ensure that policy previously included in the *Operational Standard for Ethics Committees* is now addressed by these *Guidelines*. The revision did not fundamentally change the existing ethical standards and principles set out in these *Guidelines*.

As previously, the *Guidelines* are directed primarily to investigators, who have the main ethical responsibility for good study conduct. But the *Guidelines* also continue to be directed to others with a role in health and disability research ethics – particularly the ethics committees that review studies against established ethical standards. The key objectives of developing national ethical guidelines are to:

- safeguard the rights and interests of participants in research and innovative practice
- promote high-quality ethical research for the social, cultural and economic wellbeing of society
- reflect the principles of the Treaty of Waitangi and protect Māori cultural interests, promote the wellbeing of Māori and ensure mechanisms for Māori participation in both research and ethical review
- foster awareness of ethical principles and practices among health care providers, researchers and the wider community
- give due consideration to local and national community views and perspectives on ethical review.

The 2012 revision was subject to a brief targeted consultation and the Committee is grateful to all who have contributed.



Victoria Hinson  
**Chair, National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**

## Foreword to the 2006 edition

Observational studies benefit all of us. For example, they show us whether our services are safe and effective, they tell us whether chemicals in the environment are harmful, they enable us to deal with clusters of disease and outbreaks of infection by determining their source, and they monitor the state of our country's health in key areas. In short, observational studies give us vital evidence about our health and how best to protect and improve it. They do this by using personal information for public good. To do it well they must meet high ethical standards.

Observational studies are relatively low-risk. There are two main reasons for this. In these studies, the investigators observe and analyse information about health or disability but do not alter the care or services that people receive, and secondly, there is generally a reduced potential for conflict between the investigator role and the clinician role. Observational studies differ from intervention studies, in which investigators intentionally alter people's care or services to study the safety and benefit of doing so.

The following Ethical Guidelines for Observational Studies (the *Guidelines*) are intended to facilitate high-quality studies, protect the interests of participants and underpin public assurance of good study conduct. The *Guidelines* have several internationally significant features. One of these is their wide scope, covering observational research and audits and other activities that are related to observational research. These other activities are: programme evaluation, evaluation studies, quality assurance activities, outcome analysis, benchmarking, public health investigations, public health surveillance, pharmacovigilance and resource utilisation review. Second, the *Guidelines* are directed primarily to investigators, who have ethical responsibility for good study conduct. They are also directed to ethics committees that review studies against established ethical standards, and to other interested communities and individuals. Third the *Guidelines* are structured around the process of study conduct, from formulation of the study question through to dissemination of its findings. Fourth, the *Guidelines* set out the circumstances when observational studies require ethics committee review.

The *Guidelines* base their requirements for ethical review on the principle that intensity of ethical scrutiny should be proportional to the level of risk of the activity. For procedural information about when a study requires health and disability ethics committee review, and whether it should constitute full review or expedited review, please visit [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz).

The National Ethics Advisory Committee generated the first edition of the *Guidelines* through a thorough and inclusive process over three years. This included a questionnaire to health and disability ethics committee members and researchers, public consultation on two discussion documents, interviews and group meetings with key informants and public agencies, a cross-sectoral workshop and an independent peer review report. The *Guidelines* reflect the many improvements suggested by a wide range of stakeholders through these processes. The Committee is grateful to all those who have contributed.



Andrew Moore

**Chair (2001–2010), National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**

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# 1 Introduction

- 1.1 These *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (the *Guidelines*) are issued in accordance with the statutory function of the National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Advisory Committee – Kāhui Matatika o te Motu, or NEAC), under the New Zealand Public Health and Disability Act 2000, section 16, to ‘determine nationally consistent ethical standards across the health sector’. The *Guidelines* are also developed in accordance with the Minister of Health’s request that NEAC:
- develop guidelines on conducting observational studies in an ethical manner and establish the parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research) (Minister of Health, 2001, 2004).
- 1.2 The Guidelines constitute ‘ethical standards’, for the purposes of the Code of Health and Disability Services Consumers’ Rights 1996 (the Code of Rights), Right 4(2).
- 1.3 An observational study is not a ‘clinical trial’, for the purposes of the Accident Compensation Act 2001, section 32.
- 1.4 An observational study is not ‘human reproductive research’, for the purposes of the Human Assisted Reproductive Technology Act 2004 (the HART Act). The *Guidelines* nevertheless constitute ‘applicable ethical standards’ for the purposes of the HART Act, section 27(4).
- 1.5 An observational study is not ‘medical or scientific experimentation’ or ‘medical treatment’ for the purposes of the New Zealand Bill of Rights Act 1990, sections 10 and 11.
- 1.6 These *Guidelines* are based on statements from New Zealand and international guidelines (see the Bibliography). They accord with key international guidelines, including the *World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects* (WMA 2008) and the Council for International Organizations of Medical Sciences’ *International Guidelines for Ethical Review of Epidemiological Studies* (CIOMS 1991). Researchers should be familiar with relevant sources of international and domestic ethical guidance materials as indicated in the Bibliography. In the domestic context, researchers should particularly be aware of guidelines relating to research involving Māori, such as the Health Research Council’s *Guidelines for Researchers on Health Research involving Māori* (HRC 2010), and NEAC’s resource document *Māori Research Ethics: An overview* (in press).
- 1.7 These *Guidelines* are written primarily for investigators conducting observational studies. They are structured around the process an investigator undertakes when designing and conducting a study, from the consideration of the underlying ethical considerations to the communication of study results.

- 1.8 Detailed matters concerning health and disability ethics committee (HDEC) review of observational studies are addressed in the standard operating procedures (SOPs) for HDECs established under the New Zealand Public Health and Disability Act 2000, section 11. The SOPs were created in 2012 in response to the Government response to the Select Committee inquiry into improving New Zealand's environment to support innovation through clinical trials. They provide procedural guidance to HDECs and researchers, and set out the scope of HDEC review and information about how HDECs process applications. These *Guidelines* set the ethical standards that must be met or exceeded in all health and disability research, whether or not it requires HDEC review. The SOPs apply to observational studies, but these *Guidelines* have precedence over the SOPs on any point of conflict relating to the ethical standards and principles that must be met or exceeded in all health and disability research.
- 1.9 These *Guidelines* also include references to wider legislative provisions. It is the investigator's responsibility to comply with all relevant legal requirements, including those set out in the Privacy Act 1993, the Code of Rights and the Health Information Privacy Code 1994 (the HIPC). (A useful guide to the HIPC is *Health Research and Privacy: Guidance Notes for Health Researchers and Ethics Committees* (HRC 2002b).)
- 1.10 The HIPC is issued under the Privacy Act 1993, section 46, is legally binding and has the status of a regulation. The HIPC specifies 12 information privacy rules in relation to health agencies and health information, so is applicable to observational studies. The HIPC is available on the Privacy Commissioner's website ([www.privacy.org.nz](http://www.privacy.org.nz)).
- 1.11 The Code of Rights is a regulation issued under the Health and Disability Commissioner Act 1994, section 74. The Code of Rights sets out 10 rights applicable to all health and disability services consumers, including those involved in research. Investigators conducting observational research, audits and other related activities should be familiar with their responsibilities under the Code of Rights, and should consider their study in light of the rights of (proposed) participants. The Code of Rights is available on the Health and Disability Commissioner's website ([www.hdc.org.nz](http://www.hdc.org.nz)). Specific rights from the Code of Rights are noted at relevant points in these *Guidelines*. (Note also that some provisions give legal effect to ethical standards. For example, the Code of Rights, Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards'.)
- 1.12 If you wish to comment on your experience with using these *Guidelines*, please contact NEAC at the address below. The Committee intends to review the *Guidelines* by the end of 2015, and would be grateful for your comments to inform that process.
- Email: [neac@moh.govt.nz](mailto:neac@moh.govt.nz) (with 'Observational Studies' in the subject line)
- Postal address: Observational Studies, National Ethics Advisory Committee Secretariat, PO Box 5013, Wellington 6145.

## 2 Guidelines scope and definitions

- 2.1 This document is intended primarily to guide investigators conducting observational studies, including audits and related activities. The term ‘observational studies’, as used in these *Guidelines*, refers to epidemiological and clinical observational research and to audits and related activities. Audits and other activities are included because they share ethically relevant characteristics with observational research. These *Guidelines* apply primarily to observational studies in New Zealand settings.
- 2.2 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. (In intervention or experimental studies investigators deliberately alter some feature of people’s health or disability circumstances to study the effect of doing so. Examples of intervention research include randomised controlled trials.) In observational studies the investigator has no control over study variables and merely observes outcomes. These studies are distinct from observational studies in social science research, which may include the observation of participants during an intervention. Most observational research is epidemiological or health services research, but some observational studies, including most case series and case studies, are conducted by clinicians in personal care settings.

### Types of observational research

- 2.3 The primary purpose or justification for observational research is to add to generalisable knowledge about a health or disability issue. The six main types of observational research are summarised below.
- **Case control studies** examine the relationship between an attribute and a disease by comparing those with and without the disease with respect to the presence of the attribute or level of exposure to it.
  - **Cohort studies** examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcome) by observing large numbers of people over a period of time and comparing incidence rates of the disease (or outcome) in relation to exposure levels. A cohort study may be a clinical cohort study (for example, where a group of patients with a given disease is followed to examine the prognosis).
  - **Cross-sectional studies** examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one particular point in time, by collecting health and other information concerning members of the population. These include questionnaires or surveys done for research purposes.
  - **Case reports** are reports of cases from health or disability services or research settings.

- **Case series** describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication.
- **Descriptive studies** examine the existing distribution of variables in populations, for example, analyses of cancer registry data or emergency department data by person, place or time.

## Types of audit or related activity

2.4 The primary purpose or justification for an audit or related activity is to improve delivery of the particular health or disability support service being studied or to control a threat to public health. (The results of audits and related activities should be disseminated at least to those able to take necessary action. Wider dissemination, including through publication in scientific journals, may sometimes be appropriate.) The 10 main types of audit and related activities are summarised below.

- **Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.
- **Programme evaluation** is a type of audit where a whole programme is evaluated, rather than specific interventions.
- **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.
- **Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.
- **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.
- **Benchmarking** aims to improve practice through the comparison of two or more health and disability support services.
- **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.
- **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.
- **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).

- **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.
- 2.5 A small number of observational studies include certain activities, such as specimen collection, storage and use and genetic testing, which are not addressed in these *Guidelines*. Investigators should refer to relevant international and national guidance regarding such activities. (For example, information on the collection and use of human materials can be found in *Guidelines on Ethics in Health Research* (HRC 2002a.) Note that all clinical research involving the manipulation of human genetic material must be approved by the Health Research Council’s Gene Technology Advisory Committee (HRC 2002a). See the Medicines Act 1981, section 30; the Crown Entities Act 2004, section 73(1)(c) and Schedule 1; and HRC 2002a, p 28.
- 2.6 These *Guidelines* do not apply to observational research that uses only publicly available documents or data.
- 2.7 While these *Guidelines* may be useful for investigators conducting other forms of non-intervention study, such as qualitative and social science research, note that those studies use distinct methods that may raise separate ethical issues.

## 3 Ethics of observational studies

- 3.1 This section concerns the worth of observational studies and responsibilities for the ethics of the studies.

### Worth of observational studies

- 3.2 The public is entitled to health and disability support services that are safe and effective. The public also has an interest in a safe environment. Observational studies play important roles in support of these public interests. For example, observational research might examine the relationship between exposures (such as chemicals in the environment or the use of medicines) and subsequent disease. For health services users, observational research can further the understanding and management of their disorder. Similarly, it is essential that any deficiency in health or disability support services is identified and acted upon, and audits and related activities can play key roles in this. Service providers should inform the public that observational studies are essential for the high-quality delivery of health or disability services, and that their information may be used for such activities. They should also give consumers details of the measures taken to protect participants from harm.

### Ethical requirements of observational studies

- 3.3 Investigators conducting, or involved in conducting, observational studies are responsible for ensuring these studies meet ethical standards. This is the case whether or not ethics committee review is also required. When there is more than one investigator, the principal investigator has the overall responsibility for the ethics of the activity.
- 3.4 The greater the risk of harm from an observational study, the greater the care that is required in assessing and addressing the ethical issues raised.
- 3.5 Section 11 of these *Guidelines* outlines the features of observational studies that may present more than minimal risk to participants and that require review by an ethics committee. The Ministry of Health's SOPs provide specific guidance about when HDEC review is required. If an investigator is unsure whether ethics committee review of any particular study is required, he or she should seek advice from an ethics committee.

- 3.6 Public health investigations, as defined above, do not require ethics committee review. This is because they are required for the protection of public health as a central part of public health practice, they are often of an immediate or urgent nature, and they are often required by legislation (the Health Act 1956, the Health (Infectious and Notifiable Diseases) Regulations 1966, the Tuberculosis Act 1948 or the Venereal Diseases Regulations 1982). Examples of such activities include investigations, undertaken by authorised people, into clusters of disease suspected to be caused by environmental agents, and contact tracing (in which efforts are made to locate and treat people who have had close or intimate contact with a person with a known case of a communicable disease). People conducting public health investigations are nevertheless free to seek advice from an ethics committee about any special issues that arise.
- 3.7 People conducting quality assurance activities should be familiar with the Health Practitioners Competence Assurance Act 2003 (HPCA), especially sections 54–63. When the Minister of Health has declared an activity to be a ‘protected quality assurance activity’, the HPCA protects the confidentiality of information obtained in the course of the activity and gives the investigator immunity from civil liability. See also *Protected Quality Assurance Activities under the Health Practitioners Competence Assurance Act 2003* (Ministry of Health 2004).

## 4 Underlying ethical considerations

- 4.1 The following considerations are important to the ethics of observational studies. The application and weighting of these considerations will vary depending on the nature and particular circumstances of the observational study in question.

### Respect for people

- 4.2 Respect for people, and for their rights, incorporates at least two fundamental principles:
- autonomy, which requires that people who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination
  - protection of people with impaired or diminished autonomy, which requires that people who are dependent or vulnerable be afforded security against harm.
- (See also the Code of Rights, Right 1(1): 'Every consumer has the right to be treated with respect'.)

### Māori and ethical considerations

- 4.3 *He Korowai Oranga: Māori Health Strategy* specifies that 'The Government is committed to fulfilling the special relationship between iwi and the Crown under the Treaty of Waitangi' (Minister of Health and Associate Minister of Health 2002, p 2). This commitment should be respected by all investigators and, when applicable, should be reflected in the design and conduct of observational studies. Relevant principles that apply include:
- partnership: working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected in order to achieve health gain
  - participation: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori
  - protection: actively protecting Māori individual and collective rights, and Māori data, cultural concepts, norms, practices and language in the research process.
- 4.4 Issues relating to Māori cultural and ethical values should be addressed in discussion with Māori concerned, including appropriate whānau, hapū or iwi. *He Korowai Oranga* states: 'Comprehensive, high-quality Māori health research and information is necessary to inform the Government and to assist whānau, hapū and iwi to determine and provide for their own health priorities' (Minister of Health and Associate Minister of Health 2002, p 23).

- 4.5 There should be due recognition of Māori as the tāngata whenua and indigenous people of Aotearoa New Zealand.
- 4.6 Researchers should have regard to guidelines relating to research involving Māori such as the *Guidelines for Researchers on Health Research involving Māori* (HRC 2010) and NEAC's resource document *Māori Research Ethics: An overview* (in press).

## Justice

- 4.7 Justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in a study, and for any participant, a balance of burdens and benefits.
- 4.8 Accordingly, an investigator must:
- a) avoid imposing on particular groups an unfair burden of participation in research, audits or related activities; for example, vulnerable members of communities should not bear disproportionate burdens of studies from which other members of the community are intended to benefit
  - b) design studies so the inclusion and exclusion conditions for participants are fair
  - c) not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of ethnicity, age, sex, disability or religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study.

## Beneficence and non-maleficence

- 4.9 The risks of a study should be reasonable in the light of the expected benefits.
- 4.10 Investigators should consider the features of a proposed study in the light of ethical considerations, and satisfactorily resolve ethical issues raised by the study. Not all ethical considerations weigh equally. A study may be assessed as ethically justifiable even if an usual ethical expectation, such as confidentiality of data, has not been comprehensively met, provided the potential benefits clearly outweigh the risks and the investigators can minimise the risks.
- 4.11 A proportionate approach should be taken: the greater the risk of harm from the study, the greater should be the care in addressing the ethical issues raised.
- 4.12 Above the threshold of minimal risk, a study warrants greater provision for the protection of participants. A study is within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms from participation in the study as no greater than those encountered in those aspects of everyday life that relate to the study (for example, a clinical consultation with a health care provider).

- 4.13 The potential harms associated with observational studies are generally less than with experimental studies, as no intrusive intervention takes place and participants are less likely to be in a dependent relationship with the investigator. Depending on the method used (whether previously collected information is used or new information is collected) potential harms in observational studies could include breaches of confidentiality.
- 4.14 Audits and related activities are typically minimal-risk activities. Compared with research, they typically have more predictable benefits and reduced risks. They provide benefits for people receiving health care or disability services, by being specifically directed at improving the delivery of that care or those services, or provide benefits to the public by addressing risks to public health. For this reason, in some settings it is unethical for health care or disability services, or a public health risk, not to be studied by an audit or related activity. (See also the Code of Rights, Right 4(4): ‘Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer’.)
- 4.15 In general, when there is some engagement with affected communities during the conduct of the study, there is more likely to be long-term benefit to study participants and to the community.

## Integrity

- 4.16 An investigator’s commitment to the advancement of knowledge implies a duty to conduct honest and thoughtful inquiry and rigorous analysis, and to be accountable for her or his activities.

## Diversity

- 4.17 As they conduct observational studies, investigators should understand, respect and make due allowance for diversity among participants and their communities. (See also the Code of Rights, Right 1(3): ‘Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Māori’.)

## Conflict of interest

- 4.18 Investigators should identify to co-investigators, sponsors, employers, participants and, where applicable, ethics committees any perceived, potential or actual conflict of interest he or she might have in relation to any others who are involved with the study. Such conflicts of interest can compromise the design or conduct of a study or the reliability of its results, thereby exposing study participants or others to needless risk or inconvenience.
- 4.19 As appropriate to the circumstances, any conflict of interest should be minimised.

## 5 Design of study and protocol

### Study question

- 5.1 Investigators should meet their obligations to communities by undertaking research that addresses important health problems.
- 5.2 In identifying and prioritising health problems to be studied, investigators should take into account the perceived importance of the problem to the people living in a community after information about the problem has been provided to them. However, if investigators perceive that a health problem exists but that the community is ignoring it or denying its existence, it may be appropriate to proceed with the study while simultaneously working with the community to gain its confidence and support.
- 5.3 Investigators should ensure any audit and related activities they undertake have the potential to improve health outcomes.
- 5.4 The ethical principle of justice may be interpreted as requiring efforts to reduce inequalities. Decision-making about the study question could include consideration of the study's potential to reduce health inequalities.

### Study design

- 5.5 The study design must minimise risk of harm.
- 5.6 To the extent possible and whenever appropriate, investigators should involve community representatives in the planning and conduct of the study.

### Scientifically sound

- 5.7 Scientific inadequacies in a study proposal have ethical implications. The scientific quality of a proposal should be such that the proposal's objectives can reasonably be expected to be achieved. For example, a questionnaire unlikely to achieve an adequate response rate will be scientifically inadequate. It is important that studies that include Māori participants and aim to generate conclusions relevant to Māori engage sufficient numbers of Māori participants to produce useful data and avoid imposing an unethical burden on Māori. Projects without scientific merit waste resources and needlessly use participants' donated time.

- 5.8 Every study proposal must be based on a thorough review of relevant current literature. Scientific validity is an important component of good ethical practice in research. Investigators are advised to submit their proposals to independent peer review to help optimise scientific validity. HDECs also require evidence of adequate peer review. Additional information about the features of a robust peer review process for assessing the scientific validity of research is included in the Appendix.

## Skills and resources

- 5.9 Studies must be conducted or supervised only by investigators with the necessary skills and resources to conduct the study and deal with any contingencies that may affect participants. Necessary skills may include competence in understanding different cultural understandings of knowledge and of how such understandings might impact on the analysis and results of a study.
- 5.10 People conducting audits or related activities must operate under professional standards or employment requirements that oblige them to maintain the confidentiality of patient data.

## Protocol

- 5.11 All observational studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected. A principle of proportionality applies here: the amount of detail in the written protocol and the extent of protocol review processes should be related to the level of risk the study presents to participants.
- 5.12 When relevant, the protocol should include a statistical plan indicating the rationale for the number of participants involved.

## 6 Collecting health information

- 6.1 In relation to the collection of health information, investigators should provide to observational study participants any information that a reasonable person in their circumstances would expect to receive. This is so whether or not consent to participate in the study is required. The information required (if any) will depend on the design of the observational study in question. The Code of Rights, Right 6(1)(d) states:
- Every consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including ... notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.  
(See also paragraph 3.2.)
- 6.2 Investigators should provide to study participants any information about who will have access to study data that a reasonable person in their circumstances would expect to receive. (See also the Code of Rights, Right 6(3)(a): 'Every consumer has the right to honest and accurate answers to questions relating to services, including questions about ... the identity and qualifications of the provider'.)
- 6.3 See also the HIPC, Rule 3 and Privacy Act 1993, Principle 3.

### Identifiability of health information

- 6.4 A key issue concerning health information is whether the individual concerned is 'identifiable' from the information. The data used for observational studies can be identified, potentially identifiable, partially de-identified, de-identified or anonymous. These terms are defined below.
- **Identified data:** 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.
  - **Potentially identifiable (key-coded, re-identifiable) data:** Key coding is the technique of separating personally identified data from substantive data, maintaining a potential link by assigning an arbitrary code number 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 (Lowrance 2002). Data may be single-coded, or double-coded if extra security is required. Data can also be potentially identifiable if it is possible to infer an individual's identity from them.
  - **Partially de-identified (AIDS-type code) data:** Data coded with abbreviated identifiers (for example, initials, date of birth, sex) are used for reporting AIDS, HIV and some other conditions. This allows re-identification by the clinician reporting, but is anonymous to the recipient, although duplicates can be linked.

- **De-identified (not re-identifiable, anonymised, anonymous, unlinked) data:** The process of de-identification can be irreversible if the identifiers have been removed permanently. These data are referred to as 'de-identified' data. It should be recognised that the term 'de-identified' is used frequently in other documents to refer to sets of data from which only names have been removed; in fact such data may remain 'potentially identifiable'.
- **Anonymous data:** Anonymous data have been collected without personal identifiers, and no personal identifier can be inferred from them.

## Collection of health information directly from individuals

### Approach

- 6.5 The investigator should choose a method of approaching participants that meets ethical and scientific standards.
- 6.6 Ethics committee approval is required if health records (including disease registries) are used to identify and then approach individuals for research; the approach may be made directly or by the participant's doctor or relevant health practitioner. If the approach is not to be made through the participant's health practitioner, the reasons for this should be presented to the ethics committee. In such cases, either prior agreement from the participant's health practitioner should be sought to invite the individual to take part, or the participant's health practitioner should be informed that the individual will be invited to take part. In the latter circumstance, the individual should be informed of the name of the person who agreed to their being approached.
- 6.7 The reason for seeking the consent of the person's medical adviser for an individual to be invited to take part in research is not to usurp the individual's right to make the final decision about whether to take part, but to minimise the possibility of harm or distress to them. The medical adviser should be aware of the person's situation and be able to forbid a direct approach in the unusual situation that the person could be unduly distressed. Where there is uncertainty, the medical adviser should check with the individual concerned that an approach is acceptable (HRC 2002a, p 42).
- 6.8 When approaches to participants identified through health records involve visiting or telephoning them at their home, it is generally desirable that some advance notice be given (for example, through a letter).

### Interviews

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

## Free and informed consent

- 6.10 Investigators should obtain the prior informed consent of study participants (with certain exceptions: see paragraphs 6.19–6.21, 6.27, 6.35–6.37 and especially 6.43–6.47; see also the Code of Rights, Right 7(1): ‘Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this code provides otherwise’).
- 6.11 Informed consent has two basic components.
- a) The decision is informed by adequate understanding of any information that is relevant to that decision.
  - b) The decision is voluntary, and is therefore free from undue influence such as manipulation or coercion.
- (See also the Code of Rights, Right 2: ‘Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation’.)
- 6.12 Information about the purpose of the study should be as specific as possible without compromising the validity of the study.
- 6.13 In some situations, providing very specific information about the study in advance of seeking consent would prejudice the purposes of the collection by compromising the scientific validity of the study. For example, if a mother is to be interviewed to establish whether she has been exposed to a particular medicine that might have caused a congenital abnormality in her baby, it would be wrong, when asking her to consent to the study, to give her the name of the drug in question. If the name of the drug were disclosed, this may have at least one scientifically unacceptable consequence, in that the information collected may be biased. This is because if the mother in question had a baby with a birth defect, she would have had both a reason and a longer period of time, in advance of the actual interview, to remember that she had been exposed to the drug.
- 6.14 In contrast, a mother of a healthy baby would have less reason to remember past exposure, and would not reflect on possible past exposure during the period between the consent procedure and the actual interview. This effect could lead to a spurious association between birth defects and drug exposure in the mothers interviewed; thus, if such an association were found, the finding could be scientifically invalid. In studies such as this, biased reporting can be minimised, and scientific validity assured, only by not disclosing in advance the complete details of the hypothesis under test (HRC 2002a, p 38).
- 6.15 When specific information cannot be provided at the outset, the investigator should offer to provide results to participants. (See also the Code of Rights, Right 6(3)(d): ‘Every consumer has the right to honest and accurate answers to questions relating to services, including questions about ... the results of research’.)
- 6.16 When investigators collect information directly from individuals, or seek their consent to access records, they should inform them that supplying information is voluntary.

- 6.17 The right of any person to decline to take part in a study or to withdraw from the study at any time must always be explained and respected. This includes the right to decline to answer all or any questions in a questionnaire. (See also the Code of Rights, Right 7(7): ‘Every consumer has the right to refuse services and to withdraw consent to services’.)
- 6.18 When a study involves people in dependent or unequal relationships, the investigator must ensure that their refusal to participate in, or decision to withdraw from, the study will not result in discrimination, a reduced level of care or any other disadvantage.

### People with diminished competence to give consent

- 6.19 Ethical consideration of studies involving individuals or groups who have diminished competence to give free and informed consent on their own behalf (for example, children) must seek to balance:
- a) the vulnerability that arises from the participants’ diminished competence; with
  - b) the injustice that would arise from their exclusion from the benefits of observational studies in these groups. (See also the Code of Rights, Right 7(3): ‘Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence’.)
- 6.20 Subject to applicable legal requirements, individuals who are not legally competent may be asked to become participants in observational research only when the study question can only be addressed:
- a) with the participation of those individuals from identified group(s); and
  - b) when free and informed consent is sought from their legal representative(s), such as a welfare guardian or a representative with enduring power of attorney.
- (See also the Code of Rights, Right 7(4).)
- 6.21 When free and informed consent has been obtained from an authorised third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the study, the investigator must seek to ascertain the individual’s wishes concerning his or her participation. The potential participant’s dissent will preclude his or her participation.

### Inducements

- 6.22 Investigators may seek to create legitimate motivation for participation in studies, but may not exert pressure by offering inappropriate inducements.
- 6.23 Risks involved in participation should be acceptable to participants even in the absence of inducement.
- 6.24 It is acceptable for investigators to repay the incurred expenses of participants (for example, travel costs).

- 6.25 A koha may be offered in line with the cultural norms of the study participants, but should not be of such a value that it could reasonably be interpreted as an inappropriate inducement or as a payment for participation. For this reason, it is often not appropriate to discuss koha before getting an agreement to participate. (Traditionally, koha is an acknowledgement of the knowledge and/or hospitality extended by tāngata whenua to manuhiri. It is presented as part of the pōwhiri onto a marae or other venue of the tāngata whenua. However, the definition of koha should not be restricted by reference to its traditional roots; contemporary meanings include the giving of koha in a different manner during research.)

## Documentation

- 6.26 Evidence of free and informed consent by a participant or authorised third party should ordinarily be obtained in writing.
- 6.27 When written consent is culturally unacceptable or good reasons exist for not recording consent in writing (such as in the case of anonymous data collection or telephone interviews), the procedures used to seek free and informed consent should be documented.
- 6.28 Questionnaires are often innocuous, and may even be offered by mail. Completion of the questionnaire can be taken as consent, provided the letter of invitation expressly leaves the participant free of obligation.
- 6.29 Some studies may involve interviews or questionnaires that are intrusive and may cause distress. In this case, it is appropriate to seek participants' prior consent by forewarning them of the potentially distressing nature of participation.

## Collective consent

- 6.30 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. 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 why community leaders have declined to take part. Having considered this information, the individual then has the right to decide whether to participate. Paragraphs 6.31–6.35 should be interpreted in the light of this paragraph.
- 6.31 Investigators who initiate a study within a whānau, hapū or iwi, when the investigators and participants are members of that same group, may prefer to provide, via a kaumatua 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.

- 6.32 An individual's right to decline to participate in the study, expressed in hui, should also be noted. The statement of group consent obtained in hui should allow for study participants to withdraw at any time from the study if they so wish.
- 6.33 When a study is initiated from outside the whānau, hapū or iwi, or when the investigators 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 investigators to the whānau, hapū or iwi concerned should be instituted after full discussion with and agreement by the participants and investigators. 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.
- 6.34 Not all Māori have contact with whānau, hapū or iwi, and the usual requirements for fully informed consent to participate in a study proposal will be expected in such cases.
- 6.35 When it is not possible to request informed consent from every individual to be studied (for example, in a community study of the effects of water fluoridation), the agreement of a representative of a community or group may be sought, but the representative 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. When investigators work with communities, they will consider communal rights and protection as they would individual rights and protection.

## Collection of health information from a third party

### Authorisation

- 6.36 When an investigator proposes to collect information from a third party, this should be with the authority of the individual concerned, except in specific circumstances.
- 6.37 If the investigator 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 an ethics committee on ethical and scientific grounds.

### Collection of health information from records

- 6.38 Access to medical or other records for the purposes of observational studies should be restricted to appropriately qualified investigators and study associates responsible to them.
- 6.39 Investigators should be aware that access to health information is subject to the HIPC, and that access to personal information is subject to the Privacy Act 1993. Access to personal information may also be subject to the Official Information Act 1982.
- 6.40 A named investigator to whom records are disclosed should give a written undertaking to ensure the confidentiality of the records.

- 6.41 In the case of records involving Māori health information, 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 health, and that the aggregated data is not used in a way that negatively affects Māori. See, for example, the Health (Cervical Screening (Kaitiaki)) Regulations 1995.

## Consent

- 6.42 The consent of participants should generally be obtained for using identified or potentially identifiable data for research.

## Collection of health information without consent

- 6.43 Access to identified 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; and
  - there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
  - the public interest in the study outweighs the public interest in privacy.
- 6.44 An example of when the procedures required to obtain consent were likely to cause unnecessary anxiety is a study of the use of an asthma drug as a possible cause of sudden deaths from asthma. This study compared the medical records of individuals who had died from asthma with the records of asthmatics who had been admitted to hospital but had not died. It would have been wrong to have sought the consent of the group who had not died, because informing these people of an untested hypothesis might have frightened and distressed them without good cause (HRC 2002a, p 37).
- 6.45 An investigator who proposes not to seek informed consent for use of identified or potentially identifiable data for research must explain to an ethics committee the reasons for not seeking consent, and how the study would be ethical in the absence of consent.
- 6.46 The investigator must show how safeguards will be maintained to protect confidentiality, and that the study has the goal of protecting or advancing health.
- 6.47 In the case of audits and related activities it may be ethical to use health information without additional or specific consent, as these activities are sometimes an essential part of high-quality health care delivery, so the activity may be one of the reasons why the data were collected.

## 7 Use of information

- 7.1 When identified or potentially identifiable data are used in a study, the information must not be used in a way that causes disadvantage to any participant.
- 7.2 If study data are to be used for any purpose or by any people other than as specified in the approved protocol, investigators should ascertain whether they need to submit a proposed revision of the study protocol or a new protocol to an ethics committee (see the SOPs for HDECs).
- 7.3 See also the HIPC, Rule 10 and Privacy Act 1993, Principle 10.

## 8 Confidentiality of data

### General considerations

- 8.1 Observational studies may involve collecting and storing personal information relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress.
- 8.2 Investigators 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.
- 8.3 Investigators are required to ensure the adequate physical and electronic security of data.
- 8.4 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 investigators can or cannot ensure confidentiality.
- 8.5 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).
- 8.6 When personal identifiers remain on records used for a study, investigators should be able to justify this and ensure confidentiality will be protected.
- 8.7 In the unusual event that group confidentiality cannot be maintained or is violated, investigators should take all reasonable steps to maintain or restore a group's good name and status.
- 8.8 Audits or related activities should be conducted by people who are under a professional or an employment obligation to maintain patient confidentiality. Such activity may be initiated from outside the organisation or by the organisation itself, and may be conducted by the organisation (an internal audit or related activity) or by a party external to it (an external audit or related activity).
- 8.9 Note that 'privacy' is the status of information about aspects of a person's life over which he or she claims control and 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. 'Confidentiality' is the respectful handling of information disclosed within relationships of trust, especially as regards further disclosure (Lowrance 2002).
- 8.10 See also HIPC, Rules 5 and 11 and Privacy Act 1993, Principles 5 and 11.

## Record linkage

- 8.11 An investigator must justify to an ethics committee any observational study that involves linkage between records without consent, where participants are identified or are potentially identifiable, on the basis of the following principles:
- a) the identity of participants is not disclosed except for the purposes of the record linkage and is not retained once record linkage has been completed; and
  - b) identifying information is used with sufficient security; and
  - c) the research has potential to benefit the public.
- 8.12 In the case of audits and related activities, the use of record linkages without specific or additional consent is ethically justifiable when these activities are part of high-quality health care delivery.

## 9 When to reveal information obtained by observational studies

- 9.1 If it is reasonably foreseeable that health problems previously unknown to an individual will be identified during the study process, then arrangements for referral, with the individual's consent, should be made. When findings suggest serious disease, study participants who have not given permission for the transfer of the information to their medical advisor should be urged to seek further advice. Care should be taken not to interfere with health professional–patient relationships. Investigators should usually refrain from giving an opinion about how a particular finding should be dealt with by a participant's doctor.
- 9.2 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.
- 9.3 If privacy or confidentiality must be breached, the investigator should first make a reasonable attempt to inform participants of such required infringements.

## 10 Communicating study results

- 10.1 The potential benefits of observational studies are that participants and the community will be informed of general results that pertain to their health and that studies may provide objective results that policy makers can use to formulate sound public health policy.
- 10.2 Study 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. The optimal time at which to disseminate the results of observational studies can be difficult to determine. Both premature release and unnecessarily delayed release of study results can be more harmful than beneficial to individuals and society. It may be difficult to balance the need to communicate results to other scientists with appropriate peer review and the need to communicate results to other interested parties without undue delay.
- 10.3 Investigators 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.
- 10.4 Study results and advice to communities should be publicised by whatever suitable means are available.
- 10.5 The publication of both positive and negative<sup>1</sup> study results is important, since it helps to prevent publication bias and allows for additional information to be gleaned through meta-analyses.
- 10.6 Investigators should strive to ensure that, at a minimum, study results are interpreted and reported on accurately.
- 10.7 Investigators should, when possible, anticipate and avoid misinterpretation of study results, as misinterpretation might cause harm.
- 10.8 Results of a study must not be published in a form that permits the identification of individual participants, and must be published in a form that gives due regard to cultural and other sensitivities.
- 10.9 Conflict may arise for investigators between doing no harm and openly disclosing scientific 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.

<sup>1</sup> For example, that no link was found between a particular study variable and disease.

# 11 Features of observational studies that pose more than minimal risk

- 11.1 This section outlines the features of observational research that may present more than minimal risk to participants.
- 11.2 More than minimal risk observational research requires ethics committee review (see Chapter 3 of the Ministry of Health’s SOPs on the scope of ethical review). Any observational study that has one or more of the features identified in the table below has potential to cause harm, and is therefore a more than minimal risk activity. In accordance with the SOPs, such activity requires HDEC review, unless there is an exception. The exceptions apply to situations where there is added protection for participants or another justification. If a study falls outside the scope of HDEC review and an investigator still wishes to have an ethics review, they may choose to submit the proposal to an alternative ethics committee.

**Table 1: Observational studies constituting more than minimal risk**

11.3 Departure from normal care	
Something withheld from or done to a patient that deviates from normal health care constitutes more than minimal risk (for example, when extra blood samples or biopsies are taken).	
11.4 Use of stored samples	Exception
Use, collection or storage of human tissue without informed consent and use of stored samples for study purposes other than those for which they were originally collected constitutes a more than minimal risk activity.	<p>Exceptions to this rule include:</p> <ul style="list-style-type: none"> <li>• where participants have given informed consent to future unspecified use of human tissue</li> <li>• where a statutory exception to the need to gain informed consent (as set out in the Human Tissue Act 2008, section 20(f) or the Code of Rights, Right 7(10)(c)) applies</li> <li>• where stored samples are used by health professionals undertaking one or more of the following activities to assure or improve the quality of services:               <ul style="list-style-type: none"> <li>a) a professionally recognised quality assurance programme (for example, pathologists re-reading specimens to check the accuracy of their own or a peer’s work)</li> <li>b) an external audit of services</li> <li>c) an external evaluation of services.</li> </ul> </li> </ul> <p>The justification for this is that the use is related to the primary purpose of the sample collection. See the Code of Rights, Right 7(10).</p>

11.5 Secondary use of identifiable health information without consent	Exception
<p>Investigator use of identifiable health information that was primarily collected for clinical care for a secondary purpose without consent constitutes a more than minimal risk activity.</p>	<p>Exceptions to this rule include:</p> <ul style="list-style-type: none"> <li>• where the individual has consented to this use or disclosure</li> <li>• where the information is not identifiable</li> <li>• where a statutory exception to the need to gain informed consent (as set out in the Code of Rights, Right 7(10)(c)) applies</li> <li>• where secondary use of data is for the purpose of quality assurance or outcome analysis</li> <li>• where resource review is undertaken by those employed or contracted by the health or disability support service provider holding the information.</li> </ul> <p>The justification for this is that the use is related to the primary purpose of the data collection, and in such settings only individuals bound by a professional or an employment obligation to preserve confidentiality should have access to identified or potentially identifiable information.</p>
11.6 Vulnerable participants	
<p>A study poses more than minimal risk where one or more participants are potentially vulnerable. Vulnerability is a broad category. It includes people who have restricted capability to make independent decisions about their participation in the study (ie, who might traditionally be regarded as lacking the capacity to consent to participate). It also encompasses people who may lack the ability to consent freely or may be particularly susceptible to harm either because of their health status, physical or mental capacity or employment status, or as a result of imprisonment. Non-exhaustive examples of potentially vulnerable people include:</p> <ul style="list-style-type: none"> <li>• children and young people</li> <li>• people with mental illness</li> <li>• people with serious intellectual disability</li> <li>• people with English as a second language and/or a different cultural background to the investigators (for studies whose details are primarily, or only, stated in English)</li> <li>• people whose freedom to make independent choices is restricted (eg, prisoners, employees or students of a researcher or sponsoring company).</li> </ul> <p>It is important to remember that even if a group is identified as being likely to be vulnerable, the label may not apply to all individuals in such groups, and even where it does apply, it may do so only intermittently.</p>	

## 12 Additional points

- 12.1 Publication or an intention to publish does not mean an activity is classified as research, does not make it a more than minimal risk activity, and does not trigger any requirement for ethics committee review. Any investigator who intends to publish results of any observational study should ensure the activity has been conducted in accordance with these *Guidelines*, and should inform the editor concerned whether or not ethics committee review is required. This is consistent with the guidance provided in the International Committee of Medical Journal Editors' *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and editing for biomedical publication* (2004, section 11.F).
- 12.2 When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.
- 12.3 Investigators should ensure that they comply with internal organisational requirements in respect of observational research, all audits and related activities that they conduct in or through it. The appropriate approach will vary from organisation to organisation; as such, organisations might also specify their own processes regarding notification or approval.
- 12.4 Chapter 10 of the Ministry of Health SOPs provides guidance about requirements for locality authorisation.

## Bibliography

**Note:** This bibliography is restricted to national and international guidance statements. A full bibliography of works consulted in the preparation of these *Guidelines* is available on the NEAC website ([www.neac.health.govt.nz](http://www.neac.health.govt.nz)).

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# Appendix: Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research

## Background

This document seeks to outline the principles of peer review that might be undertaken to assure New Zealand's Health and Disability Ethics Committees (HDECs) of the scientific validity of a research proposal. Scientific validity of a research project is one component of the research being ethically sound. Research with insufficient scientific validity will waste scarce resources, will misuse the trust and commitment of participants, and may needlessly expose them to risk for no appropriate return.

The term 'scientific validity' is used in the 2012 *Standard operating procedures* (SOPs) for HDECs, without definition. These *Guidelines* and the *Guidelines for Intervention Studies* (2012) refer to studies being 'scientifically sound', which encompasses the expectation that a proposal's objectives can reasonably be expected to be achieved. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* (WHO 2011) refers to 'valid scientific methods' as part of Standard 7: Ethical basis for decision-making in research ethics committees. Important factors in this standard include how the study will be conducted, the qualifications of the researcher(s), the adequacy of provisions made for monitoring and auditing, and the adequacy of the study site (eg, availability of qualified staff and appropriate infrastructures).

The Government, in its response to the Health Committee's 2011 Inquiry into improving New Zealand's environment to support innovation through clinical trials (Health Committee, June 2011), decided that researchers and research sponsors will be 'responsible for ensuring that their research has been peer-reviewed for scientific quality' (response to recommendation 14). The SOPs state that HDECs will check that appropriate peer review (of scientific validity) has been carried out, but will not conduct it themselves. HDECs may not require specific, defined changes to research protocols on the grounds of lack of scientific validity as a condition of HDEC approval.

This guidance does not explain *how* review of a research proposal can be obtained, but lays out the features of a fit-for-purpose peer review process. It is anticipated that these guidelines will be of use both to those seeking ethical approval for their health and disability research, and to those undertaking ethical review of research proposals, to verify that the scientific validity of proposed research has been assured through an appropriate peer review process.

## Peer review

The role of New Zealand's HDECs is to check that proposed health and disability research meets established ethical standards that aim to protect participants (see the SOPs). The SOPs require that researchers and sponsors ensure that the scientific validity of proposed research has been peer-reviewed before an application is made to an HDEC. In this context, peer review is the process by which an applicant can assure an HDEC that a proposal has an appropriate degree of scientific merit, feasibility and likelihood of impact.

## 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:

- **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 whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. It should determine 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. The research will be achievable within the specified timeframe and the research team has the appropriate experience and expertise to undertake the research.

## Core features of the peer review process

A peer review process should be commensurate with the type of proposal, the potential risk to participants and where the research will be undertaken. The type of peer review process that is used must be fit-for-purpose and justifiable. For example, the mechanism for delivering peer review of a graduate student project carried out largely within a tertiary institution will differ from that of a multi-centre clinical trial. Opinions from one or more peers may be sought; again, the extent of peer review should be fit-for-purpose. Despite potential differences, an appropriate process for ensuring scientific validity will have the following features:

- **Peer review delivers an informed opinion:** An effective peer review process provides perspectives from subject matter experts. It may be suitable for informed perspectives to be sought from individuals in the same organisation as the researcher, as long as the requirements of freedom from bias, equity and fairness can be met. An appropriate peer is one who can deliver an informed opinion on some or all of a proposal. Reviewers will be knowledgeable about the topic and/or context for the research, have the appropriate expertise relative to the breadth and scope of research under review and, as a result, will be well placed to make a statement as to whether the research in question has verifiable scientific merit. Peer review of scientific validity may include consideration of cultural relevance and appropriateness.
- **Peer review delivers an objective opinion:** Those acting in the capacity of reviewers are charged with delivering a balanced and considered analysis of the research. Generally, the success of the peer review process is determined by the extent to which these evaluations can be considered free of bias, equitable and fair. Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements.
  - **A consensus opinion on scientific validity is formed:** An HDEC will need to receive assurance that the peer review process has delivered support for the scientific validity of the proposed research. When a peer review process has engaged a range of experts, there needs to be a process that leads to a consensus opinion about the quality of the research.
  - **Intellectual capital in the research proposal is respected:** A peer reviewer is in a privileged position through having access to the unexploited ideas and intellectual capital of the researcher. A peer review process should require that reviewers do not disclose the substance of any research proposal, unless there is explicit permission to do so.

## Limitations of peer review

Peer reviewers typically are not privy to the operational details of a proposed research study. Research proposals usually will outline a methodology, but not explain its implementation in detail. For example, a proposal might state how many patients will be recruited, but will not necessarily explain how patients will be approached, how they might be compensated for participation, nor what information any participant information sheet might contain. Similarly, the detailed clinical trial protocols are not typically included in a peer review. (Detailed examination of a trial protocol is often undertaken by the independent data and safety monitoring committee associated with the trial.) Ethics committees should be aware that studies can be of satisfactory scientific quality as judged by peer review, but still pose ethical concerns because of how the research is to be operationalised. Necessarily, consideration of the safety of participants and researchers, and the balance of risk and benefit, by ethics committees is likely to involve scrutiny of study design and execution.