

# **Operational Standard for Ethics Committees**

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## Foreword

The Ministry of Health published the first *Standard for Hospital and Area Health Board Ethics Committees Established to Review Research and Treatment Protocols* in 1988 following the inquiry into the treatment of cervical cancer at National Women's Hospital. Since then the Standard has undergone a series of revisions to reflect the growing experience, expertise and knowledge being accumulated by health and disability ethics committees. Each revision has aimed to facilitate the effective operation of ethics committees and promote the highest standard of ethical behaviour among researchers and providers.

In July 1999 work commenced on reviewing the *1996 National Standard for Ethics Committees (National Standard)*. The goal of the review was to provide a more comprehensive resource to guide ethics committees reviewing research and innovative practice. Following extensive consultation, the *2001 Operational Standard for Ethics Committees (Operational Standard)* was developed.

I would like to take this opportunity to thank those who have participated in the review of the *National Standard* and the development of the *Operational Standard*. In particular, I would like to acknowledge the contribution of the representatives of the health and disability ethics committees and the Health Research Council Ethics Committee.

This *Operational Standard* provides guidance on a number of principles that should be considered when reviewing research proposals, and sets out consistent operational and administrative procedures common to all ethics committees. In addition, the *Operational Standard* recognises the role and functions of the National Advisory Committee on Health and Disability Support Services Ethics, the National Ethics Committee on Assisted Human Reproduction, and the Health Research Council Ethics Committee.

The National Advisory Committee on Health and Disability Support Services Ethics (National Ethics Committee) will be responsible for future revisions to the *Operational Standard*. The National Ethics Committee is likely to review the *Operational Standard* upon completion of its review of the operation of ethics committees.

Researchers and health professionals continue to challenge the boundaries of modern health care through the expansion of scientific knowledge and the resulting development of new treatments and technologies. As ethics committees are among those at the forefront of ensuring such advances occur in a safe and ethical manner, they will increasingly be faced with considering the ethical aspects of new and emerging areas of research and innovative practice. It is my hope that ethics committees will find this *Operational Standard* to be a useful and practical resource, which will assist in the consideration of emerging ethical issues.



Hon Annette King  
Minister of Health

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# 1 Ethical Review

## 1.0 Preamble

1. This *Operational Standard* applies to ethics committees that review the ethics of research and innovative practice, and provide advice on issues relating to the delivery of health and disability services.
2. The *Operational Standard* is designed to:
  - i. protect participants in research and innovative practice and consumers of health and disability services
  - ii. achieve consistency of ethical review throughout New Zealand
  - iii. provide researchers and purchasers of research with guidance on the processes for ethical review
  - iv. promote awareness of the Code of Health and Disability Service Consumers' Rights 1996
  - v. promote awareness of the Health Information Privacy Code 1994
  - vi. respect the principles of the Treaty of Waitangi by ensuring a Māori ethical practices and standards are included in review (refer to section 1.4 "Treaty of Waitangi").

## 1.1 Use of the *Operational Standard*

3. The *Operational Standard* comprises guidelines designed to promote both flexibility and consistency in ethical review throughout New Zealand and should be interpreted accordingly.

## 1.2 Purpose of the *Operational Standard*

4. The *Operational Standard* is designed to provide guidelines for the constitution and operation of ethics committees reviewing health and disability research (refer to Part 6 for the 'Constitution of Health and Disability Ethics Committees'). Ethics committees review the ethics of research and innovative practice, and provide advice on issues relating to the delivery of health and disability services.
5. The *Operational Standard* forms the basis for monitoring the operation of ethics committees, which review research and innovative practice, and provide advice on ethical issues relating to clinical decisions about the treatment of specific consumers.
6. The *Operational Standard* outlines the minimum requirements to be met by ethics committees for the purposes of section 32 of the Injury Prevention, Rehabilitation, and Compensation Act 2001 (IPRAC Act), section 25(1)(c) of the Health Research Council Act 1990, and the Health Information Privacy Code 1994.

7. All ethics committees reviewing health and disability research in New Zealand should be approved to the requirements of the *Operational Standard* by the Director-General of Health or the Health Research Council (HRC) to ensure the attainment of appropriate standards and best practice.

### **1.3 Objectives of ethical review**

8. The objectives of ethics committees are to:
  - i. safeguard the rights and interests of participants in research and innovative practice, and consumers of health and disability services
  - ii. protect Māori cultural interests, promote the wellbeing of Māori and ensure mechanisms for Māori participation in ethical review
  - iii. foster awareness of ethical principles and practices within service providers, researchers and the wider community
  - iv. consider any ethical matters relevant to health and disability services
  - v. promote excellence in research for the wellbeing of society
  - vi. give due consideration to both local and national community views and perspectives in ethical review
  - vii. assure the public that the above are being done.

### **1.4 Treaty of Waitangi**

9. The principles of the Treaty of Waitangi must be incorporated in the proceedings and processes of ethics committees; particularly relevant are the principles of:
  - i. Partnership – working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected
  - ii. Participation – involving Māori in the design, governance, management, implementation and analysis of research, especially research involving Māori
  - iii. Protection – actively protecting Māori individual and collective rights, Māori data, Māori culture, cultural concepts, values, norms, practices and language in the research process.
10. All parties involved in research and the delivery of health and disability services should respect the principles implicit in the Treaty of Waitangi.
11. Research, innovative practice and the provision of services must be undertaken in a culturally sensitive and appropriate manner in full discussion and partnership with research participants and/or health and disability services consumers. The results of any research must be appropriately disseminated in a full and frank manner. The rights of research participants and consumers of health and disability services with regard to personal data must be respected.

12. Te reo Māori is an official language of New Zealand and is highly valued by many research respondents. Research respondents should be offered the choice of responding in either Māori or English (or, alternatively, if people volunteer to respond in Māori, they should not be excluded for wanting to do so). If researchers are not fluent, appropriate alternative arrangements should be made to enable respondents to communicate in Māori.

## **1.5 Māori cultural concepts**

13. Broad Māori cultural concepts should be respected and supported through ethical review. Such concepts include Māori perspectives of health and wellbeing such as te taha tinana (the physical element), te taha wairua (the spiritual element), te taha hinengaro (the emotional and psychological elements) and te taha whānau (the family and community elements). Other important concepts are hauora, kaupapa Māori, and tikanga Māori.
14. Research on Māori or Māori health should be considered on a case by case basis to assess whether or not the research project requires explicit inclusion of Māori ethical perspectives in ethical approval documentation. Māori ethical perspectives not only operate to ensure high quality research on Māori or Māori health, but also to ensure Māori participants, tikanga, and cultural concepts are protected. In most cases a decision about inclusion of Māori ethical perspectives will not be known until the research project is presented for approval.
15. Māori ethical perspectives will be important when the situation in question would normally require observance of tikanga Māori, such as research that involves working with whānau of Māori who have recently died and/or the body of the deceased. Another example is when a research project seeks knowledge which may be considered tapu by the respondents and therefore not usually available to outsiders. Such knowledge can be held by living respondents or contained in personal documentation that has not been made public.
16. In cases where non-Māori researchers are proposing research about Māori or Māori health, ethics committees should consider these proposals in light of the principle of participation (refer to section 1.4 “Treaty of Waitangi”) and the need to protect Māori participants.

## **1.6 Human rights**

17. The Human Rights Act was passed in 1993 to enhance basic human rights protections in New Zealand by promoting freedom from certain specified forms of discrimination in a number of areas (such as employment, supply of goods and services, and accommodation). Prohibited grounds of discrimination include marital status, religious belief, colour, ethnic or national origins, age, employment status, sexual orientation, sex, ethical belief, race, disability, political opinion, and family status. Any person or body in the performance of any public function is included within the scope of the Human Rights Act 1993. Further protections of fundamental rights are contained in the New Zealand Bill of Rights Act 1990.

18. The Government has recently adopted the Bill of Rights Act standard for the purposes of applying the Human Rights Act 1993. This standard essentially states that discrimination on the grounds set out in the Human Rights Act 1993 is permitted within reasonable limits prescribed by law as maybe demonstrably justified in a free and democratic society. In considering research proposals, committees may need to give ethical consideration where discrimination may be present. Committees will also need to ensure that any activities are undertaken in accordance with the New Zealand Bill of Rights Act 1990. For further information refer to the guidelines on how to apply the standards that have been developed by the Ministry of Justice.

## **1.7 International guidelines for ethics**

19. Ethics committees should have regard to international ethical guidelines when considering particular ethical issues, particularly the following:
- i. *Declaration of Helsinki*, World Medical Association (revised 2000)
  - ii. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, the Council for International Organisations of Medical Sciences and World Health Organization (CIOMS/WHO) (1993)
  - iii. *International Guidelines for Ethical Review of Epidemiological Studies*, (CIOMS) (1991)
  - iv. *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO) (2000)
  - v. *New Zealand Regulatory Guidelines for Medicines – Volume 3: Interim Good Clinical Research Practice Guideline*, Ministry of Health (August 1998).

A comprehensive listing of these resources is provided in the Bibliography.

20. Advice on the local interpretations of these international guidelines may be sought from either the National Advisory Committee on Health and Disability Support Services Ethics (National Ethics Committee) or the Health Research Council Ethics Committee (HRC Ethics Committee).

## 2 Principles of Ethical Review

### 2.0 Essential elements of ethical review

21. A number of guiding principles govern the ethical review of proposals. The application and weighting given to each of the guiding principles are not absolute and will vary depending on the nature of the research or innovative practice. Good ethical reasoning therefore requires thought, insight and sensitivity to the context of each proposal.
22. The following principles are outlined in the sections below:

Main principles	Additional issues for Māori
Respect for persons	Respect for Māori collectives – whānau, hapū and iwi
Informed consent	Gaining consent of collectives
Privacy and confidentiality	Collective ownership of information
Validity of research proposal	Kaupapa Māori and Māori-focused methodologies
Minimisation of harm	Minimising harm to te taha whānau (family and community), te taha hinengaro (emotional wellbeing and state of mind), te taha wairua (spirit), te taha tinana (the body or physical self).
Justice	
Cultural and social responsibility	Cultural diversity, koha
Compensation for research participants	

### 2.1 Respect for persons

23. *Respect for persons* involves recognition of the personal dignity, beliefs (including cultural and religious beliefs), privacy and autonomy of individuals and the provision of special protection of those persons with diminished competence.
24. Individuals have the right to decide whether or not they wish to receive clinical treatment<sup>1</sup> or participate in research. They need not give reasons for refusing to receive clinical treatment or to participate in research.
25. Individuals have the right to discontinue treatment or to withdraw from participating in research at any time. A decision to withdraw from research or innovative practice shall not affect an individual's standard entitlements (for example, entitlements to health and disability care).

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<sup>1</sup> It should be noted that in certain circumstances set out under the Mental Health (Compulsory Assessment and Treatment) Act 1992, compulsory treatment orders can be issued by a judge in the District Court. Under such circumstances patients do not have the right to refuse treatment. It should, however, be noted that compulsory treatment orders do not give investigators the right to automatically include patients in a research project or innovative practice.

26. Respect for persons requires that greater protection be provided to those persons with diminished autonomy (such persons may include children, inmates, persons in dependent relationships, persons with an intellectual disability, and unconscious patients) to ensure that they are not subjected to abuse, exploitation or discrimination. Often, additional protection is provided to persons with diminished autonomy by requiring the input/advice of third-person representatives. Other classes of research participants that are sometimes considered to be more vulnerable include terminally ill patients, aged persons, and students and employees of the researcher.
27. Respect for Māori collectives – whānau, hapū and iwi: Most Māori are members of cultural collectives with whom they have reciprocal relationships. The relationship between individual researchers, applicants, respondents and these collectives may be relatively idiosyncratic – committees must respect the importance of collectives and collective views and the diversity of arrangements which exist.

### **Relevant legal provisions**

- Sections 10 and 11 of the New Zealand Bill of Rights Act 1990 (refer to Appendix 10).
- Rights 1, 2, 3, 4, 7 and 9 of the Code of Health and Disability Services Consumers' Rights (refer to Appendix 10).
- Section 28 of the Mental Health (Compulsory Assessment And Treatment) Act 1992 provides for the District Court to make compulsory treatment orders in respect to mentally disordered persons.
- Section 18 'Powers and Duties of Welfare Guardian' of the Protection of Personal and Property Rights Act 1988 provides that no welfare guardian has the power to consent to a person's taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or preventing serious damage to that person's health.

## **2.2 Informed consent**

28. Respect for persons is most commonly manifested through the application of informed consent. Informed consent consists of three basic components:
  - i. that adequate information is provided to enable an informed judgement to be made
  - ii. that information provided is in a form and manner that will enable it to be understood by each individual
  - iii. that the consent is voluntary in nature (participation free from manipulation, coercion, inducement or any other undue influence).

29. The information provided should include, but not be limited to, the following:
- i. the purpose, intended outcomes or benefits (to the individual and/or the community) of the treatment or research
  - ii. an explanation of the procedures to be followed, including the identification of those procedures that are experimental
  - iii. what will be required of the consumer or participant (where relevant), the total time span of the research or treatment, the nature and extent of the participant's involvement, and the number, type and volume of specimens sought
  - iv. all foreseeable risks, side-effects or potential harm that are material to the research participant, and how significant risks will be monitored and managed
  - v. arrangements relating to compensation for personal injury
  - vi. a statement to the effect that potential participants who decline to participate will nonetheless be given the best standard treatment
  - vii. the right to withdraw from the research or innovative practice at any time, and to withdraw data from any participation until a specified time, without affecting treatment or future health care
  - viii. (where relevant) advice that a new procedure or drug may not be available to the participant on cessation of the study
  - ix. an individual's rights as set out under the Code of Health and Disability Services Consumers' Rights, and the availability of consumer advocates and of relevant complaint procedures from sources independent of the researcher
  - x. the right of access to health information about that individual as set out in the Health Information Privacy Code 1994
  - xi. that any queries or concerns regarding an individual's rights as a research participant may be raised directly with a health and disability advocate or with the ethics committee that approved the proposal
  - xii. how long the data and/or tissue will be kept, how the data and/or tissue will be stored, who will be responsible for the secure storage of the data and/or tissue, and how the data and/or tissue will be destroyed
  - xiii. the research participant's access to research findings
  - xiv. the responsibilities of the researchers
  - xv. names and contact details of people leading the research and available to answer any questions, or to be notified should the participant wish to withdraw consent.
30. Where appropriate, translation facilities should be available for potential participants whose first language is not English.

31. Research involving research participants or the use of human tissue or bodily substances or innovative practice may not proceed without first obtaining consent from the individual or the individual's legal representative.
32. Consent should be obtained before human tissue or bodily substances may be used for any purpose other than that for which consent was originally given.
33. It is important that consumers, research participants or legal representatives continue to be informed throughout the duration of their participation in the research or innovative practice. This includes being kept apprised of any developments that could potentially impact on them and being informed of the results of the innovative practice or research.
34. A formal record of consent should be kept. Consent should generally be obtained and documented in writing. Situations may arise, however, when it is not practical or appropriate for consent to be given in writing (for example, in telephone interviews, anonymous questionnaires, and in some cultural contexts where it may be more appropriate to obtain consent orally). Where oral consent is given it may either be recorded on some form of audio media or noted in writing. It is also recognised that some research can only be reasonably undertaken by maintaining the anonymity of individual participants in all documentation (such as studies of illegal drug use and of family violence).
35. It is ethically acceptable, in some circumstances, to conduct certain types of research without obtaining consent from participants (the types of research where this may be appropriate are outlined in Parts 3 and 4: 'Matters Requiring Ethical Review' and 'Matters For Which Ethical Advice May Be Sought'). Rules 10 and 11 of the Health Information Privacy Code 1994 set out the circumstances in which research using previously collected health information pertaining to identifiable individuals may proceed without prior consent being obtained from individuals, subject to ethical approval.
36. New Zealand law focuses on the requirement for an 'individual' to give their consent. In some communities and cultures, consent is not always considered to be an individual matter, but involves interested parties, such as consultation with extended families or community elders. Consent should be obtained in the most culturally appropriate manner for the participant. Proposals should, where appropriate, outline the processes intended to ensure that appropriate consultation occurs. In such situations, an individual is still free to give or withhold consent.
37. Gaining consent of collectives – Where collectives have a critical role, or are the focus of research or analysis (for example statistical analyses at the iwi, hapū or whānau level), researchers will need to make arrangements to obtain a collective's informed consent.

## **Coercion, inducement and intimidation**

38. An individual's participation in research or innovative practice, or consent to use health information, must be voluntary and not subject to coercion, inducement or intimidation. Coercion, inducement or intimidation may take many forms and occur directly or indirectly through financial or other rewards (such as promises of treatment), exploiting the vulnerability of individuals, or the influence and status of the health professional or researcher.
39. It may be acceptable to reimburse individuals for their participation (this may include covering a participant's expenses). The reimbursements must be reasonable and not become an inducement that compromises the voluntary nature of an individual's participation.
40. Health professionals and researchers should take appropriate steps to ensure that coercion, inducement or intimidation will not occur and should obtain approval from an ethics committee.

## **Deception of participants**

41. The deception of participants conflicts with the principle of informed consent but may be necessary in order to accomplish certain types of research. This is often the case in research where full disclosure of the actual purpose of a study would bias a participant's reactions or behaviour. Ethics committee approval must be obtained for the proposed methodology (including the debriefing process).
42. Incomplete disclosure is justified only if it is clear that the goals of the research cannot be accomplished if full disclosure is made and the research only poses minimal risks to the participants.
43. Researchers have a responsibility to ensure that, where appropriate, participants will be informed of the deception as soon as possible after an individual's participation in the research has concluded. The debrief should include an explanation of the true purposes and nature of the research and the reasons why the deception was necessary.

## **Relevant legal provisions**

- Rights 5, 6 and 7 of the Code of Health and Disability Services Consumers' Rights (refer to Appendix 10).

## **2.3 Privacy and confidentiality**

44. Every person is entitled to privacy. Privacy and confidentiality are integral to the protection and promotion of human dignity and help to protect and maintain a person's mental or psychological wellbeing.
45. The need for research must be balanced against infringements of privacy and have the intention of minimising any necessary invasions of privacy. To lessen the

impact such access may have, steps should be taken to ensure that individuals are protected from any potential harm that might be caused as the result of access to their personal information without prior consent. Steps to protect individuals include:

- i. restricting access to information about identifiable individuals
  - ii. encrypting information
  - iii. recording information anonymously
  - iv. storing research in secure facilities.
46. Except as provided for under the law,<sup>2</sup> information (including health information) pertaining to identifiable individuals should not be collected, disclosed or used without prior consent. Consumers and research participants should be informed of the intended or anticipated uses for health information or human tissue or a bodily substance at the time consent is sought for its collection.
47. Health professionals and researchers have an obligation to prevent the unauthorised access to health information that they have collected about identifiable individuals. The results of any research should only be published in such a manner as to protect the privacy of those individuals involved (refer to the Official Information Act 1982 and the Health Information Privacy Code 1994).
48. To help preserve the privacy of individuals, where research requires research participants and they are not already known to the investigator, it is usually desirable that the holder of the information identifying a potential participant makes the initial contact to determine whether a person would be willing to participate. This may be a primary care provider.
49. Where health information about identifiable individuals is collected, disclosed, used, stored or disposed of it should be done in a manner that complies with the law and protects the privacy, confidentiality and cultural sensitivities of the participants. The Health Information Privacy Code provides guidance on these issues.
50. In scrutinising any proposal, an ethics committee should satisfy itself that, where the principal investigator intends to collect information directly from participants and consumers, they should be informed of the extent to which the confidentiality of the information provided can be guaranteed. Where the principal investigator intends to seek disclosure of information about identifiable individuals from a secondary source, the proposal should include a statement regarding the extent to which the principal investigator will maintain confidentiality of any gathered information. This will require the ethics committee and principal investigator to be aware of and understand relevant laws. As a general rule, the best protection of the confidentiality of personal information and records will be achieved through anonymity.

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<sup>2</sup> Refer to the Official Information Act 1982, the Privacy Act 1993, and the Health Information Privacy Code 1994, as appropriate.

51. Collective ownership of information – a significant point of difference between Māori and western views of information, and data, is the role and rights of collectives versus individuals. The more usual western view is that aggregate, non-individual identifying statistics are able to be promulgated publicly. In contrast, many Māori would consider that collectives, such as whānau, hapū and iwi, should be treated in the same way as individuals, and that explicit approval should be sought and received from appropriate representatives in the same way that individuals give permission for their personal data to be used.
52. Researchers who intend to collect information directly from a particular Māori collective will need to negotiate the conditions under which any information is collected and used. Researchers will need to provide the details of any such agreements when submitting research proposal for ethical review. Where researchers intend to obtain information about a particular Māori collective from alternative sources, ethics committees must consider what impact, if any, the use of the information may have on the Māori collective concerned.

### **Relevant legal provisions**

- Right 1 of the Code of Health and Disability Services Consumers' Rights (refer to Appendix 10).
- The Health Information Privacy Code 1994 sets out the requirements that must be met regarding the collection, storage, access, use and disclosure of health information pertaining to identifiable individuals.

## **2.4 Validity of research proposal**

53. Proposals for research and innovative practice must be methodologically valid to ensure that consumers or research participants are not needlessly exposed to risks or inconvenience. Proposals must therefore be able to demonstrate that:
  - i. the proposed research has the potential to address a significant issue, has the potential to advance knowledge, and that it may contribute to improved outcomes
  - ii. the rationale for the research is well made (the aims and, where appropriate, hypotheses are acceptable; original findings may result or previous research will be replicated or validated)
  - iii. the research design, methods and proposed analyses are adequate and appropriate (awareness of the relevant technical issues is clearly demonstrated; risks and limitations of the proposed research are understood; where appropriate, the statistical basis of the research and the proposed methods of analysis are well developed and sufficient to ensure a definitive outcome. Where appropriate, sample size and methods of analysis should be sufficient to provide information about Māori health)
  - iv. the research team collectively have the academic qualifications, time and facilities, topic-based knowledge, research and, where relevant, clinical experience to undertake the proposed research (this may include

consideration of the track record of publication in peer-reviewed scientific or medical journals and other professional publications, and whether or not the researchers have good networks for dissemination of results).

54. Where the committee does not have the relevant expertise, then the HRC's Standing Committee on Therapeutic Trials (SCOTT), the Genetic Technology Advisory Committee (GTAC), or the appropriate professional body should be consulted. All clinical trials involving pre-registration medicines will need to have the approval of SCOTT to proceed (refer to the Medicines Act 1981). GTAC approval is required for genetic studies before ethical approval may be sought.
55. Every research proposal must demonstrate that it is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies and, where relevant, laboratory and animal studies.
56. Every innovative practice must demonstrate that it is justifiable in terms of its potential contribution to medical knowledge and has the potential to be of direct benefit to individual consumers. Any proposal should be based on pre-clinical evaluation (where appropriate), clinical evidence, previously approved innovative practice and, where relevant, the informed peer review of the profession regarding the potential merit of the practice.
57. Kaupapa Māori and Māori-focused methodologies. Like most innovative approaches, these methodologies require validation and must demonstrate adherence to a set of standards set by professional peers. Researchers must demonstrate to ethics committees that they have consulted with appropriately skilled experts to determine the validity of approaches. Where methodological development is a component of the research, such development must be accompanied by mechanisms for respondent protection.
58. If the results of completed research are not intended to be publicly released or published, there must be adequate justification for not doing so. In any event, the results of research or innovative practice should be available to consumers or research participants.
59. Any payment to researchers from a sponsoring agency should be made explicit to the ethics committee reviewing the proposal.

## **2.5 Minimisation of harm**

60. Research and innovative practice must only be conducted in appropriate facilities, which have personnel with the expertise and resources to deal with any contingencies that may affect participants.
61. Consumers and research participants should not be exposed to undue risk or harm. While a certain amount of risk is sometimes associated with particular types of innovative practice or research, health professionals and researchers should seek to eliminate or minimise consumers' and research participants' exposure to potential

harm to the fullest extent possible given the nature of the research or innovative practice.

62. The types of harms that may result from research activities can be grouped into four broad categories: physical, psychological, social and economic. For Māori, minimisation of harm includes these categories as well as minimising harm to whānau (family and community), hinengaro (emotional wellbeing and state of mind), wairua (spirit), and tinana (the body or physical self). Harm may include such things as pain, stress, fatigue, emotional distress, embarrassment, cultural dissonance, and exploitation.
63. Minimisation of harm to Māori research participants will also be achieved by the inclusion of Māori as partners and participants in the design, implementation, management, and analysis of research about Māori or Māori health.
64. Depending on the likelihood and magnitude of potential harm, a greater degree of independent scrutiny may need to occur throughout the duration of any approved research. Research or innovative practice should be immediately discontinued if it becomes evident that the risks to, or the harm that has been suffered by, a consumer or research participant is disproportionate to the benefits of the activity.
65. In considering the nature of risks posed by a proposed innovative practice or research, ethics committees should be aware that:
  - i. brutal or inhumane treatment of human participants is never morally justified
  - ii. risks should be minimised, including avoiding using human participants if at all possible
  - iii. there must be sufficient justification for research and innovative practice involving ‘significant risk of serious impairment’ (for example, the possibility of direct benefit to the participant and manifest voluntariness of the participation)
  - iv. the appropriateness of involving vulnerable populations must be demonstrated
  - v. the proposed informed consent process must thoroughly and completely disclose the nature and likelihood of any risk or potential harm.
66. Consideration should be given to both the probability and magnitude of possible harms. In judging the ethical acceptability of research or innovative practice, unavoidable risks, including inconvenience and discomfort to consumers and human participants, need to be balanced against possible benefits to the participants.
67. Research should involve the smallest number of human participants and the smallest number of tests on these participants that will ensure scientifically valid data.
68. The implementation of research should not have an adverse affect on the access to treatment of other consumers in a facility.

## Relevant legal provisions

- Right 4 of the Code of Health and Disability Services Consumers' Rights (refer to Appendix 10).
- Sections 9 and 10 of the New Zealand Bill of Rights Act 1990 (refer to Appendix 10).

## 2.6 Justice

69. The ethical principle of distributive justice requires the fair distribution of the benefits and burdens of research within a given population. Distributive justice also imposes duties to neither neglect nor discriminate against individuals or groups who may benefit from advances in research. Research is only justified if there is a reasonable likelihood that the populations from which research participants are drawn stand to benefit from the results of the research.
70. Research must therefore:
- i. avoid imposing on particular groups, who are likely to be subject to over-researching, an unfair burden of participation in research
  - ii. not discriminate in the selection and recruitment, whether by inclusion or exclusion, of actual and future participants except where the exclusion or inclusion of particular groups is essential to the purpose of the research (discrimination can be focused on ethnicity, race, age, disability, religious affiliation, gender, sexual orientation, marital status, employment status, family status, language or spiritual/ethical/political beliefs)
  - iii. respect the principles of the Treaty of Waitangi, particularly the principles of participation, partnership, and protection, where research involves Māori.
71. Individuals who are vulnerable and unable to protect their own interests must not be exploited for the advancement of knowledge. Research participants should not be selected simply because they are readily available in settings where research is conducted, or because they are easy to manipulate as a result of their illnesses or socioeconomic conditions.
72. Care should be taken to avoid overburdening persons (for example, those who are institutionalised or with rare diseases) who are already burdened in many ways by their infirmities and environments. Research that involves risk should use other, less burdened populations, unless the research directly relates to the specific condition(s) of the individuals involved.

## 2.7 Cultural and social responsibility

73. Research procedures should be appropriate to the participants involved in the study. Research must not only be sensitive to an individual research participant's rights

and interests, but should also be conducted in an informed manner, which respects the social and cultural sensitivity of each particular population as a whole.

74. Ethics committees should be aware and respect that in some cultures the rights and autonomy of an individual may be complicated and constrained to a greater or lesser extent by those of related individuals and groups with specific authority over, or cultural ties to, that individual.
75. Ethics committees should also be aware and respect that in some cultures community values are often emphasised. Members of such societies see value in collective activities well beyond the value of each person's individual share of the benefits. New Zealand's cultural diversity means that there may be a range of views on the relative weight of individual and collective values.
76. Cultural diversity for Māori. Committees will need to be aware of the diversity of Māori and how this is reflected in research approaches and the range of Māori respondents who may participate in research.
77. Research and treatment must be undertaken in such a manner as to respect a person's needs, values and beliefs (including cultural, religious, social and ethnic).
78. Where a Māori population is the focus of a particular research proposal, respect must be given to the principles of participation, partnership, and protection that are implicit in the Treaty of Waitangi. Ethics committees should be familiar with the application of the Health Research Council's *Guidelines for Researchers on Health Research Involving Māori* (1998).
79. Where research may have an impact on a specific community or population group, committees should require researchers to demonstrate what steps they have taken to consult with those groups likely to be affected, and the feedback the researchers have received.
80. Any anticipated impacts the research may have on a particular population should be documented in each proposal (for example, change in local health care, need for further research). Where research will lead to the development of a new medical device or drug, the proposal should describe the potential availability and affordability of such devices and drugs to the research participants and to the wider public. In general, research should only involve participants from population groups that are likely to benefit from such innovations.
81. Traditionally, koha is an acknowledgement of the knowledge and/or hospitality extended by tangata whenua to manuhiri. Koha is presented as part of the powhiri onto a marae or other venue of the tangata whenua. Koha may be offered in line with the cultural norms of the researchers and/or participants in research.
82. Koha should not be confused with payments to participants (for further discussion on payments and inducements, please refer to the "Coercion, inducement and intimidation" subsection of section 2.2 "Informed Consent"). The Inland Revenue Department has developed guidelines entitled 'Payments and Gifts in the Māori Community' which address the treatment of koha as a non-payment.

## Relevant legal provisions

- Right 1 of the Code of Health and Disability Services Consumers' Rights (refer to Appendix 10).
- Human Rights Act 1993.

## 2.8 Compensation for research participants

83. For a clinical trial to be covered by the provisions under section 32 of the Injury Prevention, Rehabilitation, and Compensation Act 2001 (IPRAC Act), an ethics committee approved by the Director-General of Health or the Health Research Council must approve the trial and certify that it was satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.
84. Registered health professionals may need to complete either of the following forms:
- Form A: Declaration of Eligibility of a Clinical Trial for Accident Rehabilitation and Insurance Corporation Coverage
  - Form B: Declaration of Provision of Compensation for Injury for Participants in a Research Study for a Pharmaceutical Company or any other Organisation Involved in Health Research.
85. Either Form A or Form B needs to be completed if a registered health practitioner is providing medical treatment as part of the research. The medical misadventure provisions only cover research involving medical treatment supplied by a registered health professional. Where research does not qualify for specific coverage under section 32 of the IPRAC Act, institutions should have indemnity cover. Research participants should be advised of the nature of the cover provided.
86. In the event of an accidental injury resulting from the participation in research not specifically covered by the clinical trial provisions for medical misadventure, a participant may seek compensation under the relevant general provisions of the IPRAC Act.
87. Form A requires applicants to provide sufficiently detailed information to enable an approved ethics committee to be satisfied that the proposed research project is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out. If satisfied, the approved ethics committee would need to approve and certify the clinical trial in writing.
88. Form B requires applicants to provide sufficiently detailed information to enable an approved ethics committee to be satisfied that:
- i. the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out

- ii. participants in the proposed research will receive an acceptable level of compensation from a pharmaceutical company or any other organisation involved in health research in the event of injury to participants resulting from their involvement in the proposed research study.
89. The investigator must ensure that the appropriate form has been completed and is submitted, together with the proposal to an ethics committee approved for the purposes of section 32 of the IPRAC Act. If satisfied, the approved ethics committee would need to approve and certify the clinical trial in writing.
90. The IPRAC Act defines ‘medical misadventure’ in a strict way and the principal investigator should be aware of the limitations to cover in that area and participants should be advised accordingly. Participants should also be advised to check whether participation in the research would affect their status with regard to existing or contemplated indemnity cover, such as medical insurance, life insurance and superannuation.
91. Compensation will generally not cover expected or foreseen adverse effects from investigational therapies or other procedures performed to diagnose or prevent disease, as such outcomes could equally occur in medical practice.

## **3 Matters Requiring Ethical Review**

### **3.0 Requirements to submit proposals for ethical review**

92. Requirements to submit proposals for ethical review are derived from a variety of sources, including:
- i. the Code of Health and Disability Services Consumers' Rights
  - ii. internationally recognised conventions and statements (such as the Declaration of Helsinki, and others noted in Section 1.6 and Bibliography)
  - iii. the professional codes of conduct and registration requirements of health and disability professional bodies
  - iv. the approval requirements of research funding organisations
  - v. requirements in the Health Research Council Act 1990 regarding the ethical review of health research applications for funding grants from the Health Research Council
  - vi. the Injury Prevention, Rehabilitation, and Compensation Act 2001
  - vii. the Health Information Privacy Code 1994
  - viii. the requirements of a researcher's employer
  - ix. purchase agreements with health and disability providers
  - x. the requirements of peer-reviewed publishers of research reports.

### **3.1 Proposals to be submitted for ethical review**

93. Any health and disability research proposal or innovative treatment protocol should not proceed before:
- i. it is reviewed by an ethics committee
  - ii. the applicant is advised in writing by a properly authorised person that the proposal has met appropriate ethical standards
  - iii. the proposal has received any other required approval.
94. Researchers should not proceed until the requirements of the Code of Health and Disability Services Consumers' Rights, the Health Information Privacy Code 1994, all other regulatory requirements, and relevant international standards for ethics have been met.

95. All proposed health and disability research investigations must be submitted for review by an ethics committee where the investigation involves human participants, whether health or disability service consumers, healthy volunteers or members of the community at large, and the investigation:
- i. compares an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognised as established, either by virtue of their recent development, discovery or use in a new or unfamiliar way
  - ii. involves access to personal information for purposes other than direct consumer care or clinical audit (ethical review is required if it is intended, as part of an audit, to seek additional information from patients other than that collected during the provision of patient care; any access to health information should be in accordance with the provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994)
  - iii. seeks to further scientific or professional knowledge by means of questionnaires, interviews or other techniques of information gathering, or by means of laboratory analysis of human blood, tissues, etc, of living people, cadavers or discarded body tissues (for example, placenta)
  - iv. is research conducted by government departments unless they have a statutory exclusion (for example, Statistics New Zealand)
  - v. is observational clinical research or is a physiological study
  - vi. is a clinical trial
  - vii. is research involving the use of any form of irradiation, organ imaging or surgical technique
  - viii. involves innovative practice in health and disability services
  - ix. is a new treatment or intervention which uses pain or deprivation of basic food or drink as a means to change behaviours.
96. All proposals for the use of an established procedure in an innovative way must be submitted for ethical review prior to their adoption.
97. If a member of the public or a health professional has cause to debate the application of an innovative practice in a particular instance, the planned use of that practice shall be submitted to an ethics committee for reconsideration.
98. All research proposals should be submitted on the National Application Form, which sets out the information that needs to be supplied as part of each application. A copy of the National Application Form is available from the Health Research Council web site at [www.hrc.govt.nz](http://www.hrc.govt.nz).

## 3.2 Clinical trials involving investigational products

99. Clinical trials are a type of research involving the testing of an investigational product.<sup>3</sup> When considering the scientific and ethical aspects of clinical trials, ethics committees and researchers should be familiar with the:
- i. *New Zealand Regulatory Guidelines for Medicines – Volume 3: Interim Good Clinical Research Practice Guideline*, Ministry of Health (August 1998) (available from Medsafe web site <http://www.medsafe.govt.nz>)
  - ii. *ICH Guideline for Good Clinical Practice*
  - iii. US FDA requirements where appropriate (see Section 3.3 below).
100. The *New Zealand Guidelines for Good Clinical Research Practice* (GCRP) provide the means for ensuring that clinical studies conducted with human participants are designed and conducted to the highest scientific and ethical standards. While the GCRP, in conjunction with other consumer-based legislation, safeguards the interests of all parties involved in clinical research, it does not replace or reduce the obligations to consumers or the rights of consumers provided for in legislation such as the Code of Health and Disability Services Consumers' Rights 1996 and the Health Information Privacy Code 1994.
101. When considering issues relating to the compensation of participants in clinical trials that are to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled, ethics committees and researchers should refer to the *Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial*.

### Phase I, Phase II or Phase III trials: separate applications to be submitted

102. Separate applications must be submitted for each of Phase I, Phase II or Phase III trials. Each application must be subject to prospective review by an ethics committee for approval.

## 3.3 Approval of research receiving US federal funding

103. The United States requires that any research receiving federal funding has obtained a Federal Wide Assurance (FWA). As part of the requirements for completing an application for an FWA, a research proposal must be reviewed by an ethics committee registered with the US Office for Human Research Protections.

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<sup>3</sup> The Medicines Act 1981 and the associated Medicines Regulations 1984 provide a framework for the approval of medical products. The Medicines Assessment Advisory Committee assesses medicines for safety and efficacy. Under the Medicines Act 1981, clinical trials of new medicines cannot be undertaken before approval has been obtained from the Director-General of Health, who must seek the recommendation of the Health Research Council (HRC) about that particular proposed trial. The HRC's Standing Committee on Therapeutic Trials (SCOTT) assesses the science of proposals relating to clinical trials of new medicines, and the Gene Technology Advisory Committee (GTAC) assesses the science of proposals relating to genetic studies.

104. Information about each ethics committee must be submitted on the Institutional Review Board/Independent Ethics Committee registration form. The Ministry of Health has developed an agreed process for making applications for the registration of those ethics committees that it funds (other ethics committees will need to contact the US Office for Human Research Protections directly). The National Co-ordinator of ethics committees is responsible for submitting these applications.
105. The chairperson of each US-registered ethics committee must complete three education modules (available at: [http://137.187.172.201/cbttng\\_ohrp/default.asp](http://137.187.172.201/cbttng_ohrp/default.asp)) prior to reviewing a research proposal for the purposes of obtaining an FWA.

### **3.4 Supervised student research**

106. Supervised student research is a category of research with characteristics that require particular considerations to be taken into account.
107. Students may only conduct research under the supervision of a supervisor. The supervisor has ultimate responsibility for the research and must ensure that it is conducted in a safe and appropriate manner. Institutions should indemnify themselves for student research.
108. Student researchers, their supervisors and ethics committees have a duty to ensure that this type of research does no harm to potential participants. Research conducted by students should pose no more than minimal risk to participants (if greater than minimal risk is anticipated, the proposal should be treated to the same scrutiny as normal research).
109. As supervised student research is conducted principally for the purposes of educating students on research techniques and methodologies (with the goal of learning how to develop and conduct research proposals of sound scientific and ethical design), student research may not achieve the degree of scientific or ethical rigour that would normally be required of a non-student research proposal.
110. Proposals for supervised student research may be submitted to an ethics committee by either the student(s) or by the research supervisor according to the requirements of the educational institution involved.
111. Ethics committees should therefore review student proposals with the goal of contributing to the students' education concerning the scientific and ethical principles.

### **3.5 Innovative practice**

112. An innovative practice involves the provision of a clinical intervention (diagnostic, therapeutic or prophylactic), be it a therapeutic drug, medical device or clinical procedure, that is untested, unproven or not in common use and therefore poses its own unique set of characteristics and issues.

113. Clinical interventions are generally of an invasive nature. Certain types of clinical intervention (such as surgery, chemotherapy or radiation therapy) are known to pose a considerable risk of harm to consumers.
114. The overall goal of any innovative practice is either to provide some immediate treatment in relation to an individual consumer or consumer group concerned, or to create new efficiencies in practices that will benefit consumers on a more general basis.
115. Health care must always be tailored to the individual needs, circumstances and medical condition(s) of each consumer. It is therefore not unexpected that the care of individual patients may vary around a core of standard accepted practice. Another aspect that must be recognised, is that what may constitute accepted practice for one body of health practitioners may well be considered innovative by another. Exactly what constitutes innovative practice is, therefore, a difficult concept to define in absolute terms.
116. It would be unreasonable and impractical, given the nature of health care, to insist that every deviation from accepted practice be considered 'innovative' and require independent ethical review. Often new techniques or procedures may result from unplanned responses to medical complications arising from the treatment of an individual consumer. Health professionals must also be allowed to make minor deviations from accepted practice to adjust health care to suit the individual needs of each consumer. Having said that, it must also be recognised that a series of small incremental changes to accepted practice may eventually result in a significant shift from accepted practice. It is therefore important that all health interventions follow the principles of best clinical practice.
117. In general terms, then, an innovative practice may be considered to be a planned deviation from the currently accepted practice of a New Zealand body of health professionals involving an untested or unproven clinical intervention intended to be used on an ongoing basis. Innovative practice includes the application of known procedures in new or novel circumstances in which they have not previously been tested. It may involve new delivery practices by health practitioners, new devices, new investigative procedures, or clinical management options.
118. A non-controversial practice generally accepted within a health profession overseas may not constitute an innovative practice provided it is accepted by the New Zealand body of health professionals, and the particular health practitioner can demonstrate appropriate qualifications and possession of relevant experience and expertise to undertake the practice safely. Practices new to New Zealand that may be considered to impact on the views or interest of society (such as work in the fields of genetics, cloning, assisted human reproduction and xenotransplantation) should, however, be considered innovative practice.
119. When choosing to use an innovative practice, health practitioners have an obligation to objectively evaluate its safety and efficacy. If the outcome of such an evaluation is favourable, the innovative practice may be adopted as routine practice. Such evaluations should be conducted in the same systematic manner and

be subject to the same ethical review and informed consent requirements as other health research involving invasive procedures. The process of scientific evaluation should involve the following:

- i. conduct of appropriate pre-clinical studies (for example, in animals) or *in vitro* testing of devices
  - ii. review of research relating to the practice
  - iii. analysis of the methodology to establish validity of results
  - iv. comparison of health gains and risks against the best current method of treatment (an improved net health outcome)
  - v. comparison of benefits against current established alternatives (as beneficial as current methods)
  - vi. evaluation of the applicability of research to the local environment.
120. The decision on whether a particular practice represents an efficient use of health care resources is beyond the ambit of the ethics committee and should be made by the health and disability service where the practice will be carried out. This may occur before or after ethical approval.
121. Health practitioners must use their professional judgement in determining what is or is not an innovative practice when compared against the day-to-day clinical interventions normally attributed to the regular activities of the body of health professionals to which they belong. Judgements about what may constitute an innovative practice are best made in consultation with a group of relevant experts. Where there is doubt as to whether or not a clinical intervention constitutes an innovative practice, the matter should be referred to an appropriate ethics committee, who will make a decision after consultation with appropriate professional bodies, or others with appropriate expertise.
122. Ethics committees may require the testing and evaluation of a new medical device by independent experts with specific medical engineering experience and knowledge. Ethics committees may also require that proposed innovative practices be independently assessed by an appropriately qualified and experienced individual or group of experts. Intellectual property issues may be important for some devices. Issues of potential conflicts of interest (for example, if the inventor is the principal investigator) must be addressed in the proposal and in the consent form.
123. Defining what can be considered to be harm, balancing one type of harm against another, and defining what is an acceptable degree of harm, are difficult and ultimately very subjective decisions. Often innovative practice may involve considerable risk of harm, but that risk must be considered within the context of a consumer's individual circumstances. One aspect of autonomy is the ability of an individual to accept or refuse to expose themselves to certain types and degrees of risk of harm.
124. Consumers are entitled to decide whether or not they wish to participate in innovative practice. Such participation must, however, be in the context of the study's design (generally such studies involve a randomised control trial).

125. The circumstances of patients who are extremely ill or are faced with incurable conditions pose particular difficulties in balancing patient autonomy and protection from harm. The *Declaration of Helsinki* states that:

*In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.*

126. Except in very specific circumstances, society upholds the right of individuals to accept or refuse medical treatment.

127. Innovative practice must only be undertaken by health practitioners with appropriate qualifications and expertise and for the purpose of treating a specific medical condition of an individual consumer or consumer group.

128. The objective evaluation of innovative practice requires a specific protocol, including adequate statistical validity, where appropriate, as with other research. Where appropriate, pre-clinical animal studies should be conducted.

129. The decision on whether or not to participate must be that of the consumers, and any innovative practice may only occur after first obtaining their informed consent.

130. As part of the ethical review of a proposal the ethics committee should be satisfied that:

- i. health practitioners have in place a process that will ensure each consumer has all the appropriate information to make an informed decision regarding whether or not to participate
- ii. the innovative practice will only be undertaken by health practitioners for the specific purpose of treating a specific medical condition of an individual consumer or consumer group
- iii. appropriate safeguards are in place to ensure that independent clinical assessment occurs through the treatment process so that, should it become apparent the innovative practice is not achieving positive results or is exposing consumers to unnecessary harm, consumers can be shifted to standard treatment protocols
- iv. appropriate evaluative mechanisms are put in place to assess the effectiveness of any innovative practice.

131. Where appropriate, the ethics committee should be provided with the following information:

- i. the purpose and justification of the innovative practice
- ii. the clinical indications for the use of the innovative practice
- iii. reports in the literature of the use of the innovative practice, including information about the safety and efficacy of the innovative practice (if any)

- iv. a description of the innovative practice
- v. the standard treatment practice that would normally be offered by health professionals from a particular provider setting, and a comparison between the standard treatment practice and the innovative practice
- vi. associated risks and expected benefits of the innovative practice
- vii. the experience and qualifications of the clinician(s) who will carry out the innovative practice, including specific experience with the innovative practice (if any)
- viii. provision of follow-up care and the training required for providing such care
- ix. if an innovative device is used, a description of the innovative device, including details of mechanical testing to which it has been subjected
- x. the number and type of intended consumers to participate in the innovative practice
- xi. how consumers will be selected
- xii. information given to consumers and how informed consent is to be obtained
- xiii. assessment of the initial safety and efficacy of the innovative practice
- xiv. any ethical issues the principal investigator considers arise from the use of the innovative practice
- xv. an independent clinician, group or body to whom the proposal may be referred for scientific verification
- xvi. an approval from the provider of the health and disability service where the innovative practice will be carried out
- xvii. consent, where appropriate, from the Standing Committee on Therapeutic Trials (SCOTT), the Gene Technology Advisory Committee (GTAC), and the National Radiation Laboratory (NRL).

## **4 Matters For Which Ethical Advice May Be Sought**

132. The following matters do not require ethics committee approval. It should be noted, however, that providers and individual health professionals may wish to ask for advice on such matters. In these circumstances, ethics committees may give advice. The final decisions on such matters remain with the appropriate body.
133. Even though ethical review is not required in relation to service delivery issues, health and disability agencies should observe the highest ethical standards in all types of service delivery and should be aware of the provisions of:
- i. the Code of Health and Disability Service Consumers' Rights 1996
  - ii. the Health Information Privacy Code 1994
  - iii. other relevant codes of practice.

### **4.0 Research**

134. The following research activities do not require ethical approval:
- i. questionnaires or surveys that do not involve the collection or use of confidential or sensitive personal information (for example, patient satisfaction surveys)
  - ii. research utilising existing publicly available documents or data (for example, analysis of archival records that are publicly available, analysis of any information or data gained by a request under the Official Information Act 1982)
  - iii. observational studies in public places in which the identity of the participants remains anonymous.

### **4.1 Audit**

135. Audit involves an investigation into whether an activity meets explicit standards, as defined in an auditing document, for the purpose of checking and improving the activity audited. An audit undertaken by or under the supervision of senior members of the health care or disability service directly responsible for the care of that group of health and disability service consumers would not require ethical review.
136. Access to confidential medical/personal information held by the service must be restricted to those individuals employed or contracted by the service provider, the funder of the service or an agency responsible for overseeing the safety and quality of the service and be used solely for the purpose of auditing a service. All information must be recorded in a non-identifiable manner and any report must not identify any individual.

137. Ethical review for an audit is required if it is intended to seek from patients additional information other than that which was collected by a service during the provision of health and disability care.

## **4.2 Disclosure and use of personal health information for the purposes of monitoring the quality of care**

138. At an institutional level, the disclosure and use of health information relating to identifiable individuals for the purposes of monitoring care may go beyond the processes involved in internal clinical audit. As part of such monitoring, expertise possessed by members not involved in the health care or disability services team (for example, expertise in statistical methods, pathological diagnosis or classification) may be required. Ethical review is not required for this process as long as all persons involved are operating under the same professional standards and confidentiality requirements as the individual caregiver.
139. Ethical review for monitoring the quality of care is required if it is intended to seek from patients additional information other than that which was collected during the provision of health and disability care.

## **4.3 Resource allocation and access criteria**

140. Resource allocation and access criteria relate to whether, how much, where, to whom, and how a service should be provided. Access criteria are developed to ensure that those who are in most need will have priority of access to treatment or services. This work is developed with consumer and public input, and the ethical issues including consideration of social principles and professional ethics are worked through as part of the process. Access criteria assist providers in deciding who should have priority of access to particular services and in adjusting funding according to the needs of the population in a local area.
141. The allocation of publicly funded resources is decided by the Government, which decides on the appropriate level of funding for the health sector. The level of funding for each District Health Board (DHB) is negotiated with the Government, and DHBs purchase services required to meet local population needs.
142. Ethical issues may arise when providers are unable to deliver the best possible care because resources are not available. Ethics committees cannot recommend that more resources be made available, but may assist in making ethical clinical decisions within the resource realities.
143. Decisions about which individuals are likely to benefit most from therapy or care or which individual will receive services are clinical decisions based on the practice guidelines and access criteria. The criteria for all services should be clearly stated, and ethics committees may have a role in examining these criteria if they appear to discriminate against particular consumers or if consumers are being treated according to criteria that fall outside generally accepted criteria.

## 4.4 Practice guidelines

144. Practice guidelines are developed from consensus among professionals as to what constitutes good practice. These guidelines set the standards for specific services and can be used in the contracting process as a quality measure.

## 4.5 Provision of advice on service delivery issues

145. While the ethical review of service delivery issues is not mandatory, health professionals may, from time to time, wish to seek advice on ethical principles in relation to certain aspects of service delivery. Ethics committees have a role in protecting the interests of consumers of health and disability services by advising on a wide range of ethical issues relating to the delivery of services to individuals.
146. Consumers are protected by codes developed from legislation such as the Privacy Act 1993 and the Health and Disability Commissioner Act 1994. Many professions have codes of ethics, which are used to measure behaviour and can lead to disciplinary proceedings. Consumers are also protected by the disciplinary provisions of occupational registration legislation (for example, the Medical Practitioners Act 1995).
147. Advice may be sought in relation to policies, procedures and staff guidelines, either during the development of institutional guidelines on ethics or when changes are being made that may have an impact on consumers and their rights. Examples include:
- i. the collection, storage, use and disposal of human tissue and bodily substances
  - ii. tagging of consumer records
  - iii. policies in sensitive areas (for example, mandatory reporting of sexual abuse)
  - iv. issues relating to personal qualifications, privacy and confidentiality in the monitoring and evaluation of services.
148. Applications from individuals seeking clarification on ethical issues relating to other matters may, from time to time, come before a committee. Examples include:
- i. the transfer of critically ill patients during a doctors strike
  - ii. withdrawal of life support
  - iii. situations where a member of the public or a health practitioner has cause to question the value of the application of a new treatment in a particular instance.
149. In the area of disability services, ethical matters that may come before an ethical review service include:
- i. issues involving the difficulty of obtaining informed consent to the use of medication and behaviour control/management procedures
  - ii. resolving how services can ensure the protection of the rights of individuals who have diminished capacity.

## **4.6 Other matters on which advice may be sought**

150. Other matters on which advice may be sought include:
- i. any proposed changes to areas of previous discussion with an ethics committee
  - ii. any changes to established policies relating to ethical issues
  - iii. sensitive/controversial issues, or a decision not to accept the advice of an ethics committee.

## **4.7 General matters**

151. Ethics committees are under no obligation to provide advice. The chairperson of a committee should make a judgement regarding whether the committee has the appropriate expertise to consider and provide guidance on a particular issue.
152. In situations where the committee agrees to give advice, it should request:
- i. a written request for advice, which clearly explains the situation about which the advice is being sought
  - ii. approval to gather, where it considers it appropriate, any further information that it needs, including speaking with those individuals whom the committee chooses to approach
  - iii. a suggested timeframe for providing the advice
  - iv. acknowledgement that the applicant will make any final decision and the committee will only provide advice.
153. An ethics committee should:
- i. reserve the right to decline to give advice
  - ii. reserve the right to negotiate a timeframe for providing advice
  - iii. couch its advice in terms of the principles set out in Part 2
  - iv. follow the appropriate procedures set out in Part 7
  - v. confirm its advice in writing, substantiated by a justification in ethical terms and an outline of its process.

## **5 Ethical Review System in the Health and Disability Sector**

### **5.0 Ethical review system in the health and disability sector**

154. The ethical review system in the health and disability sector comprises a number of ethics committees established under various legislative provisions or through funding arrangements with the Director-General of Health.
155. A brief summary of the role and functions of each ethics committee is provided below.

### **5.1 National Advisory Committee on Health and Disability Support Services Ethics**

156. The National Advisory Committee on Health and Disability Support Services Ethics (National Ethics Committee) is a Ministerial advisory committee established under section 16 of the New Zealand Public Health and Disability Act 2000. The National Ethics Committee is established by and accountable to the Minister of Health.
157. The National Ethics Committee's statutory functions are to:
  - i. provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
  - ii. determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.
158. Full terms of reference for the National Ethics Committee are provided in Appendix 11.

### **5.2 National Ethics Committee on Assisted Human Reproduction**

159. The National Ethics Committee on Assisted Human Reproduction (NECAHR) is a Ministerial committee established under section 11 of the New Zealand Public Health and Disability Act 2000.
160. NECAHR's functions are to:
  - i. review assisted human reproductive proposals (including health research and innovative practice) to determine whether they are ethical and, in particular, to determine whether:
    - the rights of the people involved will be protected
    - proper account will be taken of the ethical perspectives of Māori, and other cultural, ethnic, religious, and social groups in New Zealand

- ii. develop for providers protocols and guidelines relating to the ethical issues involved with aspects of assisted human reproduction
- iii. advise the Minister of Health on ethical issues relating to assisted human reproduction
- iv. consider any other matters relating to assisted human reproduction the Minister of Health from time to time determines.

161. Full terms of reference for NECAHR are provided in Appendix 12.

### **5.3 Health Research Council Ethics Committee**

162. The Health Research Council Ethics Committee (HRC Ethics Committee) is a statutory committee established under section 24 of the Health Research Council Act 1990. Section 25 of the Act provides for the functions of the HRC Ethics Committee, which are:

- i. to consider and make recommendations to the HRC on ethical issues in relation to health research, especially those emerging through the development of new areas of health research
- ii. to provide and review ethical guidelines for the HRC
- iii. to ensure that, in respect of each application submitted to the HRC for a grant for the purposes of health research, an independent ethical assessment of the proposed health research is made either by the HRC Ethics Committee itself or by a committee approved by the HRC Ethics Committee
- iv. where an application for a grant for the purposes of health research is submitted to the HRC in respect of health research that is of national importance or great complexity, to itself make an independent ethical assessment of the proposed health research
- v. to review, at the request of any person who has made an application for a grant for the purposes of health research, the independent ethical assessment made, in respect of the proposed health research, by a committee approved by the HRC Ethics Committee
- vi. to give, in relation to ethics committees established by other bodies, advice on the membership of those committees and the procedures to be adopted, and the standards to be observed, by those committees
- vii. to provide independent comment on ethical problems that may arise in any aspect of health research
- viii. to perform any other functions (whether or not related to health research) it is for the time being given by or under any enactment, or authorised to perform by the Minister, by written notice to the HRC after consultation with it.

## **5.4 Health and disability ethics committees**

163. Health and disability ethics committees (HDECs) are funded and indemnified by the Ministry of Health to provide independent ethical review of research and innovative practice that will be conducted in their designated region of authority. The Director-General of Health may, from time to time, alter the number of HDECs and their corresponding designated regions of authority.
164. HDECs comply with this Operational Standard. The constitution and operation of HDECs is set out in Parts 6 and 7 respectively.
165. HDECs are subject to the Official Information Act 1982. The information an ethics committee holds, therefore, will be deemed by paragraph (2)(c) to be held by the Ministry of Health.

## **5.5 National Co-ordinator of health and disability ethics committees**

166. The role of the National Co-ordinator is to:
  - i. ensure the effective and efficient provision of an administrative infrastructure to the HDECs
  - ii. ensure the efficient provision of an administrative/secretarial support structure to the HDECs
  - iii. establish training programmes for both the members and administrators of HDECs
  - iv. develop systems to enhance the operation of HDECs
  - v. develop and maintain links between HDECs and relevant professional bodies
  - vi. provide support to the chairpersons of ethics committees
  - vii. ensure that administrative support is provided to enable the meeting of the chairpersons of HDECs to be held twice a year.
167. The National Co-ordinator's role includes, but is not restricted to:
  - i. standardising recruitment/appointment policies and annual reports
  - ii. establishing networking systems for administrators/secretaries and members
  - iii. monitoring committee workloads
  - iv. liaison between committees and the Ministry of Health
  - v. implementing and designing appropriate systems for committee administrators/secretaries
  - vi. producing handbooks for administrators
  - vii. developing and implementing a new database system common to all committees
  - viii. developing and implementing a national web site for HDECs

- ix. establishing efficient networking systems for the operation of HDECs
- x. liaison with the HRC over matters of ethics committee approval, and standard operating guidelines.

## **5.6 Institutional ethics committees**

168. Institutional ethics committees review many different types of research that involve human participants. The membership of institutional ethics committees that are approving health and disability research is expected to include the range of expertise required for HDECs. In addition, the membership should be adequately balanced to guard against potential conflict or professional bias, and should have the appropriate expertise to review other types of research.

## 6 Constitution of Health and Disability Ethics Committees

### 6.0 Role of health and disability ethics committees

169. The primary role of a health and disability ethics committee (HDEC) is to provide independent ethical review of innovative practice and health research that will be conducted in their designated region of authority. HDECs may also provide advice on service delivery issues.
170. In undertaking this role, HDECs will:
- i. safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy
  - ii. foster an awareness of ethical principles and practices in the health and disability sector and research community
  - iii. facilitate excellence in health research and innovative practice for the wellbeing of society
  - iv. give due consideration to local community views
  - v. ensure that the principles of the Treaty of Waitangi, particularly the principles of participation, partnership, and protection, are incorporated in the proceedings and processes and outcomes of committees
  - vi. operate in accordance with the *Operational Standard for Health and Disability Ethics Committees*
  - vii. operate in accordance with any guidelines issued or approved by the National Advisory Committee for Health and Disability Support Services Ethics.

### 6.1 Statutory approvals

171. HDECs and, where appropriate, other ethics committees, have to be approved under specific enactments for particular purposes:
- i. compensation for personal injury under the Injury Prevention, Rehabilitation, and Compensation Act 2001 (refer to section 32(5)(b) of the IPRAC Act)
  - ii. independent ethical assessments of applications submitted to the HRC (refer to section 25(1)(c) of Health Research Council Act 1990)
  - iii. review of health information for research purposes under the Health Information Privacy Code 1994.
172. Statutory approval of ethics committees is given either by the Director-General of Health (under the IPRAC Act) or the HRC (under the IPRAC Act, or the Health Research Council Act 1990). To conduct review under the Health Information Privacy Code, an ethics committee must be approved to this *Operational Standard* by the Director-General of Health or the HRC.

## 6.2 Composition and membership

173. The primary guiding principle for appointing members to a committee is to ensure that the committee has the appropriate expertise, skills, knowledge and perspectives to conduct ethics review of the best quality.
174. Committees should have a balance of experience, knowledge and perspectives. Attention should be paid to cultural diversity, gender balance and inclusion of people with disabilities. It should be recognised that individuals bring a range of skills and expertise to the work of the committee. However, members are not representatives of particular groups or professional bodies.
175. The mix of skills and expertise on a committee needs to reflect the type of research and innovative treatment they cover and the community whose interests they protect. For these reasons a committee needs to have a range of skills and expertise available to it.
176. The minimum number of members of a committee should be 10, including a lay chairperson. One half of the total membership should be lay members (refer to the Glossary for the definition of a lay member).
177. Each committee should have a composition tailored to provide it with appropriate medical, scientific, clinical and research expertise to enable it to ethically review the majority of the proposals coming before it. In general, it would be beneficial for a committee's membership to include expertise and knowledge of both qualitative and quantitative research.
178. At any time, a committee shall have one member who is a lawyer and one member with expertise in ethics (for example, a teacher of ethics, philosopher, theologian, or community-recognised person such as a Māori elder). In addition, it is important that a committee's composition also include individuals possessing a knowledge and understanding of consumer and community issues and perspectives.
179. At any time a committee shall have at least two Māori members, who should have an awareness of te reo Māori and an understanding of tikanga Māori. All members of ethics committees are expected to have knowledge of the Treaty of Waitangi and its application to ethical review.
180. Members should possess an attitude that is accepting of the value of other professions and community perspectives.
181. When appointing a member, the committee should take into account whether or not the appointment of a person as a member to the committee would raise the issue that the member could be construed, by virtue of employment, profession or relationship, to have a potential conflict or professional bias in a majority of proposals reviewed. The committee must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

182. Committees are required to maintain a list of members and their background and qualifications. This information is to be publicly available and supplied upon request. This information is reported annually to the HRC.

### **6.3 Expert advice**

183. Members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapū, and this should be supported and encouraged. However, the confidentiality of the proposal and details of the issue under review may also need to be protected. Members should obtain consent from the committee or chairperson before any such consultation takes place.
184. Where a chairperson or quorum of committee members believes there is insufficient expertise on the committee to assess an application or an issue, the committee should seek additional expert advice. The committee may also seek a second opinion.
185. Advice may be sought from recognised experts with:
- i. specialist knowledge in particular fields of science and medicine
  - ii. knowledge of the experiences and perspectives of people with disabilities
  - iii. awareness of women's health perspectives
  - iv. consumer and/or research participant perspectives
  - v. an understanding of community health issues
  - vi. an understanding of relevant cultural perspectives
  - vii. an understanding of developing Māori research methodologies
  - viii. expertise in te reo Māori.

### **6.4 Duties and responsibilities of a member**

186. This section sets out the duties and responsibilities generally expected of a person appointed as a member of a committee. This is intended to aid committee members by providing them with a common set of principles for appropriate conduct and behaviour.

#### **General**

187. Committee members should have a commitment to protecting the interests of human participants while promoting and facilitating excellence in research and innovative practice.
188. There is an expectation that committee members will make every effort to attend all committee meetings and devote sufficient time to become familiar with the affairs of the committee and the wider environment within which it operates.
189. Members have a duty to act responsibly with regard to the effective and efficient administration of the committee and the use of committee funds.

## **Conflicts of interest**

190. Committee members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the committee and its members and will ensure it retains public confidence.
191. Committee members attend meetings and undertake committee activities as independent persons responsible to the committee as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. A committee should not, therefore, assume that a particular group's interests have been taken into account because a committee member is associated with this group.
192. When committee members believe they have a conflict of interest on a subject which will prevent them from reaching an impartial decision or from undertaking an activity consistent with the committee's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.
193. A member of a committee who has a proposal before the committee or who has an involvement in the proposal such as a supervisory role shall not take part in a committee's assessment of that proposal. The member may be present to answer questions about a proposal but should take no part in the discussion surrounding the consideration of the proposal or any decision relating to the proposal. This will allow proposals to be considered in a free and frank manner.

## **6.5 Term of membership**

194. Members may be appointed for a term of up to three years and may be re-appointed to serve an additional term to allow for continuity and full use of increased experience and expertise. No member, including the chairperson, should serve on a committee for more than six successive years.
195. Unless a person vacates their office sooner, every appointed member continues in office until their successor comes into office. Membership is not transferable and cannot be delegated.
196. Committees should consider staggering retiring dates for committee members to allow for a degree of continuity.
197. After serving the maximum six-year term, members would not be considered for reappointment until at least three years after their retirement from a committee.
198. Members may apply to the committee for extended leave of absence. It is up to the committee to decide whether such requests are approved. For periods over three months, the time on leave may be added to the member's end date with the committee.

199. Where a member is continually absent from meetings or is absent for three consecutive meetings without formal leave of absence, the chairperson, in consultation with the National Co-ordinator, should address this with the member concerned.

## **6.6 Nomination of members**

200. Applications should be sought by:
- i. public announcement of vacancies by notice in local newspapers, which include details about the skills and expertise sought and the role of the committee
  - ii. direct requests to groups likely to have the required skills and expertise among their membership (these may include health and disability consumer groups, professional organisations, the research community, or groups with a focus on the protection of consumers)
  - iii. self-nomination by individuals.
201. When Māori members are sought, public notices should also be placed in appropriate Māori media. Nominations should be invited from appropriate local and national Māori groups. These include all iwi in the region, marae-based groups, and Māori community groups. Te Puni Kōkiri, the Ministry of Women's Affairs, the Ministry of Consumer Affairs, and the Ministry of Health can assist by providing contact names and addresses.
202. Sufficient time should be allowed for community groups to meet to make nominations.
203. The National Co-ordinator, in consultation with the chairperson, is responsible for advertising and collecting nominations.

## **6.7 Process of selection**

204. The selection of new members should be conducted by a group consisting of the following:
- i. chairperson of the ethics committee
  - ii. National Co-ordinator/delegate (non-voting member)
- and at least two from the following list:
- i. ethics committee member(s)
  - ii. lay or professional person(s)
  - iii. Māori representative
  - iv. independent ethical review agency representative (this may be a member of another ethics committee).
205. The selection panel should be chosen in accordance with the vacancy (for example, with a health practitioner vacancy, a health professional will be required on the panel).

206. Local iwi, hapū and other Māori groups or organisations should be consulted in the selection of Māori members.
207. The timeline and processes for the selection of members should be finalised before nominations are sought and the details should be made public to nominees and groups invited to provide nominations. The same selection process should be used for both lay and non-lay members.
208. Selection should include a short-listing process. The short-listed candidates should then be interviewed.
209. The recommendation to appoint should be by consensus decision. If the panel cannot agree on a recommendation then the vacancy must be readvertised.
210. The detailed process for the advertisement, nomination and selection of members is detailed in the administrator's manual – *Guidelines for Nomination, Selection and Training of Members of Regional Ethics Committees*.

## **6.8 Training for members**

211. Training should be provided for new members and chairpersons within six months of appointment to an ethics committee. Training should include:
  - i. essential elements of ethical review
  - ii. the Treaty of Waitangi and its application to ethical review
  - iii. awareness of Māori culture, tikanga and health and research approaches
  - iv. procedures and protocols for health research and innovative practice
  - v. overview of the health and disability sector and the research sector
  - vi. consensus decision-making and group processes
  - vii. the types of expert advice that may be needed
  - viii. introduction to the principles of the Privacy Act 1993 and the Health Information Privacy Code 1994
  - ix. individuals' rights under the Code of Health and Disability Services Consumers' Rights 1996
  - x. awareness of the needs of specific cultural groups in each geographical area.

## **6.9 Chairperson**

212. Committee members should elect a lay member chairperson annually. The chairperson will preside at every meeting of an ethics committee at which they are present. A member should generally have served 12 months on a committee before being elected as chairperson.

213. A lay member may also be elected as a deputy chairperson using the same procedure. In the absence of the chairperson, the deputy chairperson shall have the same duties and responsibilities as that of the chairperson.

## **6.10 Committee meetings**

214. Meetings shall be held at such times and places as a committee or a chairperson of a committee decides. In general, health and disability ethics committees are likely to meet on a monthly basis.

215. At any meeting, a quorum shall consist of at least six members or the minimum number constituting a majority. The quorum must include a reasonable representation of members with health professional, research, ethical and community/consumer expertise, knowledge and perspectives.

216. As part of the accountability to the public they protect, it is desirable for the meetings of committees to be open to the public. Meetings of a committee should therefore be:

- i. open meetings for the discussion of broad issues, particularly if the committee is reviewing health research
- ii. closed meetings when necessary to ensure the privacy and confidentiality of participants
- iii. closed meetings when applicants provide good and sufficient reasons for this to occur.

217. Committees should provide public notification informing when meetings are to be open to the public.

218. Applicants may attend meetings to be available to talk to their proposal and answer any questions a committee may have. Attendance is not mandatory. Committees should advise applicants that they may be asked to leave the meeting while the committee considers the proposal.

219. Subject to the provisions set out in this document, a committee may regulate its own procedures.

## **Decision-making process**

220. Every question before any meeting shall be determined by consensus decision-making. Members of committees should be free to participate fully in discussion and debate. In particular, the chairperson should have skills in consensus decision-making and conflict resolution.

221. Issues of ethical review are often complex and can involve ethical dilemmas on which there is no consistent community view. Members of ethics committees have a responsibility to identify the underlying ethical principles and to seek the best possible approach to these dilemmas.

222. Using the consensus model, the processes of discussion and debate will lead to the decision rather than a process of formal vote-casting. Under the consensus model, the proposal will be approved when every member of the committee is willing to allow the proposal to proceed. However, a single settled and consistent objection to the proposal will require that the proposal is further discussed or referred for a second opinion, or further expert advice is sought and information gathered.
223. In relation to research involving issues for Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend an ethics committee meeting or for those members views to be sought and represented at the meeting, the matter should be deferred.
224. On occasion, individual members may wish to abstain from some or all of the decision making process because of strong personal moral or religious reasons. Such abstentions shall not affect the approval process.

### **Confidentiality and information sharing**

225. All applicants should be assured that details of their applications will be kept confidential, subject to the Official Information Act 1982.
226. It is desirable for the members of ethics committees to have an opportunity to discuss issues arising from applications with key contacts and support people prior to the consideration of proposals. This process should be encouraged.
227. However, due to the need to protect possibly personal information and the commercial sensitivity of some applications, names, identifying details and written material should not be circulated or made known outside the committee. Ethics committees will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.
228. Within ethics committees, Māori members should be consulted and provide advice on the appropriate consultative process for all ethical issues concerning Māori.
229. Agendas and minutes, except for ‘in committee’ items should be available to the public. Subject to the Official Information Act 1982, copies of proposals will not be available to individuals outside the ethics committee without the prior approval of the researcher.

### **6.11 Financial and administrative accountability**

230. Committees should be adequately resourced to allow them to function effectively. The National Co-ordinator is responsible for the allocation and administration of all health and disability ethics committee budgets.

## 6.12 Records

231. Information held by committees is subject to the Privacy Act 1993 and Official Information Act 1982. The Ministry of Health will either fund committees to arrange secure storage facilities for committee records, or will make arrangements for those facilities.
232. Committee records are subject to the Archives Act 1957 which provides for the storage of government records that are no longer in current use. For the purposes of the Archives Act 1957:
- “Public records” means all papers, documents, or records of any kind whatsoever officially made or received by any Government office in the conduct of its affairs or by any employee of the Crown in the course of his official duties
  - “Public archives” means all public records that have ceased to be in current use in the Government office in which they were originally made or received or in the Government office in whose custody they have been placed, or that have been deposited in the National Archives.
233. The Archives Act 1957 requires that all public archives of the age of 25 years or over, which in the opinion of the Chief Archivist are of sufficient value to warrant their preservation as:
- (a) evidence of the organisation, functions, and transactions of the Government office in which they were originally made or received; or
  - (b) evidence of public or private personal or property rights or civic rights; or
  - (c) containing historical or general information
- shall be transferred to the custody of the Chief Archivist and be deposited in the National Archives.
234. The Chief Archivist may allow the deposit in the National Archives of public archives of less than 25 years of age if the Chief Archivist considers that they are of sufficient value for deposit (Section 10(1) of the Archives Act 1957). Any deposit of public archives under this section may be subject to any special conditions imposed by the Director-General of Health making the deposit. Committees may therefore be able to arrange for records that are no longer in use to be deposited with Archives at any time.
235. Committees should retain the records of all proposals submitted either for the duration of a research or treatment proposal if longer than 10 years, or for a minimum of 10 years from the date a proposal is approved before considering whether to archive or destroy the records. A decision about whether or not to retain, archive or destroy the records should take into consideration the nature of the treatment or research. No person may destroy or otherwise dispose of, or authorise the destruction or other disposal of, any public record or archives of any kind whatsoever that are in their possession or under their control, except with the consent of the Chief Archivist.

236. Records may only be accessed with the permission of the chairperson. The administrator of each committee is responsible for maintaining and controlling access to a committee's records. The disposal of any records must occur through secure destruction, and records should only be destroyed after obtaining the chairperson's authorisation.

### **6.13 Checklist of requirements for annual reports**

237. The following provides a checklist of requirements for annual reporting. It is expected that the checklist would be developed and improved periodically for accountability and transparency. Annual reports should be submitted to the National Advisory Committee on Health and Disability Support Services Ethics, the HRC Ethics Committee and the Director-General of Health. Annual reports are public documents and should be available upon request.
238. A list of the research and innovative treatment protocols reviewed in the preceding year that includes the following details:
- i. the research title
  - ii. principal investigator
  - iii. institution where the research is to be/has been undertaken
  - iv. an indication of whether the proposal is multi-centre, and if so, details about the lead committee
  - v. date of first review
  - vi. date of final outcome
  - vii. outcome (which will be one of: approved, provisionally approved, approval deferred, approval declined)
  - viii. other relevant matters that may be determined from time to time.
239. In compiling their reports, ethics committees should take care not to provide information that would involve a breach of the Privacy Act 1993 and/or the Health Information Privacy Code 1994.
240. Any changes in the ethics committee membership or guidelines for operation, or other substantive changes the committee or its chairperson feels should be noted (for example, restructuring in the parent organisation which might affect an ethics committee's operation).
241. A list of training undertaken by members, and a statement on processes for orientation and training of new committee members.
242. A statement on provision for ongoing training and attendance at training or other conferences and seminars for committee members. This statement should indicate how many members of the committee participated in training opportunities during the year.

243. A list of complaints received by the ethics committee (if any), the actions taken to resolve the complaint and a comment on the outcome of the complaint(s).
244. The following matters relating to Māori:
- i. the number of applications deferred because the Health Research Council's *Guidelines for Researchers on Health Research Involving Māori* relating to research involving Māori were not conformed to
  - ii. the number of applications for which consultation with Māori and/or iwi and/or hapū was considered to be appropriate
  - iii. the number of applications returned due to insufficient or no consultation with appropriate Māori and/or iwi and/or hapū
  - iv. a description about the process(es) the committee adopts in following up on the consultation undertaken by the researcher with Māori
  - v. details, where relevant, of circumstances where unsatisfactory reasons or examples were given for not including Māori in research.
245. Any areas of review that caused difficulty for the committee in making a decision on any particular protocol(s), and any questions on policy or other matters the committee may wish to put to the National Advisory Committee on Health and Disability Support Services Ethics or HRC Ethics Committee for comment or guidance.
246. If desirable, the chairperson of the ethics committee may forward a separate confidential comment to the National Advisory Committee on Health and Disability Support Services Ethics or HRC Ethics Committee noting any special concerns, requests or comments.

## **6.14 Role of committee administrators**

247. The National Co-ordinator determines the role of the administrators. The administrator's primary role is as a support person to the committee. The role and duties of administrators are set out in the administrators manual.
248. The basic elements of the administrator's role are:
- i. circulation of proposals and other documentation
  - ii. organising meeting venues and fees and allowances
  - iii. preparing meeting minutes
  - iv. preparing correspondence as approved by the committee
  - v. co-ordinating the multi-centre review process
  - vi. distributing information on ethical issues in research.

## **7 Administrative Procedures**

### **7.0 Proposals for review**

249. A National Application Form with minimum requirements regarding written consent and consumer information has been developed. All proposals must be submitted to committees on the National Application Form. A copy of the National Application Form is available from the Health Research Council web site at [www.hrc.govt.nz](http://www.hrc.govt.nz).
250. Persons wishing to submit research proposals in te reo Māori must also provide an English translation.

### **7.1 Guidance to investigators**

251. Committees should be available to provide advice to those considering making an application for ethical review. This may include giving advice on whether ethical approval for a particular proposal is required.

### **7.2 Principles of natural justice**

252. In undertaking the ethical review of proposals, ethics committees should adopt the principles of natural justice and ensure that:
- i. all processes are open, transparent and fair
  - ii. the committee is unbiased in considering applications for ethical approval
  - iii. investigators and/or sponsors are:
    - advised of the process to be undertaken
    - given the opportunity to comment on issues (a reasonable period of time should be given for the parties to respond)
    - kept informed of the progress of a review
    - advised of the outcome of the review
  - iv. in making decisions, no conflict of interest exists or appears to exist (this issue is addressed further under section 6.4 ‘Duties and responsibilities of a member’)
  - v. reasons are given for any decisions or recommendations made. This is of particular importance when:
    - ethical approval is not granted to an application
    - ethical approval is subsequently withdrawn (as the result of a researcher’s or health practitioner’s deviation from an approved protocol)
    - a health practitioner or researcher is directed to suspend a health research project/innovative practice until a complaint can be resolved.

### 7.3 Turnaround times

253. It is desirable that the turnaround time for the consideration of proposals should be as short as possible to avoid hindering the undertaking of acceptable research.
254. Applications received prior to the submission cut-off date for the next scheduled meeting of a committee should, if possible, be dealt with at the meeting rather than deferred because of lack of time. If necessary, an extra meeting may be scheduled or the existing meeting time extended.
255. If it is clear on receipt of a proposal that it is incomplete and that further information will be required before it can be definitively considered, this information should be sought prior to the meeting, at the discretion of the chairperson.

### 7.4 Submission cut-off dates

256. It is important that members of committees be given sufficient time to review and consider submissions prior to a meeting. Each committee should determine a cut-off date before each meeting from which point submissions will not generally be accepted. Committees are under no obligation to consider submissions received after this cut-off date. Once set, a cut-off date should not be changed.
257. Committees should advertise upcoming meeting and cut-off dates to allow sufficient time for submissions to be made. Committees should provide contact details for the committee administrator so that investigators and the public may contact the committee directly regarding upcoming meetings.

### 7.5 Approval processes and terminology

258. It is important to adopt a consistent approach to granting or declining ethical approval of a proposal. It is recommended that the following terminology be used in advising applicants of a committee's decisions:
  - i. ***Approved***, either with or without comments or questions addressed to the applicant; any replies to a committee's comments or questions to be forwarded in due course.
  - ii. ***Provisionally approved***, subject to recommended revisions of the proposal and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded via the committee administrator to the chairperson and/or delegated committee members to consider the revisions that have been made and provide final approval.
  - iii. ***Approval deferred***, pending substantial revisions of the proposal and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded to the committee for reconsideration and final approval.

- iv. *Approval declined*, reasons for declining the approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration. Where appropriate, suggestions should be made for restructuring the proposal along ethically acceptable lines.
259. Every decision, comment or direction of an ethics committee should be made in writing to the principal investigator.

## **7.6 Reporting and monitoring requirements**

260. As part of the conditions of approving a proposal, committees may require an independent review or audit of approved research or innovative practice at any time.
261. Committees should require researchers to submit progress reports as a condition of ethical approval. Reports are required at least yearly, but may, depending on the nature of the proposal, be required more frequently.
262. In general, researchers should be required to immediately report all serious or unanticipated adverse events to the committee. Committees should determine the exact requirements for reporting adverse events on a case-by-case basis taking into account the expected severity of anticipated adverse effects and the nature of a particular proposal.
263. Researchers should also be required to advise participants if new information relating to the safety of the study becomes available.
264. Reporting requirements should include instruction regarding the timeframe in which adverse events should be reported. In the case of multi-centre proposals, reporting should be made to both the local ethics committee and the primary committee that approved the research.
265. Health professionals and researchers should be required, on the completion or abandonment of an approved and implemented proposal, to report on the findings of the research or the outcomes of the treatment. Where an approved application has been abandoned, the reasons for its abandonment should be stated. As part of the conditions of approving a proposal, committees may, depending on the nature of the research and the degree of practicality, require health professionals and researchers to provide a summary of the research findings or treatment outcomes to all participants (this should include notification of the occurrence of any adverse effects).

## **7.7 Changes to approved applications**

266. Any significant alterations to a previously approved proposal must receive prior approval from an Ethics Committee. Significant alterations include changes to:
- i. personnel – any changes to named researchers responsible for conducting or supervising the research at each particular site; any change to the type/nature of research staff in face-to-face contact with participants, or having access to health information or confidential data about identifiable individuals
  - ii. method/procedures
  - iii. design
  - iv. duration of a study
  - v. characteristics of proposed participants
  - vi. method of recruitment
  - vii. information sheets
  - viii. informed consent procedures.
267. Where an amendment is approved for a multicentre trial, it is the responsibility of the primary committee to advise the secondary committees of the alterations to the study.
268. The only exception to the above is where an alteration is required to ensure safety. Such an exception should be reported immediately to the primary and secondary committees. Formal approval for the alteration must be obtained if it is to become an ongoing amendment to the study protocol.

## **7.8 Delegation of decisions**

269. Where a full meeting of a committee has considered and given conditional approval based on the applicant meeting specified requirements, the full meeting of the committee may assign one or more members with the appropriate expertise to assess whether the applicant has met the specified conditions and, if so, to grant final approval.
270. Those delegated with this responsibility must satisfy themselves that the applicant has adequately met the specified conditions. Further amendments may need to be negotiated with the applicant. If the specified conditions cannot satisfactorily be met, the applicant should be advised that the application will need to be referred again to the committee to be considered at its next meeting.
271. The chairperson may have delegated authority to approve the following:
- i. protocols that are non-contentious (for example, use of non-intrusive questionnaires or other simple observational methods)
  - ii. requests for the use of tissue/body parts that would normally be discarded and where the consumer has given consent

- iii. student projects where time is at a premium (medical students, in particular, are given six weeks to develop a research proposal, obtain ethical approval, carry out the research, and prepare a report)
  - iv. minor amendments and extensions to existing protocols
  - v. full approvals where an approval in principle has previously been granted by the committee and the researcher has complied with the requests of the committee.
272. Where any action or decision has been made under delegated authority, the chairperson or other delegated persons shall report back to the committee at the next committee meeting.

## **7.9 Advice from other ethics committees**

273. An ethics committee may consult and receive advice from other ethics committees regarding procedures or proposals. The committee should carefully consider any advice received. The final decision, however, rests with the committee considering the proposal or procedural issue. The committee should be able to justify any decision made. Ethics committees should document any advice received from another ethics committee and should include reference to the advice received in its annual report.

## **7.10 Review of a decision**

274. Committees have an obligation to review any new information that relates to any previous decision to grant or decline ethical approval of a proposal (this includes the investigation of reports that a proposal is not being implemented in a safe and ethical manner). Committees should advise applicants that any decision may be reviewed on the basis of new information in the future.
275. A committee may be requested to review its previous decision in relation to a proposal in the light of new information. The committee should ask those requesting a review of a decision to put their request in writing and to enclose any relevant new information.
276. When a request for review is received, the committee should review any new information and decide whether there are sufficient grounds for changing its initial decision to grant or decline ethical approval of a proposal.
277. Any review should be conducted in an open and transparent manner. All relevant parties should be advised that a review of new information is being undertaken and be kept informed of the progress of the review (refer to section 7.2 ‘Principles of natural justice’).

278. If the committee decides that the new information raises sufficient grounds for changing its decision, the committee should advise all parties accordingly. Depending on the nature of the proposal and the information supporting the request for review, it may be appropriate for the committee to request that the originator of the proposal cease all activities covered by the proposal until the outcome of the review is known.
279. Committees should advise all parties of the outcome of the review and request that the parties concerned indicate whether they are satisfied with the outcome of the review. If all parties are not satisfied with the outcome of the review, a request for a second opinion should be made to the National Ethics Committee or the HRC Ethics Committee.

## **7.11 Withdrawal of ethical approval**

280. When ethical approval is given to a proposal, committees should advise health practitioners and researchers that if they fail to meet any conditions upon which approval is contingent, or if they deviate from an approved protocol without first obtaining the committee's consent, the proposal will be deemed not to have been approved by an ethics committee.
281. Consumers and research participants must be protected from undue harm. Circumstances may arise in which a committee should withdraw ethical approval from a proposal in order to protect participants. Circumstances where ethical approval may be withdrawn include:
- i. when complaints that appear to have some substance have been received from participants
  - ii. where a proposal has deviated from approved protocols
  - iii. where new information becomes available that indicates that the safety of participants may be compromised
  - iv. where an applicant has not reported adverse outcomes to the committee
  - v. where an applicant has not met one or more conditions placed on them when ethical approval was given (this may include not meeting reporting requirements specified at the time of ethical approval).
282. When considering the withdrawal of ethical approval, a committee should follow the principles of natural justice. The health practitioner or researcher should be given an opportunity to comment on any evidence or complaints.
283. Where ethical approval is withdrawn, the applicant should be notified in writing. The committee should request that the applicant cease all activities and advise participants of the removal of ethical approval. It may also be appropriate for a committee to notify:
- i. the organisation employing and/or funding the applicant
  - ii. the institution at which the research is being conducted
  - iii. the Health and Disability Commissioner

- iv. the National Ethics Committee
- v. other health and disability ethics committees
- vi. the HRC Ethics Committee
- vii. the appropriate professional body
- viii. the Ministry of Health.

## **7.12 Second opinions**

284. Second opinions may be sought by an ethics committee in the process of considering a proposal, or by the investigator submitting the proposal who disagrees with a decision made by an ethics committee. (Note that it may be appropriate, depending on the circumstances, to lodge a complaint or seek advice. Also independent comment could be made by the National Ethics Committee or the HRC Ethics Committee.)
285. Requests for a second opinion on a research proposal, including any proposal with a research element, should be referred to the National Ethics Committee or the HRC Ethics Committee. The National Ethics Committee or the HRC Ethics Committee can be contacted for further details before a second opinion is requested. Other proposals (such as service or treatment proposals) should be referred to the National Ethics Committee.
286. Principles of natural justice underlie the second opinion process. All relevant parties should be advised of the process that will be undertaken, should be given opportunity to comment and respond, and should be kept informed.
287. A second opinion request must be accompanied by all relevant and up-to-date information, including a copy of the original application, the written comments supporting the original decision, and a description of the specific issues that form the basis of the request for a second opinion.
288. The committee providing the second opinion (for example, the National Ethics Committee or the HRC Ethics Committee) will take into account information from both the investigator who submitted the application and the original ethics committee and, where appropriate, further submissions made by other relevant parties. Other information available at the time the original decision was made, or new information that has come to light since, may be reviewed in order to determine whether that information is relevant to the decision made. In some circumstances, a draft second opinion for comment may be provided to the relevant parties.
289. A second opinion is not regarded as a higher judgement but rather as a review of the proposal by an independent committee. The second opinion is not binding and neither the National Ethics Committee nor the HRC Ethics Committee is an appeal body in the strict legal sense.
290. The final decision rests with the original ethics committee, which must take into account the second opinion. The original ethics committee must provide reasons

for the final decision to both the applicant and the committee from which the second opinion was sought.

291. In its annual report, an ethics committee must report on any proposal for which a second opinion was sought.

### **Second opinions regarding multi-centre research proposals**

292. In view of the administrative procedure for multi-centre research proposal applications, the concerns of any committee should be clearly identified before a second opinion is requested. Such a request would usually be sought after the primary committee has made a decision.
293. The primary committee and the relevant secondary committee(s) must take into account the second opinion when making the final decision, and must provide reasons for the final decision to both the applicant and the committee from which the second opinion was sought.

### **7.13 Complaints procedure regarding administrative matters**

294. Complaints may be made regarding the performance or conduct of committee members or the administrative procedures of a committee (such as the process used to appoint members). Complaints should generally be made in writing. These may be received directly by the committee itself or by the National Co-ordinator.
295. In all instances, the chairperson and members will be informed of the complaint and the committee concerned will seek to resolve the matter. The chairperson is required to report to the National Co-ordinator regarding any complaint received in relation to administrative matters and the resolution of the complaint.
296. If an administrative complaint cannot be resolved it should be directed to the National Co-ordinator for an independent review and decision.
297. All complaints should be recorded and included in the committee's annual report.

### **7.14 Complaints regarding decisions of committees**

298. Complaints may be made regarding the decisions of ethics committees. Complaints should generally be made in writing. Where verbal complaints are received, the committee should document the complaint in writing. The committee may need to assist some complainants in preparing a written complaint. These may be received directly by the committee itself, the National Ethics Committee, or by the HRC Ethics Committee. The National Co-ordinator should be advised of any complaints.
299. Every committee should have a written document that describes its procedure for dealing with such complaints. Copies of the complaint procedure should be available on request. Complainants should be kept informed about the progress of

their complaint and should be informed in writing about the resolution of the complaint.

300. As has been previously noted, it is important for ethics committees to have regard to the requirements of current legislation and the principles of natural justice (refer to section 7.2). If an ethics committee's advice or recommendations affect the rights or interests of any person, the ethics committee may be held to be exercising 'public power'. The decisions of an ethics committee may therefore be subject to judicial review at common law or to investigation under, for example, the Human Rights Act 1993 or the New Zealand Bill of Rights Act 1990. The occurrence of a judicial review is rare and its focus is on an assessment of the fairness of the process used by the body that made a decision.
301. The processes noted in this section do not preclude recourse to the legal process. Complainants, not satisfied with the outcome of a decision of the committee or a complaint, may seek a judicial review of an ethics committee's decision or lodge a complaint with another appropriate authority (such as the Human Rights Commissioner).

## **7.15 Process for reviewing multi-centre research proposals**

302. Each multi-centre research proposal application should nominate one person as the principal investigator.
303. The primary committee is the committee in the area/locality where the principal investigator is based, and is responsible for the general administration of the approval process on behalf of all committees involved for the proposal.
304. The principal investigator will be responsible for simultaneously sending the appropriate number of copies of the proposal to each and every ethics committee in all areas/localities involved in the study, and for indicating which is the primary committee. The application form must indicate all other centres at which the study will be conducted, and, if appropriate, contain statements from local researchers and their institutions indicating their willingness to participate.
305. The principal investigator will provide local names and contact details in the information sheets and consent forms for each area/locality.
306. Only one Declaration A or B should be completed by the principal investigator noting that it covers all centres and all participants in New Zealand. (It is not necessary for each local researcher to complete Declaration A or B for their own centre.)
307. Secondary committees will consider the proposal and respond to the primary committee with any matters of substance within six weeks of receipt of the protocol (for example, indicating any recommended alterations to the proposal or communicating its concerns, together with reasons). Only significant issues should be addressed by secondary committees; for example, typos should be left to the primary committee.

308. The primary committee will collate all the views of secondary committees. If any committee raises concerns (paragraph 304 sets out the process for resolving concerns relating to scientific validity), the chairperson of the primary committee will attempt to facilitate speedy resolution of the issues by communication (for example, correspondence or teleconference) with the chairperson(s) of the respective committee(s) that expressed the concerns. The primary committee will then provide to the principal investigator a concise summary, referenced to the relevant parts of the proposal. The principal investigator will respond to the primary committee. The primary committee will, after discussing the principal investigator's responses with the secondary committees, make a decision based on consensus.
309. If there is a concern related to the scientific validity of the proposal, the chairperson of the primary committee should ask the expert member(s) of the primary committee to attempt resolution by discussion with the expert members of the other relevant committees. The chairperson of the primary committee may need to contact the principal investigator to seek more information or clarification, and the principal investigator's responses must be communicated to secondary committees. Scientific robustness is important, and where there still remains any disagreement, independent expert advice must be sought by the primary committee.
310. If any disagreement remains after the above process is completed, the decision on the scientific validity of the proposal will be made by the primary committee in the light of the scientific advice it has received. The primary committee will convey its decision, together with that advice, and any comments from the principal investigator, to the secondary committees.
- Note: although issues of scientific validity are relevant matters for ethical consideration, it is important that ethics committees are not perceived to be authorities on scientific matters. Nevertheless, a conclusive decision on the proposal has to be made and, in the case of a multi-centre research proposal, this should come from the primary committee, but only after it has sought and received expert scientific advice that has been widely canvassed from scientific experts.
311. The primary committee or principal investigator may seek a second opinion from the National Ethics Committee or the HRC Ethics Committee after the primary committee has made a decision. The second opinion is not binding.
312. A committee may withdraw its particular area/locality from the study, but only on the basis of local or ethically relevant matters. Examples of when a committee may withdraw its area from a particular study include:
- i. concerns relating to relevant local iwi matters
  - ii. concerns relating to the local researcher (for example, expertise, suitability or appropriateness)
  - iii. concerns about the identity of research participants where a small population is involved.
313. If it is the primary committee that wishes to withdraw its particular area/locality from the study on that basis, and (an)other committee(s) wish(es) to proceed with

the proposal, the nomination of a new primary committee must be made. This should be done in consultation with the principal investigator.

314. An area/locality should not be withdrawn from a study until ethical concerns have been articulated and, if appropriate, a second opinion sought. The implication for the overall design of the study resulting from the withdrawal of a particular area/locality must be taken into account. The primary committee should consult with the principal investigator in reaching its conclusion on this issue.
315. The responsibility for keeping the principal investigator informed or for seeking comments/responses from the principal investigator lies with the chairperson of the primary committee.
316. The primary committee will forward to each secondary committee a copy of the final approval, comments provided to the investigator(s), responses from the investigator(s), and the names of centres for which approval has been given.
317. The primary committee will be responsible for obtaining annual and final reports, and for forwarding them to secondary committees.

### **Adding additional centres to an approved research proposal**

318. The following sets out the process for an application that proposes to add one or more centres to a study that has already received ethical approval ('add-on application'). The guiding principle for any committee reviewing an add-on application is that it should take into account the decision and all relevant matters about previous application(s) relating to the study.
  - i. The add-on application must name all other centres that have been noted in the previous application(s) relating to the study.
  - ii. The committee that reviews an add-on application must seek and take into consideration the decision and comments of the committee(s) that considered the previous application(s) for the study.
  - iii. The committee that reviews an add-on application should, after making its decision and before informing the investigator of its decision, communicate with the primary committee that was responsible for the previous application(s) relating to the study.
  - iv. Annual reporting on a study that has been approved as an add-on application must be provided by the researcher(s) to both the:
    - committee that reviewed the add-on application
    - primary committee that has been responsible for previous applications relating to the study.

## 7.16 Record keeping

319. A committee should maintain an effective system for recording all proposals for innovative practice and health research received and reviewed. As well as all the pertinent facts of each proposal, the records should note:
  - i. whether or not ethical approval was granted or declined and the date of that decision
  - ii. reasons for any decision (referencing supporting evidence)
  - iii. approval or non-approval of any changes
  - iv. any terms and conditions, including monitoring
  - v. details specifically related to multi-centre research.
320. Accurate minutes of each meeting should be kept and confirmed by a quorum of those members who attended a particular meeting.

# Appendix 1: Guidelines for Health Research with Children

321. This appendix (paragraphs 318–326) presents the ethical guidelines developed by Nicola Peart and David Holdaway on health research with children (for full references refer to the original article).<sup>4</sup> For further information on issues relating to research with children refer to:
- i. Peart N, Holdaway D. 1998. Legal and ethical issues of health research with children. *Childrenz Issues* 2: 42–6.
  - ii. Peart N. 2000. Health research with children: the New Zealand experience. *Current Legal Issues* 3: 421–39.
  - iii. Ministry of Health. 1999. *Consent in Child and Youth Health: Information for practitioners*. Wellington: Ministry of Health.
322. The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical considerations should be in place for reviewing research with children.

## Principles

323. These Guidelines are based on six principles, which are mostly taken from the Guidelines of the Royal College of Paediatrics and Child Health 1999 and the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1996.
- i. Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner.
  - ii. Children are not small adults; they have their own unique set of interests.
  - iii. Research should only be done with children if comparable research with adults could not answer the same question and the purpose of the research is to obtain knowledge relevant to the health needs of children.
  - iv. A research procedure which is not intended directly to benefit the child participant is not necessarily unethical.
  - v. All proposals involving health research with children should be submitted to an accredited ethics committee.
  - vi. Legally valid consent should be obtained from the child, parent or guardian as appropriate. When parental consent is obtained, the assent or consent of the children should wherever possible also be obtained by the researcher.

## ***Nature and design of research***

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<sup>4</sup> Peart N, Holdaway D. 2000. Ethical Guidelines for Health Research with Children. *New Zealand Bioethics Journal* 1(2): 3–9.

324. Before undertaking research with children the investigator must ensure that:
- i. children will not be involved in research that might equally well be carried out with adults
  - ii. the purpose of the research is to obtain knowledge relevant to the health needs of children
  - iii. if a choice of age groups is possible, older children should be involved in preference to younger ones
  - iv. the research is designed or supervised and carried out by people experienced in working with children
  - v. the number of children involved is limited to the number which is scientifically and clinically essential.

## **Risk**

325. Research procedures or interventions which are intended to provide direct therapeutic benefit to the child participants may be undertaken if:
- i. the risk is justified by the anticipated benefit to the child participants
  - ii. any relation of the anticipated benefit to the risk is likely to be at least as favourable to the child participant as any available alternative.
326. Research procedures or interventions which are not intended to be of direct benefit to the child participants, but which are likely to yield generalisable knowledge about the child's disorder or condition which is of vital importance for the understanding or amelioration of the child's disorder or condition, may be undertaken if:
- i. any risk represents a minor increase over minimal risk
  - ii. 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.
327. Research procedures which are not intended to be of direct benefit to the child participants, and do not come within the scope of research set out in paragraph 325 or 326 above, may be undertaken only if the risk presented by the interventions to the child participant is:
- i. minimal
  - ii. commensurate with the importance of the knowledge to be gained.

## **Informed consent**

### ***Information***

328. When inviting children to participate in any research the investigator 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 best suited to their needs.

- i. Each child must be given full information about the research in a form that he or she can readily understand.
- ii. Children must be advised of their right to decline participation and their right to withdraw from the research at any time without giving a reason.
- iii. Investigators must give the children an opportunity to ask questions and to have those questions answered to the children's satisfaction.
- iv. If proxy consent is required, the proxy must also be given full information about the research and be advised of the child's right to decline participation or withdraw from the research at any time.
- v. The proxy must be given an opportunity to ask questions and have them answered to the proxy's satisfaction.

### **Consent**

329. Before undertaking research with children the investigator must ensure that appropriate consent is sought on the basis of the information provided:
  - i. The consent of a child of or over the age of 16 must be obtained and has the same effect as if the child were of full age.
  - ii. If the child is below the age of 16, but has the competence to understand the nature, risks and consequences of the research:
    - (a) the consent of the child must be obtained and
    - (b) that consent will have the same effect as if the child were of full age.
  - iii. If the child is below the age of 16, and lacks the necessary competence to give legally effective consent:
    - (a) the child's parent or legal guardian must give permission for the child's participation
    - (b) the child's assent must be obtained unless the child is unable to communicate
    - (c) the refusal of a child to participate in research must be respected unless:
      - according to the research protocol the child would receive therapy for which there is no medically acceptable alternative; or
      - the research comes within the scope of paragraph 325 above.
  - iv. 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 (as in paragraphs 326 and 327 above).
  - v. The requirement for written consent should take into consideration the age and competence of the child.

## **Inducements**

330. Families and children must not receive any financial payments or other reward for participating in the research. Only expenses resulting from participation may be reimbursed.

## **Health research data**

331. Retention and use of personally identifiable health research data:
- i. Research data pertaining to the child participants should be retained by the researcher for ten years after the child has attained the age of 16.
  - ii. Children have the right to withdraw consent to the continued use or retention of personally identifiable health research data once they attain the age of 16.

## **Points to consider**

332. Ethics committees should consider the following points:
- i. Does the research have an identifiable prospect of direct benefit to the individual child participant? Can that benefit be achieved through alternative means?
  - ii. Does the research have an identifiable prospect of risk to the individual child participant? What safeguards are proposed to minimise these risks? When procedures involving greater than minimal risk to children are anticipated, are convincing scientific and ethical justifications given?
  - iii. Is the inclusion of healthy participants justified?
  - iv. Do studies involving placebo controls place the child at greater risk by withholding from selected participants potentially therapeutic research drugs or interventions?
  - v. When possible, have appropriate studies been conducted on animals and adults first? Will older children be enrolled before younger ones?
  - vi. Are mechanisms in place to ensure that children are involved as research participants in ways that do not undermine their dignity as young persons?
  - vii. Are there special problems that call for the presence of a monitor or advocate during consent procedures?
  - viii. Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?
  - ix. Are there any special problems such as confidentiality and reporting that might arise in sensitive research such as research about child abuse or sexual practices of teenagers?
  - x. If conditions present in children have implications for other family members' health statuses, are appropriate mechanisms proposed for dealing with the larger family unit (for example, genetic risks or HIV infection)?
  - xi. Should parents be required to be present during the conduct of the research?

- xii. Are proposed participants to be very young?
- xiii. Are the procedures involved painful?
- xiv. Must participants stay overnight in the hospital when they otherwise would not have to?

### **Applicable laws and regulations**

- 333. Section 25 of the Guardianship Act 1968 governs consent to any medical, surgical, or dental procedure in relation to a child.

## Appendix 2: Research involving People with Intellectual Disabilities: Issues of Informed Consent and Participation

334. This appendix draws extensively on the 1998 paper *Research Involving People with Intellectual Disabilities: Issues of Informed Consent and Participation*, by Anne Bray, Director, Donald Beasley Institute Inc (for full references refer to the original paper).<sup>5</sup>

### Introduction

335. The predominant ethical concern in research involving individuals with intellectual disabilities relates to the extent to which such individuals are able to give informed consent to participate in research. People with intellectual disabilities may be at risk of information not being provided at an appropriate level, of not being able to understand or reason adequately about the information, or of being easily coerced into taking part.
336. People with intellectual disabilities have the same rights as other members of New Zealand society. These rights include the right to choose whether to participate in research and the right to be protected from any undue risks from participation in research.
337. Historically they have experienced disadvantage, over-protection and abuse. Their right to give informed consent has typically been ignored, and unwarranted assumptions have been made about their lack of legal competence.
338. Research evidence and changing conceptions of individual rights have led to statutory changes which recognise a continuum of competence and its specificity to particular situations for a particular individual.
339. In ethically reviewing research involving people with intellectual disabilities ethics committees should ensure that:
- i. any research undertaken is well designed and focuses on an issue of significant importance to people with intellectual disabilities
  - ii. the rights of people with intellectual disabilities to make their own choices and give informed consent is respected
  - iii. people with intellectual disabilities are protected from undue risks, exploitation and abuse.
340. Ethics committees that regularly review research involving people with intellectual disability should consider including among their members one or more individuals who are knowledgeable about and experienced in working with those participants.

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<sup>5</sup> Bray A. 1998. *Research Involving People with Intellectual Disabilities: Issues of informed consent and participation*. Donald Beasley Institute Inc.

## Capacity to give informed consent

341. It has often been assumed that anyone who has any degree of intellectual disability is therefore incapable of giving informed consent to treatment or involvement in research. The capacity to give informed consent is a continuum, and a person's capacity to make decisions may vary depending on the specific topic or area of life under consideration.
342. People with intellectual disabilities vary widely in their degree of intellectual disability and in their ability to understand, reason and communicate. Many people with intellectual disabilities will be capable of making decisions or giving informed consent, depending on the nature of the *specific* decision in question. The capacity of an individual to give informed consent should be assessed on a case-by-case basis.
343. When considering the competence of a person with an intellectual disability to give informed consent it should be recognised that different decisions demand different levels of competence. In other words, a person with an intellectual disability may not be competent to give informed consent to participate in a clinical trial of psychoactive drugs but may well be competent to consent to be interviewed about his/her experiences of community living.
344. Issues of competence to consent are highly significant for people with intellectual disabilities in their daily lives. Questions arise in the provision of health and disability services, their rights to undertake legal contracts, criminal liability, ability to be a witness in a trial – to mention a few.
345. Factors to consider when ethically reviewing research proposals involving people with intellectual disabilities include the following.
  - i. People with intellectual disabilities are not usually concerned about the implications of research for public policy, but are more likely to be interested in what changes the research can bring about for them personally.
  - ii. People with intellectual disabilities often have difficulty separating hypothetical situations from personal anxieties and concerns.
  - iii. People with intellectual disabilities often have fewer opportunities to acquire ordinary knowledge (for example, due to lack of or inappropriate education, segregation, over-protection, lack of access to information).
  - iv. The most difficult area for people with intellectual disabilities to understand is the area of legal rights. They may have limited experience of their voluntary decisions being respected.
  - v. People with intellectual disabilities often have a tendency to comply with the perceived demands of an authority figure.
  - vi. Even persons with severe disabilities may be able to make decisions if given the opportunity, support and training to do so.

346. People with intellectual disabilities may have specific difficulties relevant to informed consent, including:
- i. a reduced vocabulary and understanding of abstract words and ideas
  - ii. shorter attention spans and reduced short-term memory capacity
  - iii. limited abstraction skills (ie, concrete and literal understanding of questions and situations)
  - iv. a reluctance to rarely say they do not understand unless directly asked
  - v. difficulty following long, run-on sentences
  - vi. difficulty answering time-related questions.
347. Proposals for research involving people with intellectual disabilities should clearly describe:
- i. the proposed sample of participants and the possible range of intellectual disabilities to be included
  - ii. how the researcher will determine competence to give informed consent for each individual participant
  - iii. a rationale for the decisions on judgement of competence in terms of the complexity of the research and/or the possible risks to participants.

### **The provision of information to potential participants**

348. Ethics committees should pay particular attention to how researchers intend to provide information to potential participants with intellectual disabilities.
349. A person with an intellectual disability has the right to receive information that he or she can understand, and which takes account of his or her *individual* circumstances, such as level of understanding, reading ability, and knowledge about research and research requirements.
350. People with intellectual disabilities can be very valuable advisers to researchers on the wording of information sheets. Whenever possible, information sheets and consent forms should be trialled with a group of people who are similar to potential study participants.
351. Adequate time must be allowed for the process of obtaining informed consent from people with intellectual disabilities. Whenever possible, information about the research should be provided to each participant on an individual, face-to-face basis.
352. Careful consideration should be given to how other people who are concerned members of the person's support network will be informed about the research, while ensuring that potential participants experience no coercion in making their decision whether or not to take part in the research.
353. A permanent record of the process of information provision should be kept.

## **Recording consent**

354. While written consent is the usual method of recording informed consent in research, some people with intellectual disabilities may be unable to read and/or write, and other methods of obtaining and recording informed consent may be more appropriate.
355. The critical ethical issue relates to obtaining consent based on information and non-coercion. To assure other people that this has occurred, it is necessary to have a permanent record. An audiotape of an oral discussion of the researcher and a participant involving information provision and decision-making can provide an even fuller record of the validity of the consent obtained than a signature on a consent form.

## **Points to consider**

356. Ethics committees should consider the following points.
- i. Will the information provided adequately meet the range of understanding likely to be present in the research sample?
  - ii. Does the researcher have the appropriate experience with people with intellectual disabilities to ensure that he/she understands their possible communication, knowledge and reasoning difficulties, and tendency to acquiesce to ‘authority figures’?
  - iii. Has the researcher sought advice from any people with intellectual disabilities themselves on the wording used in information sheets and consent forms?
  - iv. If the researcher proposes to record oral consent, what experience does he/she have in communicating with people with intellectual disabilities?

## **Applicable laws and regulations**

357. Applicable legislation includes:
- i. sections 6 and 18 of the Protection of Personal and Property Rights Act 1988
  - ii. section 17 of the Judicature Act 1908.
358. Case law with regard to section 17 of the Judicature Act 1908 has said that the approval of the court is required when the:
- i. principal or a major aim of the surgical procedure has a non-therapeutic purpose
  - ii. medical procedure involves interference with a basic human right.

## **Appendix 3: Research involving Unconscious Participants**

359. Research involving unconscious participants may involve the use of an innovative practice or the evaluation of an established therapeutic practice or treatment (refer to Appendix 4). In some circumstances research may involve the delivery of therapeutic interventions in emergency situations (such as consumers requiring intensive care). Whatever the case, research involving unconscious participants raises special problems regarding informed consent.
360. This appendix addresses issues arising where individuals are unconscious at the time their participation in research is being considered. In cases in which the requirement for treatment is foreseeable and participants can be identified in advance (for example, a study to be performed after elective major surgery), informed consent may be obtained well before the surgery.

### **Ethical issues**

361. There is a general expectation that research involving participants will not be conducted without first obtaining informed consent from each participant. Research involving unconscious participants differs from standard research because the participants are unable to provide informed consent.
362. In a situation where a therapeutic intervention is needed and there is no alternative method of approved or generally recognised therapy that provides an equal or greater likelihood of benefiting the consumer, either by saving the person's life or improving or preventing deterioration in their physical and mental health, an innovative practice might be used to treat a consumer who cannot give informed consent if, in the opinion of the health professional, it is the most promising treatment available and it is, in their opinion, in the best interest of the consumer.
363. Consumers, their families and/or legal representatives should be provided with pertinent information when, and if, it becomes possible and appropriate to do so.
364. Wherever possible, families and/or legal representatives should be informed and given the opportunity to express their views prior to undertaking any research. The health professional should take into account the views of those suitable persons who are interested in the welfare of the consumer and are available to advise the provider. In emergency situations, decisions about a consumer's treatment (and hence, in some cases, their participation in research) may have to be made too quickly to consult with families and/or legal representatives. Whatever the case, the health practitioner must always act in the best interests of the consumer.
365. When a consumer recovers consciousness and is able to give informed consent, researchers should seek their consent to continue with the research.

366. If the proposed treatment is contrary to the known wishes of the consumer, the consumer should be excluded from the study and provided with standard care.

### **Research involving the provision of health care**

367. Research involving unconscious participants may involve the provision of health care. Health practitioners are required to observe a standard of care and skill reasonably to be expected in the circumstances in which treatment is provided.
368. Except in specific circumstances, health practitioners are also required to obtain informed consent from the consumer or a person entitled to give consent on behalf of that consumer before providing treatment.
369. One of the exceptions is in an emergency situation, where a health practitioners may, out of necessity, treat a consumer where the consumer cannot give consent and it is not possible to obtain consent from a person entitled to give consent on behalf of that consumer. The action or treatment must be appropriate and reasonable in the circumstances and not more extensive than required. Any action or treatment must be in the best interest of the consumer's life or physical or mental health and must not be contrary to the known wishes of the consumer.

### **Risks and benefits**

370. The risks and benefits of studies involving unconscious consumers may vary from extremely high to negligible. At one extreme, where significant incapacity or death is almost certain, a new therapeutic measure may offer a reasonable chance for recovery, sustaining life, or preventing serious and permanent deficits. In other situations, the potential benefits and risks may be equally great – one may not 'outweigh' the other. Drugs given in an effort to save the lives of trauma victims might do so at the risk of preserving those lives in a persistent vegetative state. Many studies involving unconscious consumers may be almost without risk yet yield information useful in the treatment of the consumer (for example, monitoring certain physiological events by non-invasive means).
371. Ethics committees should ensure that the risks are minimised, the confidence in the anticipated benefits is justifiable, and the risks are reasonable in relation to the anticipated benefits.

### **The legality of research involving unconscious consumers**

372. The legality of undertaking research on unconscious people is not completely clear and until this particular situation is raised before the courts it will continue to remain so. The area of law is governed by a number of different pieces of legislation, together with the common law. Relevant references include:

- i. rights 4(4), 6(1)(d), 7(1), 7(2), 7(4), 7(5), and 7(6) of the Code of Health and Disability Services Consumers' Rights 1996 (refer to Appendix 10)
  - ii. section 33 of the Injury Prevention, Rehabilitation, and Compensation Act 2001
  - iii. sections 61 and 61A of the Crimes Act 1961
  - iv. sections 10 and 11 of the New Zealand Bill of Rights Act 1990.
373. Both the Bill of Rights and the Code of Health and Disability Services Consumers' Rights relate to a person being physically involved in the research. When considering the legality of research involving unconscious consumers it is therefore important to distinguish between research where individuals directly participate (such as with an innovative practice or a clinical trial) and research that utilises information normally gathered during the course of the delivery of a currently recognised health care practice or treatment (such as the clinical evaluation of a particular treatment).
374. If the latter is the case (the research does not involve any additional information gathering above what would normally be associated with a particular treatment), then research can proceed if conducted in compliance with the Health Information Privacy Code 1994.
375. Where research would require the physical involvement of a consumer, each specific case will need to be assessed to determine whether the proposed research is in compliance with the law. The following factors should form the basis of the assessment:
- What is the age of the unconscious person?
  - Can another person legally consent (parent, legal guardian, holder of enduring power of attorney)?
  - What kind of research is involved (for example, leading experimentation, audit or review of data)?
  - Is the research in the best interests of the individual consumer?
  - What orders has the consumer given in a power of attorney or otherwise?
  - How long is the consumer expected to be unconscious?
  - What do the consumer's relatives think?
376. The list is not exhaustive, and depending on the particular circumstances other considerations may be relevant.
377. Ethics committees should require researchers to demonstrate that they have adequate procedures in place for determining in each specific case whether or not the unconscious person may legally be included as a participant of the proposed research.

## **Appendix 4: Clinical Evaluation of Established Therapeutic Practices**

378. Many established therapeutic practices have not been subjected to rigorous scrutiny and evaluation. In some cases two or more alternative therapeutic practices may be in accepted use. The decision to use one practice over another is largely based on the experiences of individual health practitioners.
379. In recent years there has been an increasing move to scientifically evaluate the safety and efficacy of established therapeutic practices. A significant number of accepted therapeutic practices have been found to be either non-beneficial or in some cases harmful to the consumers concerned.

### **Need to evaluate established therapeutic practices**

380. One of the fundamental principles behind the delivery of health care is that health practitioners act in the best interests of the consumer. Where two or more alternative treatments are available, health practitioners should choose the treatment with least risk and most benefit. How then does this equate to situations where two or more established therapeutic practices exist yet have not been scientifically validated?
381. Clinical equipoise exists where, based on the available evidence, the comparative safety and efficacy of two or more alternative therapeutic practices is uncertain. It is therefore not possible to accurately judge the merits of the differing treatments. If the available evidence demonstrates that an available therapeutic practice is safer and more effective than the others, clinical equipoise does not exist.
382. Where an established therapeutic practice has not been scientifically validated and its safety and efficacy are uncertain, health practitioners should evaluate the practice to determine whether the delivery of that therapeutic practice is in fact in the best interests of their consumer.
383. The generally accepted method of evaluating alternative therapeutic practices is through randomised controlled trials.

### **Ethical issues**

384. As health practitioners are legally and professionally accountable for the decisions they make about delivering particular therapeutic practices, the ultimate decision about the type of therapeutic intervention offered to consumers rests with the individual health professional concerned.
385. Proposals to undertake research to evaluate established therapeutic practices should demonstrate to the satisfaction of an ethics committee that clinical equipoise exists.

386. Ethics committees should consider the comparative risks and benefits associated with the alternative therapeutic practices. When considering risks to consumers, committees should consider the reasonably expected treatment risk of each intervention in light of the seriousness of the injuries or illnesses of consumers needing these therapeutic practices.
387. Ethics committees should ensure that the research methodology will facilitate the objective evaluation of the therapeutic practice.
388. Ethics committees should ensure that the consumers, families and/or legal representatives are provided with sufficient information about the nature of the alternative therapeutic practices and how it will be determined which therapeutic intervention the consumer will receive.

### **Legal issues**

389. The Injury Prevention, Rehabilitation, and Compensation Act 2001 (IPRAC Act) provides that a medical error is the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances, and includes a negligent act of failing to obtain informed consent from the consumer or from another defined person if the consumer does not have the legal capacity to provide consent.
390. The Crimes Act 1961 protects any person who performs a surgical operation, with reasonable skill and care, from criminal responsibility if the operation is necessary and is performed for the consumer's benefit. This protection is extended further if the operation is performed for a lawful purpose with consent (from the consumer or from any person lawfully entitled to consent on the consumer's behalf), whether the operation is necessary or not.

## Appendix 5: Research Involving Consumers with a Terminal Illness

391. This appendix has been largely based on the section on research involving consumers with a terminal illness presented in the Institutional Review Board Guidebook 1993.<sup>6</sup>
392. Consumers with a terminal illness are those suffering from a deteriorating life-threatening disease or condition for which no effective standard treatment exists. It is generally considered unacceptable to ask such persons to participate in research for which alternative, not similarly burdened, populations of participants exist. Nevertheless, it may often be necessary to involve consumers with a terminal illness in research concerning their disease and its treatment. Further, consumers with a terminal illness should not be excluded simply because of their status from research in which they may want to participate. One can imagine that altruism and a desire to bring good from adversity may well motivate persons suffering from life-threatening illnesses to become involved in health or behavioural research. Still, individuals with a terminal illness are a vulnerable population of research participants, and therefore require additional protection against coercion and undue influence.
393. Ethics committees have a role both in considering circumstances in which consumers with a terminal illness are appropriately excluded from research because they are a vulnerable group, and in providing persons who have no therapeutic alternatives the opportunity to receive the possible benefits of experimental interventions.
394. If an ethics committee regularly reviews research involving consumers with a terminal illness, it should include among its members one or more individuals knowledgeable about and experienced in working with these participants.

### Overview

395. In many contexts, research involving a terminal illness and its treatment requires the involvement of consumers with a terminal illness when alternative populations for study do not exist or when involving alternative populations would be ethically unjustifiable. Two important reasons for concern regarding research involving consumers with a terminal illness are: (1) they tend to be more vulnerable to coercion or undue influence than healthy adult research participants; and (2) research involving consumers with a terminal illness is likely to present more than minimal risk.

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<sup>6</sup> US Department of Health and Human Services. 1993. Chapter VI: Special Classes of Subjects. Section G: Terminally Ill Patients. *Institutional Review Board Guidebook*. Office for Human Subject Protections.

396. The risk of coercion and undue influence may be caused by a variety of factors. In addition to the fact that severe illness often affects a person's competence, consumers with a terminal illness may be vulnerable to coercion or undue influence because of a real or perceived belief that participation is necessary to receive continuing care from health professionals or because the receipt of any treatment is perceived as preferable to receiving no treatment. Although consumers with a terminal illness should be protected from an understandable tendency to enrol in research under false hopes, ethics committees should not take too protective an attitude toward competent consumers simply because they have a terminal illness. Some consumers with a terminal illness may find participation in research a satisfying way of imparting some good to others out of their own misfortune.
397. It is important to distinguish between risks that may be justified by anticipated benefits for the research participants and risks associated with procedures performed purely for research purposes.
398. A particularly difficult issue relating to research involving consumers with a terminal illness arises in connection with the conduct of Phase 1 drug trials in which the drugs involved are known to be particularly toxic (for example, a new form of cancer chemotherapy). In some of these studies, any benefit to the participant is, at best, highly unlikely. Despite the 'therapeutic intent' of the investigators to benefit the participant, participants may in fact experience a decline in health status, no improvements in terms of quality of life, or only a short extension to their lives. It is extremely important that prospective participants be clearly informed of the nature and likelihood of the risks and benefits associated with this kind of research. The challenge to the investigator and the ethics committees is to provide consumers with an accurate description of the potential benefits without engendering false hope.
399. The HIV epidemic has heightened awareness of mechanisms for including in research persons who have serious and life-threatening illness. Increasingly, individuals and advocacy groups have emphasised the need for opportunities for consumers with a terminal illness to exercise their right of autonomy: to weigh for themselves the risks and benefits of participating in research on drugs, even where relatively little is known about the safety or effectiveness of the drugs. Because they may be in the very early stages of the development of their illnesses, many desperately ill individuals would like to take investigational drugs that may not be available except through limited, well-controlled clinical trials.

### **General considerations**

400. Ethics committees should give careful attention to research involving consumers with a terminal illness; they should also consider requiring special procedures for protecting the rights and wellbeing of these participants. Ethics committees should satisfy themselves that the nature, magnitude, and probability of the risks and benefits of the research have been identified as clearly and as accurately as possible. Special attention should be paid to the consent process, both in terms of the accuracy of the information to be provided and the manner in which consent is sought. As a general rule, accurate information concerning eligibility for

participation (diagnosis and prognosis), treatment options, and risks and benefits should be conveyed clearly and in a manner that will neither engender false hope nor eliminate all hope.

401. Ethics committees must also consider including other information the consumer might find relevant to making an informed decision to participate. For example, participants should be told whether or not participation in the study is a condition for receiving treatment, and any costs to the consumer of the research should be stated explicitly. Ethics committees should consider whether any payment may constitute an undue inducement, particularly if the participant population is economically disadvantaged. Consumers should be provided with relevant information well in advance of making a decision about participation, and consultation with others such as family members, close friends, or medical consultants should be encouraged.
402. Ethics committees may also find it advisable to require that the clinical investigator be someone other than the consumer's physician, that emergency services be readily available, or that there be frequent monitoring of the progress of the research. Factors to consider in making such decisions include:
  - i. anticipated toxicity of the therapeutic interventions
  - ii. extent to which participants are likely to be debilitated by either their illness or their therapy
  - iii. the remaining life expectancy of the participants
  - iv. whether participation in the research would require a change in residence (for example, from home or hospice to a hospital or research institution).

### **Points to consider**

403. Ethics committees should consider the following points:
  - i. Must the research involve consumers with a terminal illness to achieve its objectives?
  - ii. Is a clear explanation of the consumer's eligibility for the study provided?
  - iii. Are specific treatment alternatives, including the option of no treatment, described?
  - iv. Are the potential benefits and risks (and their probability) realistically and simply stated?
  - v. Are the ways in which participation may affect the consumer's lifestyle clearly described (for example, 'You will be hospitalised each month for five to seven days')?
  - vi. Is the consumer assured that he or she can withdraw from the study at any time? If withdrawal from the research will result in a consumer's discharge from a research unit or end the consumer's access to health care that has been provided in conjunction with the research, is that fully explained?

- vii. Should a witness or health and disability consumer advocate be present during consent negotiations?
- viii. Is there reason to require that the consumer's physician not be the clinical investigator?
- ix. If a drug is administered at the community level, does the participant's physician have access to information about the drug's potential usefulness and potential risks?

## Appendix 6: Research involving Older Persons

404. This appendix has been largely based on the section on research involving older persons presented in the Institutional Review Board Guidebook 1993.<sup>7</sup>
405. As the New Zealand population ages, research on the ageing process and conditions and diseases that disproportionately affect older persons has become increasingly important. The participation of older persons in research poses several issues for ethics committees; primary among them is the question of whether and when older persons need special protections. In seeking to protect research participants, ethics committees must be careful not to be over-protective with regard to older persons.

### General considerations

406. It is generally agreed that older persons are, as a group, heterogeneous and not usually in need of special protections, except in two circumstances: cognitive impairment and institutionalisation. Under those conditions, the same considerations are applicable as with any other person in the same circumstances.
407. There is no age at which prospective participants should become ineligible to participate in research. Most older people are neither cognitively impaired nor live in institutional settings. Nevertheless, investigators may avoid older persons as participants because of difficulties in recruiting them to participate. Also, conducting research with older consumers may be more difficult and more costly.
408. A major problem is that older people tend to have multiple conditions/co-morbidities and this may complicate research that tries to isolate a particular intervention for a particular condition. Older people have more complications than younger people from medical drugs. As the likelihood of unfavourable drug interactions increases with the greater the number of drugs an individual takes, for older people it is important to limit the number and dose of drugs prescribed. Symptoms of many diseases in older age may also vary quite markedly from symptoms of the same disease in earlier life.<sup>8</sup>
409. Older persons may have hearing or vision problems and may therefore require more time to have the study explained to them. They also drop out of studies at a higher rate than do younger participants, so that investigators may need to recruit more participants initially to account for this possibility.
410. Despite these difficulties, the inclusion of older persons in the research enterprise is important. Ethics committees should ensure that where they are excluded or treated specially, older persons are in need of protection and are not the object of disdain,

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<sup>7</sup> US Department of Health and Human Services. 1993. Chapter VI: Special Classes of Subjects. Section H: Elderly/Aged Persons. *Institutional Review Board Guidebook*. Office for Human Subject Protections.

<sup>8</sup> Prime Ministerial Task Force. 1997. Reference from Appendix D: Disease Effects in Old Age, Facing the Future: A Strategic Plan, Final Report of Prime Ministerial Task Force on Positive Ageing (July).

stereotyping or paternalism. Together, researchers and ethics committees should enable older persons to share in the benefits and burdens of research.

411. Ethics committees should treat cognitive impairment in older participants as they would cognitive impairment in any prospective participant. The participant population should comprise cognitively-impaired persons only when competent participants are not appropriate for the study, if the study is related to a problem unique to persons with that disability, and if the study involves minimal risk.
412. The use of age as the criterion of ability to consent and therefore participate in research is not valid. Studies have shown that education, health status and inadequate communication about the research rather than age contribute to lack of comprehension and recall. While it is recognised that memory may be a problem for some older participants (thus putting into question their ability to provide continuing consent), the question for ethics committees is whether, despite some impairment to competence, participants can make reasonable choices.
413. In the past, persons in nursing homes or other institutions have been selected as participants because of their easy accessibility. It is now recognised, however, that conditions in institutional settings increase the chances for coercion and undue influence because of the lack of freedom inherent in such situations. Research in these settings should therefore be avoided, unless the involvement of the institutional population is necessary to the conduct of the research (for example, the disease or condition is endemic to the institutional setting, persons who suffer from the disease or condition reside primarily in institutions, or the study focuses on the institutional setting itself).
414. In considering research of this nature, ethics committees should be aware that what may seem trivial to the average person in terms of risk, discomfort, disorientation, or dehumanising effects may not seem so trivial to the potentially vulnerable populations in institutional settings.

### **Points to consider**

415. Ethics committees should consider the following points:
  - i. Does the proposed consent process provide mechanisms for determining the adequacy of prospective participants' comprehension and recall?
  - ii. How will participants' competence to consent be determined?
  - iii. Will the research take place in an institutional setting? Has the possibility of coercion and undue influence been sufficiently minimised?
  - iv. If older people have been excluded from the research, are the reasons valid?
  - v. Does the research methodology make adequate provision for older people (and others) with hearing and/or vision problems or with difficulty in communicating (due to stroke, multiple sclerosis, Parkinsonism, etc)?

## Appendix 7: Research involving Healthy Participants

416. This appendix has been largely based on the section on research involving normal participants presented in the Institutional Review Board Guidebook 1993.<sup>9</sup>
417. The involvement of healthy participants in research may present special concerns with which ethics committees should be familiar. Certain groups of healthy participants (such as students, employees, prison inmates and institutionalised persons) may be considered as being in dependent relationships which may, if not carefully managed, affect their ability to freely chose whether or not to participate in particular research projects.

### Healthy participants

418. Special concerns surround the involvement of healthy persons who volunteer to participate in research. Primarily, the principles involved are beneficence and respect for persons. Beneficent actions can be described by two general rules: (1) do not harm; and (2) maximise possible benefits and minimise possible harms. Volunteers for whom no therapeutic benefit can result from participation in research should, therefore, be exposed to risks that are minimised to the greatest extent possible. While the minimisation of risks is an important requisite for any research involving human participants, the altruistic motivation of the normal volunteer's agreement to participate (contributing to scientific knowledge for the benefit of society) heightens the concern for the risks to which such participants should ethically be exposed.
419. The principle of respect for persons requires that research participants be, where capable of doing so, allowed to act autonomously and to express their right of self-determination. These principles underlie the process of informed consent, which involves providing participants with all relevant information about the study, including the risks and benefits involved, in clear and simple language, and ensuring that the information is understood and appreciated. Furthermore, the agreement to participate must be voluntary, and the consent negotiations must be free from elements of coercion or undue inducement to participate.

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<sup>9</sup> US Department of Health and Human Services. 1993. Chapter VI: Special Classes of Subjects. Section E: Prisoners and Section J: Students, Employees, and Normal Volunteers. *Institutional Review Board Guidebook*. Office for Human Subject Protections.

420. In research involving healthy participants, particularly where the research involves more than minimal risk, ethics committees must ensure that any monetary payments to participants are not so great as to constitute an undue inducement. This issue may be particularly difficult for ethics committees to deal with. Since participants who volunteer to participate in such studies are usually compensated for their time and discomfort, ethics committees should seriously scrutinise the payment schedules to ensure that any compensation offered is commensurate with the time, discomfort and risk involved. Even so, where a research procedure involves serious discomfort and/or the real, though slight, possibility of serious harm (for example, studies that involve the insertion and positioning of catheters in veins or the heart), one can easily imagine that the motivation of persons who volunteer to participate may be monetary. Information about reimbursement of expenses should be made available to participants before they agree to participate.
421. Ethics committees should pay particular attention to the proposed study population and whether it may comprise persons who are likely to be vulnerable to coercion or undue influence, such as persons who are educationally or economically disadvantaged.
422. One area where healthy participants are employed in research is in Phase 1 drug trials. The justification for the involvement of normal, healthy participants is the need for volunteers whose experience with the trial materials is more easily analysed because of the existence of fewer confounding factors. While Phase 1 trials are the first use of experimental drugs and devices in humans, preliminary studies involving animals provide investigators with data indicating a high likelihood of safe use in humans. Ethics committees should scrutinise the likelihood of risk, including the availability of animal data and ensure that this information is available to research participants.
423. Healthy participants, such as students and employees, should be recruited through general announcements or advertisements, rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence, either because of the relationship between the recruiter and the prospective participant, or the methods of communication employed by the recruiter that may act to persuade prospective participants to participate, thus compromising the voluntariness of the agreement to participate.
424. Investigators and ethics committees should carefully consider what will happen if and when a normal volunteer should become sick or be injured during the research. As with any research involving human participants, such issues should be clearly spelled out in the informed consent document, and should be reviewed carefully with the prospective participant. For example, participants should be told whether any medical treatments will be made available should injury occur and, if so, what they consist of; whom to contact should a research-related injury occur; and that they may discontinue participation at any time without penalty or loss of benefits to which they would otherwise be entitled. In addition, where appropriate, participants should be told whether they will be dropped from the study in the event of injury or illness, and whether they will be required to pay for treatment of research-related injuries or illness. Where illness in healthy volunteers does occur,

particularly during a drug study, investigation by an independent physician may be warranted.

425. Ethics committees should ensure that information sheets provide participants with appropriate advice about accident compensation coverage and what indemnity arrangements will be available where ACC coverage is not provided. Participants generally have little understanding and appreciation of the limits of compensation coverage and need to be appropriately informed before agreeing to participate in any research project.

## **Students**

426. Universities, and the association of investigators with them, provide investigators with a ready pool of research participants: students. Many ethics committees have faced the question of whether and in what way students may participate in research. Two questions that have been posed are whether students – medical students, in particular – should be allowed to participate in health research (and whether special protections should be adopted to restrict their participation), and whether participation in research can appropriately be included as a course component which can contribute to the final grade. If such a component is included it should be optional, in that the student is offered an alternative course component without penalty.
427. The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favour with academic staff (for example, that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (by seeming ‘unco-operative’, not part of the scientific community).
428. Prohibiting all student participation in research, however, may be an over-protective reaction. An alternative way to protect against coercion is to require that researchers advertise for participants generally (for example, through notices posted in the school or department) rather than recruit individual students directly. As with any research involving a potentially vulnerable participant population, ethics committees should pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.
429. Another concern raised by the involvement of students as research participants is confidentiality. As with research involving human participants generally, ethics committees should be aware that research involving the collection of data on sensitive topics such as mental health, sexual activity or the use of illicit drugs or alcohol presents risks to participants which they should be made aware of and from which they should be protected, to the greatest extent possible. The close environment of the university amplifies this problem.

430. Where students are likely to be participating in research, ethics committees should consider including a student member or consulting with students where appropriate.

## **Employees**

431. The issues with respect to employees as research participants are essentially identical to those involving students as research participants: coercion or undue influence, and confidentiality. As medical students have seemed ideal participants by health researchers, employees of drug companies have been seen by investigators as ideal participants in some ways, because of their ability to comprehend the protocol and to understand the importance of the research and compliance with the protocol.
432. Just as student participation raises questions of the ability to exercise free choice because of the possibility that grades or other important factors will be affected by decisions to participate, employee research programmes raise the possibility that the decision will affect performance evaluations or job advancement. It may also be difficult to maintain the confidentiality of personal medical information or research data when the participants are also employees, particularly when the employer is also a medical institution.

## **Prison inmates**

433. The involvement of inmates in research was once common because the stability of inmate life (controlled diet, ready availability of participants for follow-up) made prisons attractive research environments. More recently, however, it has been recognised that the very fact of incarceration may make it difficult or impossible for inmates to give voluntary, informed consent.
434. The first question ethics committees must ask when a protocol proposes to use prison inmates as a study population is whether that population was chosen simply out of convenience to the investigator.
435. Some procedures that would inconvenience free participants are not a burden to inmates. However, the nature of incarceration may conflict with the ethical principle of autonomy which requires that the participant 'be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'.
436. The primary issue surrounding the participation of inmates in research has always been whether inmates have a real choice regarding their participation in research, or whether their situation prohibits the exercise of free choice. A secondary issue is whether confidentiality of participation and of data can be adequately maintained in the prison.

437. The circumstances common in prisons create environments in which the offer to participate in research is necessarily coercive or creates an undue influence in favour of participation. The desire to obtain the advantages offered to those who agree to participate may preclude their ability to weigh fairly the risks and benefits involved in participation. For example, the investigator may propose to move the research participants to special units where they are given medical care and where the living conditions are better than those provided to the general prison population. Even the opportunity to leave the prison cell and interact with people from outside the prison may act as an undue inducement to participate in research.
438. In addition to problems of coercion and undue inducement, the involvement of inmates in research raises questions of burden and benefit. Inmates should neither bear an unfair share of the burden of participating in research, nor be excluded from its benefits, to the extent that voluntary participation is possible.
439. Inmates' rights to self-determination (autonomy) should not be circumscribed more than required by applicable regulations. Ethics committees should refrain from assuming, without cause, that prospective inmate-participants will lack the ability to make autonomous decisions about participation in research. To the extent that inmate-participants are found able to voluntarily consent to participation, and to the extent allowable under applicable regulations, inmates should be allowed the opportunity to participate in potentially beneficial research.
440. Finally, confidentiality is extremely difficult to maintain in an environment such as prisons in which there is no privacy. In prisons, people do not move about freely; the movements of inmates are carefully tracked. When inmates are moved around (for example, to go to a research appointment), everyone will know about it. Prison records, including medical records, are accessible to persons who in other settings would not have access to such personal information. Consider the inmate participating in HIV-related research. How will the sensitive nature of the research be kept secret? Before an ethics committee approves any research in prisons, the investigator must be able to ensure that the necessary confidentiality can and will be maintained so that the participants are not subjected to any risk from participation.
441. Ethics committees should determine whether any advantages (better living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison) obtained through participation in the research are of sufficient magnitude to influence the voluntariness of an inmate's choice to participate. Ethics committees must also decide if the risks involved in the research are commensurate with risks that would be accepted by non-inmate volunteers. Committees must ensure that the procedures for selecting participants are fair and immune from arbitrary intervention by prison authorities or inmates.

## Appendix 8: Research involving Māori

442. This appendix has drawn on a number of publications including those produced by the purchasers of Māori research and Māori researchers themselves. Source documents are referenced in the Bibliography.
443. Māori health research practice and theory is developing rapidly. A number of guidelines and standards for undertaking research with and about Māori have been developed over the years. Examples include the Health Research Council *Guidelines for Researchers on Health Research Involving Māori*, Pomare et al (1995) *Hauora: Māori Standards of Health III*, and the *Hongoeka Declaration for Māori Health Researchers* (refer to Te Pumanawa Hauora ki Te Whanganui-a-Tara (Ed.). (1996). *Hui Whakapiripiri: A Hui To Discuss Strategic Directions for Māori Health Research*. Wellington: University of Otago). Many of the issues important to Māori researchers and research participants are covered in the text of this document. Other issues which should also be considered include:
- the Rights of Indigenous Peoples over their cultural and intellectual property (the Mataatua Declaration)
  - the recognition of diverse Māori realities
  - the opportunity for Māori to monitor, critique, and discuss, including in hui and public forums, all research impacting on Māori health
  - the strengthening and development of Māori health researchers.
444. Other indigenous approaches are important comparators to the Māori research developmental approach and this is reflected in a recent agreement on indigenous health research between New Zealand, Canada and Australia (Canadian Institutes of Health Research, National Health and Medical Research Council of Australia, and Health Research Council of New Zealand, 2001).

### Principles

445. The three Treaty of Waitangi principles of partnership, participation and protection should inform the interface between Māori and research.
- Partnership – working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected
  - Participation – involving Māori in the design, governance, management, implementation and analysis of research, especially research involving Māori
  - Protection – actively protecting Māori individual and collective rights, Māori data, Māori culture, cultural concepts, values, norms, practices and language in the research process.

## **Partnership**

446. Consultation is a key component in the development of research on a Māori health issue and for involving Māori as partners and participants in the research process.
447. In the past there have been many instances of misunderstanding resulting from differences in opinions as to what constitutes consultation. Consultation is a two way communication process for presenting and receiving information before final decisions are made, in order to influence those decisions. It is a dynamic and flexible process, which is well summarised by Justice McGechan: “Consultation does not mean negotiation or agreement. It means:
- setting out a proposal not fully decided upon
  - adequately informing a party about relevant information upon which the proposal is based
  - listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal)
  - undertaking that task in a genuine and not cosmetic manner
  - reaching a decision that may or may not alter the original proposal.”

## **Participation**

448. Māori participation in the governance and management of research must also be enabled. Participation by Māori in the research process is especially important in research that focuses on Māori or Māori health. The full range of research methodologies may be applied to Māori and Māori health. This range covers many innovative approaches, especially including kaupapa Māori methodologies, which have been developed by Māori researchers and Māori research units.

## **Protection**

449. Māori participants must be afforded the same protection as all other participants in research with particular acknowledgement of cultural diversity for Māori. This includes protection of individual and collective rights and ownership of data as well as protection from harm. In addition Māori culture, language, cultural beliefs, practices, values and norms must also be supported and protected. Te reo Māori, one of New Zealand’s two official languages, is a special case in point, as are the respective roles and rights of Māori collectives – whānau, hapū, and iwi – and individual Māori.

## **Informed consent**

450. While written consent is the usual method of recording informed consent in research, some Māori may prefer to give their consent orally.

## Points to consider

451. Ethics committees should consider the following points:

- Are mechanisms in place to ensure that Māori are involved as research participants in ways that do not undermine their cultural integrity?
- Are there any special problems such as confidentiality and reporting that might arise in sensitive research such as research about child abuse or sexual practices of rangatahi?
- Are special needs of rangatahi Māori, such as counselling and confidentiality, accounted for in the research design?
- When is it appropriate for parents or other whānau members to be present during the conduct of the research?
- If conditions present in participants have implications for other whānau members' health statuses, are appropriate mechanisms proposed for dealing with the larger family unit (for example, genetic risks or HIV infection)?
- Are mechanisms in place to ensure that tikanga Māori will be observed?
- Are mechanisms in place to ensure the Māori individuals and groups are not marginalised in the research process or by the presentation of the research results?

## Appendix 9: History of Health and Disability Ethics in New Zealand

452. The Medical Research Council (MRC), the predecessor of the Health Research Council, was constituted under the Medical Research Council Act 1950. The MRC developed procedures covering the ethics of experimentation. Applicants to the MRC for project or programme grants were required to sign an ethical agreement stating that they had read and agreed to abide by the principles outlined in the MRC's brochure *Projects and Programme Grants*. In addition, they had to signify that in any research project involving experiment with animal or human subjects, a properly constituted university or hospital ethics committee (or the Ethical Committee of the MRC) had examined and agreed to the ethics of the proposal.
453. Ethical guidelines for research using human participants based on the *Declaration of Helsinki 1964* were first formally adopted in New Zealand in 1968. These guidelines were later revised to incorporate elements relating to informed consent, vulnerable research participants, social, community and health service research.
454. The MRC developed a handbook, which included guidelines on research ethics in human experimentation. Many of the general principles set out primarily for the guidance of clinical researchers were also applicable to those undertaking population studies and other forms of health services research. The handbook also contained a section on the use of medical information for research which was derived from a published statement by the British MRC (British Medical Journal 1973; 1:213-216).
455. Useful as this information was, it did not adequately cover the needs of health service researchers, especially those from non-medical backgrounds. Recognising the limited guidance available for the conduct of health service research in New Zealand, the Health Services Research Committee (jointly established by the MRC and the Department of Health) decided to initiate work aimed at eventually producing an ethical guide or code of practice for health service research in New Zealand. The early work was done by the Department of Health's Management Services and Research Unit. In July 1982 the Unit produced a draft code of practice, which was distributed for comment to those interested and involved in health service research and related research in New Zealand. In light of the response the code was redrafted.
456. In 1983 the Health Services Research Committee released *A Guide to Health Services Research in New Zealand*.
457. With the powers given by the Act, the MRC established an ethics committee which, by May 1984, was called the Committee on Ethics in Research.

458. In 1987 the Inquiry into the Treatment of Cervical Cancer at National Women's Hospital (the Cartwright Inquiry) commenced. In 1988 the *Report of the Cervical Cancer Inquiry* concluded that all research undertaken by health agencies should be reviewed by an ethics committee and that ethical standards 'must be applied rigorously to research and treatment protocols on behalf of the patients'.
459. Following the Cartwright Inquiry, area health boards around the country were given the responsibility of establishing ethics committees for the purpose of considering ethical issues in each board's own research projects and in their health service as a whole.
460. In 1988 the Department of Health began the development of a universal standard for hospital and area health board ethics committees established to review research and treatment protocols.
461. In February 1988 the Department of Health met with representatives of the area health boards' ethics committees, the Auckland and Otago medical schools and the MRC. A draft standard, prepared by the Director of the MRC and the Chief Health Officer and based on the Auckland Hospital model, was considered. The meeting made several recommendations, including the objectives of such ethics committees.
462. The draft *Standard*, amended to take into account the recommendations of the Cartwright Inquiry, was presented to the chairpersons of the area health boards as an agenda paper for their meeting with the Minister of Health in September 1988. Several amendments were made and the chairpersons requested a month's hiatus to enable consultation and the submission of further enhancements before adoption. The enhancements received were incorporated and the *Standard* was promulgated at the end of October 1988.
463. The *Standard* was promulgated while the Review of the Organisation and Public Funding of Biomedical and Health Systems Research in New Zealand was being undertaken. A role for the MRC could not be incorporated in the Standard without pre-empting the report of that review team.
464. Area health boards consulted with community groups regarding the proposed structure and function of their ethics committees.
465. On 28 October 1988 the Department of Health distributed the Standard for Hospital and Area Health Board Ethics Committees Established to Review Research and Treatment Protocols.
466. In November 1989 the chairpersons of the area health boards' ethics committees again met with the Department of Health to consider amendments to the *Standard for Hospital and Area Health Board Ethics Committees Established to Review Research and Treatment Protocols*.

467. The Health Research Council (HRC) and the HRC Ethics Committee were established under the Health Research Council Act 1990. The functions of the HRC, as provided in section 5 of that Act, include initiating and supporting health research and advising the Minister of Health on national health research policy. Section 24 of the Health Research Council Act 1990 established the HRC Ethics Committee to consider and make recommendations to the HRC on ethical issues in relation to health research, especially those emerging through the development of new areas of health research. The HRC Ethics Committee has a statutory responsibility to provide advice about ethics committees established by bodies other than the HRC regarding the membership of those committees, procedures to be adopted, and standards to be observed by those committees. The HRC also has a duty to provide independent comment on ethical problems that may arise in any aspect of health research.
468. In December 1991 the Department of Health distributed the *Standard for Ethics Committees Established to Review Research and Ethical Aspects of Health Care* to the chairpersons of the area health board ethics committees. The revised Standard reflected many practical suggestions and improvements emanating from the experience gained over the area health board ethics committees' first three years of operation. The revised *Standard* aimed to make ethics committees operate more effectively to promote the highest standard of ethical behaviour among researchers and health professionals.
469. In May 1993 the Privacy Act 1993 was passed and the office of the Privacy Commissioner was established later that year.
470. When the new government's health reforms were implemented in July 1993, and area health boards were replaced by Crown health enterprises, the funding for health and disability ethics committees transferred to the regional health authorities (RHAs).
471. RHAs were given the option of either establishing ethics committees as committees of the RHA boards under clause 13 of the second schedule to the Health and Disability Services Act 1993, or contracting ethics committees to provide ethical review under section 32(2) of that Act. Under either option, RHAs were required to ensure that health and disability ethics committees were established and operated in accordance with the 1991 *Standard for Ethics Committees Established to Review Research and Ethical Aspects of Health Care* (1991 Standard) promulgated by the Ministry of Health, and were required to ensure that the deliberations of the committees were independent of the RHAs. In three regions (Southern, Central and North Health) the regional ethics committees were sub-committees of the RHA boards, and in Midland the committees were contracted through the chairpersons.
472. With the introduction of health reforms the opportunity was taken to put the structure and the inter-relationship between the ethical committees and the HRC under fresh scrutiny.

473. Section 7 of the Health and Disability Services Act 1993 provided for the establishment of advisory committees to the Minister of Health. It was proposed that a National Advisory Committee on Health and Disability Services Ethics (NACHDSE) be established under this provision.
474. To assist in the establishment of the proposed NACHDSE, the Crown established an Interim Taskgroup on Health and Disability Service Ethics (Interim Taskgroup) in April 1993. Also established in April 1993 was the Interim National Ethics Committee on Assisted Reproductive Technology (INECART). INECART was responsible for the ethical review of proposals concerned with assisted reproductive technologies.
475. The Interim Taskgroup was required to:
- i. provide an interim report to the Director-General of Health by 29 October 1993 on its recommendations on the revised 1991 *Standard* to ensure it was compatible with the health reforms and the new structure of ethical review and to ensure satisfactory protection for consumers of health and disability services and participants in associated research
  - ii. recommend interim approval and monitoring mechanisms for health and disability ethics committees in accordance with the revised *National Standard*
  - iii. provide a final report to the Director-General of Health by 28 February 1994 on the structure of health and disability ethics committees and the structure, role, configuration and membership of the proposed NACHDSE.
476. On the initiative of Te Puni Kōkiri, the Māori Working Group on Health Sector Ethics was established to assist the Interim Taskgroup on Health and Disability Service Ethics, and in particular its Māori members, to find ways of reflecting tikanga in the process of ethical review. The group met at Te Puni Kōkiri on 10 December 1993 and focused on two issues:
- i. developing an acceptable ethical committee structure for Māori
  - ii. considering the Māori aspects of the *Standard for Ethics Committees*.
477. The Māori Working Group reported in February 1994, outlining recommended amendments to the 1991 *Standard* (the report was replicated in Appendix 7 of the Interim Taskgroup's Report).
478. The Interim Taskgroup reported to the Director-General in February 1994. The Taskgroup considered that the two key aims of health and disability ethics committees were:
- i. to protect consumers of health and disability services and research participants by providing ethical review of research and procedures used in the delivery of health and disability support services
  - ii. to provide ethical advice and input into health and disability care research, policy and practices which reflects local and community ethical perspectives and values.

479. The Taskgroup noted that: ‘Local ethics committees can thus provide review of two types of material:
- i. that for which independent ethical review is *required*. Requirements derive from legislation, funding agreements and obligations, professional codes, other legal obligations and requirements of funding and purchasing bodies. The areas currently included are research and innovative treatments, both therapeutic and diagnostic.
  - ii. that for which independent ethical review may be *appropriate*. This could include provision of guidelines for treatment policies for local providers, review of existing treatment protocols, consideration of ethical issues relating to individual cases, the efficacy of information and consent procedures (for example, forms) and advice or input from the community on particular ethical issues. For example, on request existing committees have provided comment on informed consent procedures and autopsy policies for particular providers.’
480. The Taskgroup’s report made a number of recommendations, including:
- i. that a single set of local ethics committees be retained which have responsibility for undertaking ethical review of both research and service/treatment issues for health and disability support services
  - ii. setting the desirable structure, role, configuration and membership of the proposed NACHDSE
  - iii. that local committees be accountable to and monitored by NACHDSE
  - iv. that NACHDSE be ultimately responsible for the accreditation and monitoring of local ethics committees for the health and disability services sector
  - v. that NACHDSE request the HRC Ethics Committee to act as its agent and to undertake the accreditation process in accordance with the revised *Standard*
  - vi. that advice on the proposed changes to a single *Standard* for the operation of local ethics committees be jointly agreed between NACHDSE and the HRC Ethics Committee.
481. As part of its considerations the Taskgroup considered the issue of amending the 1991 *Standard* to make it applicable to all types of ethics committees. The Taskgroup was concerned that the 1991 *Standard* could become ‘diluted’ if it was rewritten to have universal applicability.
482. In May 1994 an *Interim National Standard for Ethics Committee* was circulated to health and disability ethics committees to guide their operation and ethical review processes.
483. The Health Information Privacy Code 1994 came into force on 30 July 1994. This code of practice applies specific rules to agencies in the health sector to better ensure the protection of individual privacy and health information relating to identifiable individuals. The code applies to all agencies providing health and disability services to individuals. It also applies to other agencies which do not provide health services to individuals but which are part of the health sector, such

as regional health authorities ACC, Ministry of Health, HRC, health insurers and professional disciplinary bodies.

484. The National Advisory Committee on Health and Disability Service Ethics (NACHDSE), under section 7 of the Health and Disability Services Act 1993, was established in 1994. NACHDSE's primary functions were to:
- i. advise the Minister of Health on ethical issues relating to health and disability services and research
  - ii. draft and review the *National Standard for Ethics Committees* and develop national guidelines to assist with health and disability ethics committees operations
  - iii. encourage the networking of committees to improve their effectiveness and efficiency, including the co-ordination of meetings of the chairpersons of health and disability ethics committees.
485. The Health and Disability Commissioner Act 1994 was passed in October 1994 and the Commissioner's Office was established in 1995.
486. In March 1995 INECART was disbanded and the National Ethics Committee on Assisted Human Reproduction (NECAHR) was established under section 46 of the Health and Disability Services Act 1993.
487. In 1995 a working party consisting of representatives from NACHDSE, HRC, health and disability ethics committees and the Ministry of Health was convened to review the 1994 *Interim National Standard*.
488. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 came into force on 1 July 1996. The regulations apply to all types of health and disability services and research. The Code sets out the rights of all consumers receiving services from a health and disability provider and when acting as participants in research or teaching. In addition to the Code a nationwide advocacy service was established.
489. The working party reviewing the 1994 *Interim National Standard* completed work on a new revised *National Standard for Ethics Committees* in 1996. The 1996 *National Standard* contained considerably more detail on the constitution, operation and accountability of regional ethics committees than the 1991 *Standard*. It also reflected the broader responsibilities of ethics committees to review research and innovative treatment protocols used in the disability and health sector. The *Standard* included some preliminary guidelines for the provision of advice on the ethical aspects of issues regarding health and disability services while recognising this as an area where further work was needed.
490. With the disestablishment of the RHAs in 1997 the responsibility for the funding and servicing of health and disability ethics committees was transferred to the Transitional Health Authority and to the Health Funding Authority when it was established in 1998.

491. In 1999, following a review of the structure of ethics in New Zealand by the Ministry of Health, and Cabinet approval, NACHDSE was disestablished. The review concluded that the key tasks of NACHDSE were to:
- i. provide advice to the Minister of Health on ethical matters of national significance relating to health and disability services
  - ii. develop the *National Standard for Ethics Committees* and guidelines, and the monitoring of their use
  - iii. monitor the health and disability ethics committees compliance with the *National Standard for Ethics Committees*
  - iv. provide second opinions on service and treatment issues.
492. These functions, while necessary, did not need to be carried out by a Ministerial advisory committee appointed by statute. It was agreed that the Ministry of Health would contract out some of the functions and others would be undertaken by the HRC Ethics Committee.
493. In 1999 the Ministry of Health began the review of the 1996 *National Standard for Ethics Committees*. A working group was established to provide advice to the Ministry regarding the revision of the *Standard*. The Working Group met six times between 7 July 1999 and 27 June 2000.
494. In January 2001 the New Zealand Public Health and Disability Act 2000 came into force. Section 16 of this Act requires that the National Advisory Committee on Health and Disability Support Services Ethics (National Ethics Committee) be established. The National Ethics Committee was established by and is accountable to the Minister of Health. The National Ethics Committee's statutory functions are to:
- i. provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
  - ii. determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.
495. On 10 April 2001 the *Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* was publicly released. The report made a number of recommendations regarding ethics committees, as follows:
- i. There needs to be change to guidelines under which ethics committees operate to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.
  - ii. There should be a review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

- iii. Ethics committees require guidance regarding the application of the Privacy Act 1993 and the Health Information Privacy Code 1994. Ethics committees need to be informed that the interpretation of legislation relating to personal privacy is for the agency holding a consumer's data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.
- iv. Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.
- v. A national ethics committee should be established for the assessment of multi-centre or national studies.
- vi. The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.

# Appendix 10: List of Relevant New Zealand Legislation and Codes

## Introduction

496. In the health environment, a variety of different statutory responsibilities and obligations are placed on those wishing to undertake health research, innovative practice and clinical practice. A number of powers and responsibilities have also been placed directly on committees.
497. This appendix provides a list of the relevant legislation that either directly impacts on the operation of committees or which should be considered when ethically reviewing applications. Committees should ensure that they remain apprised of any changes to existing legislation.
498. It is recommended that each ethics committee have a copy of the following legislation.

## Legislation

- Injury Prevention, Rehabilitation, and Compensation Act 2001
- Health and Disability Commissioner Act 1994
- Health Research Council Act 1990
- Mental Health (Compulsory Assessment and Treatment) Act 1992
- New Zealand Bill of Rights Act 1990
- Official Information Act 1982
- Privacy Act 1993
- Protection of Personal and Property Rights Act 1988
- Human Rights Act 1993
- Archives Act 1957.

## Regulations

- Health and Disability Commissioner (Code Of Health and Disability Services Consumers' Rights) Regulations 1996
- Health (Retention of Health Information) Regulations 1996.

## Codes

- Health Information Privacy Code 1994
- Interim New Zealand Guidelines for Good Clinical Research Practice.

## Specific references

499. A number of references have been made throughout the *Operational Standard* to specific sections of legislation and regulations. For convenience, those references

have been provided below. It is important, however, that any consideration of these sections be undertaken in the context of the relevant act or regulation as a whole.

## **Code of Health and Disability Services Consumers' Rights**

### **1. Consumers have rights and providers have duties**

- (1) Every consumer has the rights in this Code.
- (2) Every provider is subject to the duties in this Code.
- (3) Every provider must take action to:
  - (a) Inform consumers of their rights; and
  - (b) Enable consumers to exercise their rights.

### **2. Rights of consumers and duties of providers**

The rights of consumers and the duties of providers under this Code are as follows:

#### **Right 1: Right to be treated with respect**

- (1) Every consumer has the right to be treated with respect.
- (2) Every consumer has the right to have his or her privacy respected.
- (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.

#### **Right 2: Right to freedom from discrimination, coercion, harassment, and exploitation**

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial, or other exploitation.

#### **Right 3: Right to dignity and independence**

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

#### **Right 4: Right to services of an appropriate standard**

- (1) Every consumer has the right to have services provided with reasonable care and skill.
- (2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
- (3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
- (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.

- (5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

**Right 5: Right to effective communication**

- (1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.
- (2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

**Right 6: Right to be fully informed**

- (1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including:
  - (a) An explanation of his or her condition; and
  - (b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
  - (c) Advice of the estimated time within which the services will be provided; and
  - (d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
  - (e) Any other information required by legal, professional, ethical, and other relevant standards; and
  - (f) The results of tests; and
  - (g) The results of procedures.
- (2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.
- (3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about:
  - (a) The identity and qualifications of the provider; and
  - (b) The recommendation of the provider; and
  - (c) How to obtain an opinion from another provider; and
  - (d) The results of research.
- (4) Every consumer has the right to receive, on request, a written summary of information provided.

## **Right 7: Right to make an informed choice and give informed consent**

- (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.
- (2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
- (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.
- (4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where:
  - (a) It is in the best interests of the consumer; and
  - (b) Reasonable steps have been taken to ascertain the views of the consumer; and
  - (c) Either:
    - (i) If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
    - (ii) If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
- (5) Every consumer may use an advance directive in accordance with the common law.
- (6) Where informed consent to a health care procedure is required, it must be in writing if:
  - (a) The consumer is to participate in any research; or
  - (b) The procedure is experimental; or
  - (c) The consumer will be under general anaesthetic; or
  - (d) There is a significant risk of adverse effects on the consumer.
- (7) Every consumer has the right to refuse services and to withdraw consent to services.
- (8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.
- (9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
- (10) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.

**Right 8: Right to support**

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

**Right 9: Rights in respect of teaching or research**

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

**Right 10: Right to complain**

- (1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.
- (2) Every consumer may make a complaint to:
  - (a) The individual or individuals who provided the services complained of; and
  - (b) Any person authorised to receive complaints about that provider; and
  - (c) Any other appropriate person, including:
    - (i) An independent advocate provided under the Health and Disability Commissioner Act 1994; and
    - (ii) The Health and Disability Commissioner.
- (3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
- (4) Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.
- (5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
- (6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that:
  - (a) The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
  - (b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of:
    - (i) Independent advocates provided under the Health and Disability Commissioner Act 1994; and
    - (ii) The Health and Disability Commissioner; and
  - (c) The consumer's complaint and the actions of the provider regarding that complaint are documented; and
  - (d) The consumer receives all information held by the provider that is or may be relevant to the complaint.

- (7) Within 10 working days of giving written acknowledgement of a complaint, the provider must:
  - (a) Decide whether the provider:
    - (i) Accepts that the complaint is justified; or
    - (ii) Does not accept that the complaint is justified; or
  - (b) If it decides that more time is needed to investigate the complaint:
    - (i) Determine how much additional time is needed; and
    - (ii) If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.
- (8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of:
  - (a) The reasons for the decision; and
  - (b) Any actions the provider proposes to take; and
  - (c) Any appeal procedure the provider has in place.

### **3. Provider compliance**

- (1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
- (2) The onus is on the provider to prove that it took reasonable actions.
- (3) For the purposes of this clause, “the circumstances” means all the relevant circumstances, including the consumer’s clinical circumstances and the provider’s resource constraints.

### **4. Definitions**

In this Code, unless the context otherwise requires:

“Advance directive” means a written or oral directive:

- (a) By which a consumer makes a choice about a possible future health care procedure; and
- (b) That is intended to be effective only when he or she is not competent.

“Choice” means a decision:

- (a) To receive services;
- (b) To refuse services;
- (c) To withdraw consent to services.

“Consumer” means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer.

“Discrimination” means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993.

“Duties” includes duties and obligations corresponding to the rights in this Code.

“Exploitation” includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence.

“Optimise the quality of life” means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances.

“Privacy” means all matters of privacy in respect of a consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates.

“Provider” means a health care provider or a disability services provider.

“Research” means health research or disability research.

“Rights” includes rights corresponding to the duties in this Code.

“Services” means health services, or disability services, or both; and includes health care procedures.

“Teaching” includes training of providers.

## **5. Other enactments**

Nothing in this Code requires a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

## **6. Other rights not affected**

An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.

## **New Zealand Bill of Rights Act 1990**

### **3 Application**

This Bill of Rights applies only to acts done:

- (a) By the legislative, executive, or judicial branches of the government of New Zealand; or
- (b) By any person or body in the performance of any public function, power, or duty conferred or imposed on that person or body by or pursuant to law.

#### **4 Other enactments not affected**

No court shall, in relation to any enactment (whether passed or made before or after the commencement of this Bill of Rights):

- (a) Hold any provision of the enactment to be impliedly repealed or revoked, or to be in any way invalid or ineffective; or
- (b) Decline to apply any provision of the enactment by reason only that the provision is inconsistent with any provision of this Bill of Rights.

#### **9 Right not to be subjected to torture or cruel treatment**

Everyone has the right not to be subjected to torture or to cruel, degrading, or disproportionately severe treatment or punishment.

#### **10 Right not to be subjected to medical or scientific experimentation**

Every person has the right not to be subjected to medical or scientific experimentation without that person's consent.

#### **11 Right to refuse to undergo medical treatment**

Everyone has the right to refuse to undergo any medical treatment.

### **Guardianship Act 1968**

#### **6 Guardianship of children**

- (1) Subject to the provisions of this Act, the father and the mother of a child shall each be a guardian of the child.
- (2) Subject to the provisions of this Act, the mother of a child shall be the sole guardian of the child if –
  - (a) She is not married to the father of the child, and either:
    - (i) Has never been married to the father; or
    - (ii) Her marriage to the father of the child was dissolved before the child was conceived; and
  - (b) She and the father of the child were not living together as husband and wife at the time the child was born.
- (3) Where the mother of a child is, or was at the time of her death, its sole guardian by virtue of subsection (2) of this section the father of the child may apply to the Court to be appointed as guardian of the child, either in addition to or instead of the mother or any guardian appointed by her, and the Court may in its discretion make such order on the application as it thinks proper.
- (4) On the death of the father or the mother the surviving parent, if he or she was then a guardian of the child, shall, subject to the provisions of this Act, be the sole guardian of the child.

## **25 Consents to operations**

- (1) Subject to subsection (6) of this section, the consent of a child of or over the age of 16 years to any donation of blood by him, or to any medical, surgical, or dental procedure (including a blood transfusion) to be carried out on him for his benefit by a person professionally qualified to carry it out, shall have the same effect as if he were of full age.
- (2) The consent of or refusal to consent by a child to any donation of blood or to any medical, surgical, or dental procedure (including a blood transfusion) whether to be carried out on him or on any other person, shall if the child is or has been married have the same effect as if he were of full age.
- (3) Where the consent of any other person to any medical, surgical, or dental procedure (including a blood transfusion) to be carried out on a child is necessary or sufficient, consent may be given:
  - (a) By a guardian of the child; or
  - (b) If there is no guardian in New Zealand or no such guardian can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent; or
  - (c) If there is no person in New Zealand who has been so acting, or if no such person can be found with reasonable diligence or is capable of giving consent, by a District Court Judge or the chief executive.
- (4) Where a child has been lawfully placed for the purpose of adoption in the home of any person that person shall be deemed to be a guardian of the child for the purposes of subsection (3) of this section.
- (5) Nothing in this section shall limit or affect any enactment or rule of law whereby in any circumstances:
  - (a) No consent or no express consent is necessary; or
  - (b) The consent of the child in addition to that of any other person is necessary; or
  - (c) Subject to subsection (2) of this section the consent of any other person instead of the consent of the child is sufficient.
- (6) Except to the extent that this section enables a blood transfusion (as defined in subsection (1) of section 126B of the Health Act 1956) to be administered to a child without the consent of any other person, nothing in this section shall affect the provisions of the said section 126B.

## **25A Consents to abortions**

Notwithstanding anything in section 25 of this Act, a female child (of whatever age) may:

- (a) Consent to the carrying out on her of any medical or surgical procedure for the purpose of terminating her pregnancy by a person professionally qualified to carry it out; or
- (b) Refuse her consent to the carrying out on her of any such procedure, and her consent or refusal to consent shall have the same effect as if she were of full age.

## **Protection of Personal and Property Rights Act 1988**

### **6 *Jurisdiction of Court under this Part***

- (1) Subject to subsection (2) of this section, a Court shall have jurisdiction under this Part of this Act in respect of any person who is ordinarily resident in New Zealand and who:
  - (a) Lacks, wholly or partly, the capacity to understand the nature, and to foresee the consequences, of decisions in respect of matters relating to his or her personal care and welfare; or
  - (b) Has the capacity to understand the nature, and to foresee the consequences, of decisions in respect of matters relating to his or her personal care and welfare, but wholly lacks the capacity to communicate decisions in respect of such matters.
- (2) Subject to section 12(3) of this Act, no Court shall have jurisdiction under this Part of this Act in respect of any person who has not attained the age of 20 years and who is not and never has been married.

### **12 *Court may appoint welfare guardian***

- (3) A Court may make an order under subsection (1) of this section in respect of any person who has not attained the age of 20 years and who is not and never has been married if, but only if:
  - (a) No parent or guardian of that person is then living; or
  - (b) No parent or guardian of that person is in regular contact with that person, and the Court is satisfied in all the circumstances that it would be in the interests of that person to appoint a welfare guardian for that person.

### **18 *Powers and duties of welfare guardian***

- (1) No Court shall empower a welfare guardian, and no welfare guardian shall have power:
  - (a) To make any decision relating to the entering into marriage by the person for whom the welfare guardian is acting, or to the dissolution of that person's marriage; or
  - (b) To make any decision relating to the adoption of any child of that person; or
  - (c) To refuse consent to the administering to that person of any standard medical treatment or procedure intended to save that person's life or to prevent serious damage to that person's health; or
  - (d) To consent to the administering to that person of electro-convulsive treatment; or
  - (e) To consent to the performance on that person of any surgery or other treatment designed to destroy any part of the brain or any brain function for the purpose of changing that person's behaviour; or
  - (f) To consent to that person's taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or of preventing serious damage to that person's health.

- (2) Subject to subsection (1) of this section, a welfare guardian shall have all such powers as may be reasonably required to enable the welfare guardian to make and implement decisions for the person for whom the welfare guardian is acting in respect of each aspect specified by the Court in the order by which the appointment of the welfare guardian is made.
- (3) In exercising those powers, the first and paramount consideration of a welfare guardian shall be the promotion and protection of the welfare and best interests of the person for whom the welfare guardian is acting, while seeking at all times to encourage that person to develop and exercise such capacity as that person has to understand the nature and foresee the consequences of decisions relating to the personal care and welfare of that person, and to communicate such decisions.
- (4) Without limiting the generality of subsection (3) of this section, a welfare guardian shall:
  - (a) Encourage the person for whom the welfare guardian is acting to act on his or her own behalf to the greatest extent possible; and
  - (b) Seek to facilitate the integration of the person for whom the welfare guardian is acting into the community to the greatest extent possible; and
  - (c) Consult, so far as may be practicable:
    - (i) The person for whom the welfare guardian is acting; and
    - (ii) Such other persons, as are, in the opinion of the welfare guardian, interested in the welfare of the person and competent to advise the welfare guardian in relation to the personal care and welfare of that person; and
    - (iii) A representative of any group that is engaged, otherwise than for commercial gain, in the provision of services and facilities for the welfare of persons in respect of whom the Court has jurisdiction in accordance with section 6 of this Act, and that, in the opinion of the welfare guardian, is interested in the welfare of the person and competent to advise the welfare guardian in relation to the personal care and welfare of that person.
- (5) In addition to subsection (4)(c) of this section, where the person for whom the welfare guardian is acting is subject to a property order, the welfare guardian shall consult on a regular basis with the manager of that person's property to ensure that the interests of that person are not prejudiced through any breakdown in communication between the welfare guardian and the manager.
- (6) A welfare guardian may apply to a Court for directions relating to the exercise of the powers of the welfare guardian, and the Court may give such directions as it thinks fit.

## **Judicature Act 1908**

### **17 *Jurisdiction as to mentally disordered persons, etc***

The Court shall also have within New Zealand all the jurisdiction and control over the persons and estates of idiots, mentally disordered persons, and persons of unsound mind, and over the managers of such persons and estates respectively, as the Lord Chancellor of

England, or any Judge or Judges of Her Majesty's High Court of Justice or of Her Majesty's Court of Appeal, so far as the same may be applicable to the circumstances of New Zealand, has or have in England under the Sign-manual of Her Majesty or otherwise.

# Appendix 11: Terms of Reference for the National Advisory Committee on Health and Disability Support Services Ethics

## The Role of the Committee

The National Advisory Committee on Health and Disability Support Services Ethics (“the National Ethics Committee”) is a ministerial advisory committee established under section 16 of the New Zealand Health and Disability Act 2000 (“the Act”). The National Ethics Committee is established by and accountable to the Minister of Health.

The National Ethics Committee’s statutory functions are to:

- i. provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services);
- ii. determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

As part of its functions the National Ethics Committee is also required to:

- i. consult with any members of the public, persons involved in the funding or provision of services, and other persons that the committee considers appropriate before providing advice on an issue (section 16(4) refers);
- ii. at least annually, deliver to the Minister of Health a report setting out its activities and summarising its advice on the matters referred to it under section 16 of the Act by the Minister of Health.

In undertaking its functions, the National Ethics Committee is expected to:

- i. provide advice on priority issues of national significance as requested by the Minister of Health;
- ii. provide advice to the Minister of Health regarding ethical issues concerning emerging areas of health research and innovative practice. The advice is to include the National Ethics Committee’s rationale for its advice and any relevant evidence and/or documentation;
- iii. provide advice to the Minister of Health regarding aspects of ethical review in New Zealand including the setting of principles and guidelines in relation to each of the different types of health research and innovative practice. The advice is to include the National Ethics Committee’s rationale for its advice and any relevant evidence and/or documentation;
- iv. develop and promote national ethical guidelines for health research and health and disability support services (the guidelines should address how to conduct different types of health research [including ethical issues relating to Māori health research] and innovative practice in an ethical manner and should establish parameters for, and provide guidance on, the ethical review of such types of health research and health and disability support services);

- v. monitor and review the operation of the health and disability ethics committees for the purposes of providing direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector;
- vi. undertake its tasks in a manner consistent with the principles of the Treaty of Waitangi;
- vii. provide a second opinion in relation to decisions of health and disability ethics committees, the National Ethics Committee on Assisted Human Reproduction and any other ethical review committee established by the Minister of Health under section 16(3) of the Act.

In response to the recommendations of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region, the first task of the National Ethics Committee will be to:

- i. review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand;
- ii. develop guidelines on conducting observational studies in an ethical manner and establish parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research);
- iii. consider the application of second opinion and appeal processes and recommend their appropriate use for ethics committees.

### **Composition of the Committee**

The National Ethics Committee shall consist of not more than 12 members appointed by the Minister of Health (“the Minister”). The National Ethics Committee’s membership shall include:

- i. two health professionals (one of whom must be a registered medical practitioner)
- ii. two health researchers (one of whom should have knowledge and expertise of qualitative research and one of whom should have knowledge and expertise of quantitative research)
- iii. one epidemiologist
- iv. three other members (must not be a health professional or health researcher. One of whom must be a lawyer and one who must be an ethicist. Includes persons with a knowledge and understanding of the ethics of health research and the provision of health care, and academic staff)
- v. three community/consumer representatives (must not be health professionals, health researchers, or professional members)
- vi. one member nominated by the Health Research Council.

At any time, the National Ethics Committee shall have at least two Māori members; one of whom shall be a person with Māori research/ethics background.

The Director-General of Health will appoint an advisor to the National Ethics Committee who will be responsible for providing advice regarding government policy and the mechanics of government.

### **Terms and conditions of appointment**

Members of the National Ethics Committee are appointed by the Minister of Health for a term of office of up to three years. The terms of office of members of the National Ethics Committee will be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than 6 consecutive years. Unless a person sooner vacates their office, every appointed member of the National Ethics Committee shall continue in office until their successor comes into office. Any member of the National Ethics Committee may at any time resign as a member by advising the Minister of Health in writing.

Any member of the National Ethics Committee may at any time be removed from office by the Minister of Health for inability to perform the functions of office, bankruptcy, neglect of duty, or misconduct, proved to the satisfaction of the Minister.

The Minister may from time to time alter or reconstitute the National Ethics Committee, or discharge any member of the National Ethics Committee or appoint new members to the National Ethics Committee for the purpose of decreasing or increasing the membership or filling any vacancies.

### **Chairperson**

The Minister will from time to time appoint a member of the National Ethics Committee to be its Chairperson. The Chairperson will preside at every meeting of the National Ethics Committee at which they are present. The Chairperson may from time to time appoint a member as Deputy-Chairperson.

### **Duties and responsibilities of a member**

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of the National Ethics Committee. This is intended to aid members of the National Ethics Committee by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the National Ethics Committee and its members.

As an independent statutory body, the National Ethics Committee has an obligation to conduct its activities in an open and ethical manner. The National Ethics Committee has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference.

## **General**

1. The National Ethics Committee members should have a commitment to work for the greater good of the committee.
2. There is an expectation that members will make every effort to attend all the National Ethics Committee meetings and devote sufficient time to become familiar with the affairs of the committee and the wider environment within which it operates.
3. Members have a duty to act responsibly with regard to the effective and efficient administration of the National Ethics Committee and the use of committee funds.

## **Conflicts of interest**

4. Members must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the National Ethics Committee and its members and will ensure it retains public confidence.
5. Members attend meetings and undertake committee activities as independent persons responsible to the committee as a whole. Members are not appointed as representatives of professional organisations and groups. The National Ethics Committee should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.
6. When members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or undertaking an activity consistent with the committee's functions, they must declare that conflict of interest and withdraw themselves from the discussion and/or activity.
7. A member of the National Ethics Committee who has a proposal before the committee or who has an involvement in a proposal, such as a supervisory role, shall not take part in the National Ethics Committee's assessment of that proposal. The member may be present to answer questions about a proposal but should be asked to leave the meeting while the remaining members consider the proposal. This will allow proposals to be considered in a free and frank manner.

## **Confidentiality**

8. The public has a right to be informed about the issues being considered by the National Ethics Committee. The National Ethics Committee should have procedures in place regarding the release of information and processing requests for information.
9. Individual members must observe the following duties in relation to committee information. These provisions ensure that the National Ethics Committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.

- i. Meetings of the National Ethics Committee, including agenda material and draft minutes, are confidential. Members must ensure that the confidentiality of committee business is maintained.
- ii. Members are free to express their own views within the context of committee meetings, or the general business of the National Ethics Committee.
- iii. Members must publicly support a course of action decided by the National Ethics Committee. If unable to do so, members must not publicly comment on decisions.
- iv. At no time should members individually divulge details of committee matters or decisions of the National Ethics Committee to persons who are not committee members. Disclosure of committee business to anyone outside the committee must be on the decision of the committee, or between meetings, at the discretion of the Chairperson of the National Ethics Committee. In choosing to release or withhold information, the committee must comply with the provisions of the Official Information Act 1982 and the Privacy Act 1993.
- v. Committee members must ensure that committee documents are kept secure to ensure that the confidentiality of committee work is maintained. Release of committee correspondence or papers can only be made with the approval of the committee.

### **Working arrangements**

The National Ethics Committee will agree a work programme with the Minister of Health. The National Ethics Committee will be serviced by permanent staff, sufficient to meet the committee's statutory requirements, that will be based in the Ministry of Health.

In carrying out its terms of reference, the National Ethics Committee must:

- i. provide the Minister of Health with advance notice of any media statements or reports to be published
- ii. ensure its advice is published and widely available
- iii. ensure that, in developing any advice, guidelines, or its views in relation to an appeal, an appropriate balance exists between protecting the rights and well-being of patients and research participants and facilitating health research and innovative practice
- iv. ensure that, where appropriate, any advice or guidelines contain clear guidance regarding the application of ethical principles that is appropriate to the type of health research or innovative practice being considered (due regard should be given to the different nature of qualitative and quantitative approaches to research)
- v. ensure that any advice, guidelines, and views in relation to an appeal, comply with the laws of New Zealand
- vi. ensure appropriate consultation has occurred in accordance with the requirements set out below.

## **Consultation**

Where appropriate, the National Ethics Committee must make reasonable attempts to consult with:

- i. health and disability ethics committees
- ii. the National Ethics Committee on Assisted Human Reproduction
- iii. the Health Research Council Ethics Committee
- iv. any other Ethics Committee established by the Minister of Health
- v. organisations known to the committee to represent affected patients or other groups of the community
- vi. relevant whānau, hapū, and iwi
- vii. a reasonably representative sample of affected patients or members of the public or (if the National Ethics Committee thinks it more appropriate) a reasonably representative sample of people who would be entitled to consent on behalf of the affected patients or members of the public
- viii. a reasonably representative sample of affected health researchers and/or affected health professionals
- ix. relevant government bodies.

## **Performance measures**

The National Ethics Committee will be effectively meeting its tasks when it provides relevant and timely advice to the Minister of Health based on research, analysis and consultation with appropriate groups and organisations.

The National Ethics Committee must:

- i. agree in advance a work programme with the Minister of Health
- ii. achieve its agreed work programme
- iii. stay within its allocated budget

## **Meetings of the committee**

Meetings shall be held at such times and places as the National Ethics Committee or the Chairperson of the National Ethics Committee decides.

At any meeting, a quorum shall consist six members. A quorum must include either the Chairperson or Deputy-Chairperson. An endeavour will be made to ensure reasonable representation of community/consumer members and members with specialist knowledge of and experience.

Every question before any meeting shall generally be determined by consensus decision-making. Where a consensus cannot be reached a majority vote will apply. Where a decision cannot be reached through consensus and a majority vote is made, the Chairperson shall have the casting vote.

Subject to the provisions set out above, the National Ethics Committee may regulate its own procedures.

### **Reporting requirements**

The National Ethics Committee is required to:

- i. keep minutes of all committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made
- ii. prepare an annual report to the Minister of Health setting out its activities and comparing its performance to its agreed work programme and summarising any advice that it has given to the Minister of Health. The report is to include the National Ethics Committee's rationale for its advice and any relevant evidence and/or documentation. This report will be tabled by the Minister of Health in the House of Representatives pursuant to section 16(7) of the Act.

### **Servicing of the committee**

The Ministry of Health will employ staff to service the National Ethics Committee out of the Committee's allocated budget and consistent with the Memorandum of Understanding between the National Ethics Committee and the Ministry of Health.

### **Fees and allowances**

Members of the National Ethics Committee are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies. The Chairperson will receive \$430 per day (plus half a day's preparation fee) and an allowance of two extra days per month to cover additional work undertaken by the Chairperson. The attendance fee for members is set at \$320 per day (plus half a day's preparation fee). The Ministry of Health pays for actual and reasonable travel and accommodation expenses of the National Ethics Committee members.

Authorised by Hon Annette King, Minister of Health, in November 2001.

# Appendix 12: Terms of Reference for the National Ethics Committee on Assisted Human Reproduction

## The role of the committee

The National Ethics Committee on Assisted Human Reproduction (“NECAHR”) is a ministerial committee established under section 11 of the New Zealand Public Health and Disability Act 2000 (“the Act”).

NECAHR’s functions are to:

- i. review assisted human reproductive proposals (including health research and innovative treatment) to determine whether they are ethical and, in particular, to determine whether:
  - the rights of the people involved will be protected
  - proper account will be taken of the ethical perspectives of Māori, and other cultural, ethnic, religious, and social groups in New Zealand
- ii. develop for providers protocols and guidelines relating to the ethical issues involved with aspects of assisted human reproduction
- iii. advise the Minister of Health on ethical issues relating to assisted human reproduction
- iv. consider any other matters relating to assisted human reproduction the Minister of Health from time to time determines.

## Composition of the committee

Individuals appointed to NECAHR have a range of experience, from first-time appointees with little or no experience as a member of such committees to members with extensive experience. NECAHR draws considerable benefits from having a diverse membership with a range of skills, attributes, and experience.

NECAHR shall consist of not more than 10 members appointed by the Minister of Health (“the Minister”). NECAHR’s membership shall include members with specialist knowledge of and experience in assisted human reproductive procedures. NECAHR shall have at least two Māori members. At any time, at least half the members of NECAHR shall be lay members.

For the purposes of appointments to NECAHR, a lay member is defined as anyone who:

- i. is not a registered health professional engaged in health care delivery or employed in the provision of health or disability services
- ii. is not involved as a researcher in health and disability research in the field of assisted human reproduction

- iii. may not be construed by virtue of current or previous employment to have a potential conflict or professional bias in assessing a majority of applications presented to NECAHR for ethical review.

The Director-General of Health will appoint one person to represent the Ministry of Health. It will be the responsibility of that person to provide NECAHR with information regarding government policy and ministerial views.

### **Terms and conditions of appointment**

Members of NECAHR are appointed by the Minister of Health under section 16(3) of the New Zealand Public Health and Disability Act 2000 for a term of office of up to three years. Members may be reappointed from time to time. No member may hold office for more than 9 consecutive years. Unless a person sooner vacates their office, every appointed member of NECAHR shall continue in office until their successor comes into office. Any member of NECAHR may at any time resign as a member by advising the Minister in writing.

Any member of NECAHR may at any time be removed from office by the Minister for disability, bankruptcy, neglect of duty, or misconduct, proved to the satisfaction of the Minister.

The Minister may from time to time alter or reconstitute NECAHR, or discharge any member of NECAHR or appoint new members to NECAHR for the purpose of decreasing or increasing the membership or filling any vacancies.

### **Chairperson**

The Minister will from time to time appoint a member of NECAHR to be its Chairperson. The Chairperson will preside at every meeting of NECAHR at which they are present. The Chairperson may from time to time appoint a member as Deputy-Chairperson.

### **Duties and responsibilities of a member**

This section sets out the Minister's expectations regarding the duties and responsibilities of a person appointed as a member of NECAHR. This is intended to aid members of NECAHR by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect NECAHR and its members from exposure to legal challenges.

As an independent statutory body, NECAHR has an obligation to conduct its activities in an open and ethical manner. NECAHR has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference.

### **General**

1. NECAHR members should have a commitment to work for the greater good of the committee.

2. There is an expectation that members will make every effort to attend all NECAHR meetings and devote sufficient time to become familiar with the affairs of the committee and the wider environment within which it operates.
3. Members have a duty to act responsibly with regard to the effective and efficient administration of NECAHR and the use of committee funds.

### ***Conflicts of interest***

4. Members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect NECAHR and its members and will ensure it retains public confidence.
5. Members attend meetings and undertake committee activities as independent persons responsible to the committee as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. NECAHR should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.
6. When members believe they have a conflict of interest on a subject which will prevent them from reaching an impartial decision or undertaking an activity consistent with the committee's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.
7. A member of NECAHR who has a proposal before the committee or who has an involvement in the proposal such as a supervisory role shall not take part in NECAHR's assessment of that proposal. The member may be present to answer questions about a proposal but should be asked to leave the meeting while the remaining members consider the proposal. This will allow proposals to be considered in a free and frank manner.

### ***Confidentiality***

8. The public has a right to be informed about the issues being considered by NECAHR. NECAHR should have procedures in place regarding the release of information and processing requests for information.
9. NECAHR also has a duty to protect the rights of those making applications for ethical review. NECAHR should therefore determine what information can be appropriately released, and to whom and under what circumstances information should be released. The following duties in relation to committee information should be observed by individual members. These provisions ensure that the NECAHR committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.
  - i. Meetings of NECAHR, including agenda material and minutes, are confidential. Members should ensure that the confidentiality of committee business is maintained.

- ii. Members are free to express their own views within the context of committee meetings, or the general business of NECAHR.
- iii. Members should publicly support a course of action decided by NECAHR. If unable to do so, members should not publicly comment on decisions.
- iv. At no time should members individually divulge details of committee matters or decisions of NECAHR to persons who are not committee members. Disclosure of committee business to anyone outside the committee should be on the decision of the committee, or between meetings, at the discretion of the Chairperson of NECAHR. In choosing to release or withhold information, the committee must comply with the provisions of the Official Information Act 1982 and the Privacy Act 1993.
- v. Committee members should ensure that committee documents are kept secure to ensure that the confidentiality of committee work is maintained. Release of committee correspondence or papers can only be made with the approval of the committee.

### **Fees and allowances**

Members of NECAHR, and of any sub-committees appointed by NECAHR, are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies. Currently the Chairperson receives an honorarium of \$10,000 per annum, and the attendance fee for members is set at \$250 per day (plus half a day's preparation fee). NECAHR pays for actual and reasonable travel and accommodation expenses.

### **Meetings of the committee**

Meetings shall be held at such times and places as NECAHR or the Chairperson of NECAHR decide.

At any meeting, a quorum shall consist either of half the total number of members when that number is even, or the majority of the members when that number is odd. The quorum must include a balance of lay members and members with specialist knowledge of and experience in assisted human reproductive procedures.

Every question before any meeting shall be determined by consensus decision making.

Subject to the provisions set out above, NECAHR may regulate its own procedures.

### **Working arrangements**

In carrying out its terms of reference, NECAHR:

- i. will be serviced by the Ministry of Health
- ii. will be provided with personal indemnity insurance by the Ministry of Health
- iii. may carry out information gathering and research as is reasonably required

- iv. may consult such other expert persons that are considered reasonably necessary to carry out the committee's functions
- v. may not disclose any confidential information without the approval of the Minister of Health
- vi. none of the individual members will make media statements without the consent of the committee
- vii. the committee should advise the Minister of Health prior to making any media statements or publishing any reports.

### **Key ethical principles**

When scrutinising proposals, NECAHR should be satisfied that the following key ethical principles have been adequately upheld before giving ethical approval for a proposal to proceed:

- i. participants'<sup>10</sup> right to autonomy
- ii. participants' right to informed consent
- iii. protection of participants from undue harm
- iv. freedom from coercion and inducement
- v. participants right to privacy
- vi. principles and obligations under the Treaty of Waitangi
- vii. cultural equity and partnership
- viii. research and treatment merit.

### **Principles of natural justice**

In undertaking the ethical review of applications, NECAHR should adopt the principles of natural justice. NECAHR should therefore ensure that:

- i. it has the appropriate expertise available to adequately review each proposal
- ii. all processes are open, transparent, and fair
- iii. it is unbiased in considering applications for ethical approval
- iv. all relevant parties are:
  - advised of the process to be undertaken
  - given the opportunity to be heard and to comment on issues (a reasonable period of time should be given for the parties to respond)
  - kept informed of the progress of a review
  - advised of the outcome of the review
- v. in making decisions, no conflict of interest exists or appears to exist
- vi. reasons are given for any decisions or recommendations made. This is of particular importance when:

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<sup>10</sup> For the purposes of these "Participants" refers to the clients of providers of fertility services, and also includes a potential child when appropriate.

- ethical approval is not granted to an application
- a health professional or researcher is directed to suspend a health research project/innovative practice until a complaint can be resolved
- ethical approval is subsequently withdrawn.

### **Review of a decision**

NECAHR has an obligation to review any new information which pertains to any previous decision to grant or decline ethical approval of a proposal. NECAHR should advise applicants that any decision may be reviewed on the basis of new information in the future.

Any person may, at any time, request that NECAHR review a proposal in the light of new information. NECAHR should ask those requesting a review of a decision to put their request in writing and to enclose the relevant new information.

When a request for review is received, NECAHR should review any new information and decide whether there are sufficient grounds for changing its initial decision to grant or decline ethical approval of a proposal.

Any review should be conducted in an open and transparent manner. All relevant parties should be advised that a review of new information is being undertaken and kept informed of a review's progress.

If NECAHR decides that the new information raises sufficient grounds for changing its decision, NECAHR should advise all parties accordingly. Depending on the nature of the proposal and the information supporting the request for review, it may be appropriate for NECAHR to request that the originator of the proposal cease all activities covered by the proposal until the outcome of the review is known.

NECAHR should advise all parties of the outcome of the review and request that the parties concerned indicate whether they are satisfied with the outcome of the review. If all parties are not satisfied with the outcome of the review, the issue should be referred to either the HRC Ethics Committee (in the case of issues relating to health research) or the Director-General of Health (in all other cases). An independent person or group appointed by the Director-General or HRC Ethics Committee will undertake a review of the decision making process used by the committee.

### **Withdrawal of ethical approval**

It is important to protect patients and research participants from undue harm. Circumstances may arise in which NECAHR should withdraw ethical approval from a proposal in order to protect participants. Circumstances where ethical approval may be withdrawn include:

- i. when complaints that appear to have some substance have been received from participants
- ii. where a proposal has deviated from approved protocols

- iii. where new information becomes available that indicates that the safety of participants may be at risk
- iv. where an applicant has not reported significant or unexpected adverse outcomes to the committee
- v. where an applicant has not met one or more conditions placed on them when ethical approval was given (this may include not meeting reporting requirements specified at the time of ethical approval).

When ethical approval is given to a proposal, NECAHR should advise health professionals and researchers that, if they fail to meet any conditions upon which approval is contingent or if they deviate from an approved protocol without first obtaining the committee's consent, the proposal will automatically cease to have ethical approval.

When considering the withdrawal of ethical approval, NECAHR should follow the principles of natural justice. The health professional or researcher should be given an opportunity to comment on any evidence or complaints.

Where ethical approval is withdrawn, the applicant should be notified in writing. NECAHR should request the applicant to cease all activities and advise participants of the removal of ethical approval. It may also be appropriate for a committee to notify:

- the organisation employing or funding the applicant
- the Health and Disability Commissioner
- other health and disability ethics committees
- the Health Research Council Ethics Committee
- the appropriate health professional body
- the Ministry of Health.

### **Independent assessment of decision-making process**

A person who submitted a proposal for ethical review to NECAHR may seek a second opinion regarding NECAHR's decision to withhold ethical approval. Requests for a second opinion should generally be made in writing. Second opinions should be directed to the Director-General of Health.

When a request for a second opinion is received, the Director-General of Health will establish an independent advisory group (consisting of members with the appropriate expertise) to provide a second opinion.

A second opinion will adhere to the principles of natural justice. All relevant parties will be advised of the process that will be undertaken and will be kept informed of the progress of the second opinion process.

A second opinion:

- i. is concerned with issues related to the ethics of the proposal

- ii. is not regarded as a higher judgement but rather as a review of NECAHR's decision making process
- iii. does not overturn NECAHR's decision; in other words, the conclusions of the advisory group that provides the independent assessment does not bind NECAHR to take any particular action
- iv. should be taken into account by NECAHR when reconsidering the proposal and reaching its final decision.

The final decision regarding the granting or withholding of ethical approval rests with NECAHR.

The advisory group assessing NECAHR's decision making process will:

- i. take into account the decision reached by NECAHR after it conducted an initial review of the proposal
- ii. give written reasons supporting its conclusions.

The advisory group that provides the second opinion may comment on whether NECAHR had:

- i. received adequate information from the applicant
- ii. taken reasonable and appropriate steps to gather and consider all relevant information. Factors that may be considered include:
  - the availability of information
  - whether additional information could have been sought from the applicant, experts, or from other committees which may have considered related proposals
- iii. been in a position to adequately consider and assess the application through possessing or seconding appropriate expertise
- iv. adhered to the principles of natural justice
- v. adequately recorded and conveyed to the applicant those factors which were considered critical to the decision.

The advisory group is not restricted to the material that was considered by NECAHR. Other information that was available at the time when the original decision was made or new information that has come to light may be considered in order to determine whether that information is relevant to the decision of the initial review.

## **Reporting requirements**

NECAHR is required to:

- i. keep minutes of all committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made
- ii. prepare a brief annual report to the Minister summarising the work of the committee for the past year.

## **Performance measurement**

The committee will be effectively undertaking its tasks when it:

- i. provides timely and comprehensive ethical review of proposals involving assisted human reproduction
- ii. provides timely advice to the Minister of Health on issues relating to assisted human reproduction
- iii. develops and drafts protocols to assist fertility clinics in developing proposals for health research and innovative practice relating to assisted human reproduction
- iv. performs these functions within the budget provided.

## **Servicing of the committee**

The Ministry of Health will provide the services of a committee secretary. The duties of the secretary will be to:

- i. prepare draft minutes
- ii. prepare agenda and meeting notes
- iii. draft correspondence, reports, etc as directed by the committee
- iv. circulate papers and written material to committee members
- v. organise meeting venue and catering as required
- vi. make travel and accommodation arrangements
- vii. arrange for the timely and accurate payment of meeting fees and allowances
- viii. administer the committee budget.

Authorised by Hon Annette King, Minister of Health, in March 2001.

## Appendix 13: Health and Disability Ethics Committees

Committee	Administrator's address	Administrator's telephone
Auckland X	C/o Ministry of Health 3rd Floor, Unisys Building 650 Great South Road Penrose Private Bag 92-522 Wellesley Street AUCKLAND	Phone (09) 580 9105 Fax (09) 580 9001 E-mail: pat_chainey@moh.govt.nz
Auckland Y	C/o Ministry of Health 3rd Floor, Unisys Building 650 Great South Road Penrose Private Bag 92-522 Wellesley Street AUCKLAND	Phone (09) 580 9105 Fax (09) 580 9001 E-mail: pat_chainey@moh.govt.nz
Bay of Plenty	Carol Campbell c/o ADCAM PO Box 134 WHAKATANE	Phone (07) 308 5030 Fax (07) 308 5033 E-mail: adcam@pop.ihug.co.nz
Canterbury	Ministry of Health 4th Floor 250 Oxford Street PO Box 3877 CHRISTCHURCH	Phone (03) 372 3018 Fax (03) 372 1015 E-mail: sally_cook@moh.govt.nz
Hawke's Bay	Hawke's Bay Ethics Committee PO Box 5144 Greenmeadows NAPIER	Phone/fax (06) 844 0360 E-mail: hb.ethics@xtra.co.nz
Manawatu/Wanganui	Room 14 Rimu Hostel Palmerston North Hospital PO Box 5203 PALMERSTON NORTH	Phone (06) 356 7773 Fax (06) 356 7773 E-mail: mwethics@xtra.co.nz
National Co-ordinator	Ministry of Health PO Box 5849 DUNEDIN	Phone (03) 474 8098 Mobile 025 807 878 Fax (03) 474 8090 E-mail: carol_algie@moh.govt.nz
Nelson/Marlborough	1st Floor FMG Building 44 Halifax Street PO Box 672 NELSON	Phone (03) 546 6219 Fax (03) 546 7295 E-mail: cathy@pss.co.nz
Otago	Ministry of Health PO Box 5849 DUNEDIN	Phone(03) 474 8562 Fax (03) 474 8582 E-mail: lynda_young@moh.govt.nz
Southland	PO Box 116 INVERCARGILL	Phone (03) 230 4409 Fax (03) 230 4409 E-mail: southland.ethics@clear.net.nz

<b>Committee</b>	<b>Administrator's address</b>	<b>Administrator's telephone</b>
Tairāwhiti	PO Box 1245 GISBORNE	Phone (06) 867 7874 Fax (06) 867 1562 E-mail: trudi.roe@xtra.co.nz
Taranaki	PO Box 555 NEW PLYMOUTH	Phone (06) 758 9086 Fax (06) 758 9278 E-mail: ethics@stafflink.co.nz
Waikato	PO Box 322 2 Glencoe Place HAMILTON	Phone (07) 846 1539 Fax (07) 846 1496 E-mail: wai.ethics@clear.net.nz
Wellington	Wellington Hospital PO Box 7902 WELLINGTON	Phone (04) 385 5999 ext 5185 Fax (04) 385 5840 E-mail: claire.l@wec.org.nz
West Coast	West Coast Ethics Committee 17 Weenink Road GREYMOUTH	Home phone (03) 768 7505 Home fax (03) 768 5095 E-mail: barbara.beckford@xtra.co.nz

## Appendix 14: Other Committees

### Health Research Council

The Health Research Council (HRC) was established by the Health Research Council Act 1990. The functions of the HRC, as provided in section 5 of that Act, include:

- i. initiating and supporting health research
- ii. advising the Minister of Health on national health research policy
- iii. promoting and disseminating the results of health research in ways that will be most effective in encouraging their contribution to health science, health policy, and health care delivery
- iv. ensuring the development and application of appropriate assessment standards by committees or subcommittees that assess health research proposals.

Contact: Dr Bruce Scoggins  
Chief Executive  
Health Research Council  
PO Box 5541  
Wellesley Street  
AUCKLAND  
Phone: (09) 303-5203  
Fax: (09) 303-5205  
E-mail: [bscoggins@hrc.govt.nz](mailto:bscoggins@hrc.govt.nz)  
HRC Website: <http://www.hrc.govt.nz>

### Health Research Council Ethics Committee

The HRC Ethics Committee is established as a statutory committee of the HRC under section 24 of the Health Research Council Act 1990. The HRC Ethics Committee considers and makes recommendations to the HRC on ethical issues in relation to health research, especially those emerging through the development of new areas of health research (section 25(1)(a) of the Health Research Council Act 1990).

In respect of each application submitted to the HRC for a grant for the purposes of health research, the HRC Ethics Committee is empowered to ensure that an independent ethical assessment of the proposed health research is made either by itself or by a committee approved by the HRC Ethics Committee (section 25(1)(c) of the Health Research Council Act 1990).

In relation to ethics committees established by other bodies, the HRC Ethics Committee has the statutory function to give advice on:

- i. the membership of those committees
- ii. the procedures to be adopted, and the standards to be observed, by those committees (section 25(1)(f) of the Health Research Council Act 1990).

Chairperson: Ms Marge Scott  
Contact: Ms Jean Gibbons  
Secretary  
Health Research Council Ethics Committee  
PO Box 5541  
Wellesley Street  
AUCKLAND  
Phone: (09) 303-5216  
Fax: (09) 303-5205

### **Health Research Council Māori Health Committee**

The HRC Māori Health Committee is established as a statutory committee of the HRC under section 21 of the Health Research Council Act 1990. The principal functions of the Māori Health Committee are to advise the HRC on health research into issues that affect Māori people, with particular reference to research impinging on cultural factors affecting the Māori people, including those that affect the gathering of information, and the verification and validation of information (section 22 of the Health Research Council Act 1990).

Chairperson: Dr Chris Cunningham  
Phone: (04) 380-0620 (Massey University Wellington Campus)  
Contact: Ms Louisa Wall  
Manager  
Māori Health Research  
Health Research Council  
PO Box 5541  
Wellesley Street  
AUCKLAND  
Phone: (09) 303-5220  
Fax: (09) 303-5205  
E-mail: lwall@hrc.govt.nz

### **Data Safety Monitoring Board**

The Data Safety Monitoring Board (DSMB) is a standing committee of the HRC. Its primary role is to monitor large-scale public good clinical trials referred to it by the principal investigator, trial sponsor, or the relevant ethics committee. The diseases being studied will usually be life threatening or have severe irreversible morbidity attached to them. Prior to DSMB review, the protocol will have been both peer reviewed and reviewed by a protocol review group.

The monitoring of clinical trials has two main scientific and ethical objectives: the first is to ensure that the trial is conducted according to the approved protocol, and high quality data is obtained; the second is to ensure that the trial remains scientifically and ethically sound throughout its duration. The DSMB may recommend to the study investigators and sponsors that the trial be terminated where safety and efficacy data indicates that participants are being exposed to unacceptable levels of risk.

Contact: Dr Andrew Hvizdos  
Health Research Council  
PO Box 5541  
Wellesley Street  
AUCKLAND  
Phone: 09 303-5206  
Fax: 09 303-5205  
Email: ahvizdos@hrc.govt.nz

### **The Standing Committee on Therapeutic Trials (SCOTT)**

The Standing Committee on Therapeutic Trials (SCOTT) is a committee of the HRC. It is convened to provide recommendations to the Director-General of Health on the scientific validity of applications for clinical trials on new medicines. All clinical trials involving pre-registration medicines will need to have the approval of SCOTT to proceed.

Section 30 of the Medicines Act 1981 empowers the Director-General of Health on the advice of the HRC to permit the use of medicines that have not received marketing consent, to be used in clinical trials for the purpose of obtaining clinical and scientific information. Post-registration medicines used in clinical trials do not require approval of SCOTT but undergo the process of ethical review.

Chairperson: Dr Richard Robson

Contacts Ms Colleen Moore  
Secretary  
Department of Clinical Pharmacology  
Christchurch Hospital  
Private Bag 4710  
CHRISTCHURCH  
Phone: (03) 364-0655  
Fax: (03) 372-9477  
email: Carolyn.lynn@chmeds.ac.nz

## **The Gene Technology Advisory Committee (GTAC)**

The Gene Technology Advisory Committee (GTAC) is a standing committee of the HRC. The function of GTAC is to review, for the purposes of seeking an exemption under section 30 of the Medicines Act 1981 or as required by the HRC, any of the HRC's committees or an ethics committee:

- i. proposals for clinical trials that include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells into human participants for the purpose of gene therapy or cell marking
- ii. proposals for clinical trials in which the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory), or genetically manipulated micro-organisms, viruses or cells is designed to stimulate an immune response against the participant's own cells, as in the treatment of certain cancers
- iii. proposals for clinical trials in which nucleic acids either from or within cells from animal species are transferred into human participants for the purpose of disease treatment (xenotransplantation)
- iv. proposals for clinical trials in which human nucleic acids have been introduced into the genome of an animal species, including genetically manipulated micro-organisms, for the purpose of developing products to be used for either disease prevention or treatment in human participants
- v. proposals for clinical trials involving vaccines in which nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells have been introduced to stimulate an immune response to antigenic determinants of an infectious agent.

Chairperson: Dr Ingrid Winship

Contact: Dr Bruce Scoggins  
Chief Executive  
Health Research Council  
PO Box 5541  
Wellesley Street  
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Phone: (09) 303-5203  
Fax: (09) 303-5205  
E-mail: bscoggins@hrc.govt.nz

## **National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Committee)**

The National Ethics Committee was established by and is accountable to the Minister of Health. Its primary role is to provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services) and determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

Chairperson: Dr Andrew Moore  
Contact: Barbara Burt  
Senior Analyst  
Ministry of Health  
PO Box 5013  
WELLINGTON  
Phone: (04) 496-2172  
Fax: (04) 496-2340  
E-mail: barbara\_burt@moh.govt.nz

### **National Ethics Committee on Assisted Human Reproduction (NECAHR)**

NECAHR was established by and is accountable to the Minister of Health. Its role is to provide ethical review of proposals for research and new, untried or innovative practices relating to assisted human reproduction, and to provide advice to the Minister of Health on issues relating to assisted human reproductive issues.

Chairperson: Rosemary De Luca  
Contact: Jenny Hawes (Secretary)  
Analyst  
Ministry of Health  
PO Box 5013  
WELLINGTON  
Phone: (04) 496-2259  
Fax: (04) 496-2340  
E-mail: jenny\_hawes@moh.govt.nz

## Glossary

The definitions set out in this glossary apply to terms as they are used in this Standard. The terms may have different meanings in other contexts.

Advance directive	<p>Right 7(5) of the Code of Health and Disability Services Consumers' Rights provides that consumers may use an advance directive in accordance with the common law.</p> <p>The Code defines an advance directive as a written or oral directive where a consumer makes a choice about a possible future health care procedure that is intended to be effective only when they are not competent.</p>
Adverse event	<p>An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.</p>
Adverse event/ effect/drug reaction (clinical trial)	<p>Any undesirable event occurring to a participant during a clinical study, whether or not considered related to the investigational product(s). See also 'serious adverse event'.</p> <p>An adverse event would be regarded as being related to the use of the investigational product if there is a reasonable possibility that the event may have been caused by the investigational product as suspected by the investigator or sponsor. This does not necessarily reflect a conclusion by either the sponsor, the investigator or the regulatory authority that the report constitutes an admission that the product caused or contributed to the adverse event.</p>
Anonymised health information	<p>Health information presented in such a way that it does not enable the identification of an individual.</p>
Anonymity	<p>Data collected in such a manner so not to identify individual participants/sources.</p>
Audit	<p>An investigation into whether an activity meets explicit standards, as defined in an auditing document, for the purpose of checking and improving the activity audited. Audit involves examining practice and outcomes in a particular time and place to see whether they conform with expectations, with a view to informing and improving management rather than adding to general knowledge.</p>
Autonomy	<p>The personal capacity to consider alternatives, make choices and act without undue influence or interference of others.</p>
Beneficence	<p>An ethical principle that entails an obligation to protect persons from undue harm while maximising possible benefits and minimising possible risks.</p>

Clinical practice	The day-to-day activities normally attributed as the regular duties of a body of health practitioners during the course of delivering a health service.
Clinical trial	<p>Any research on human subjects conducted to gain new knowledge into mental and physical health and disease. It would exclude research based on the analysis of secondary sources of health information. Clinical trials involve a wide range of health professionals with different qualifications, skills and expertise and would usually be conducted in hospitals, other health care settings, the community and academic host institutions (Definition from <i>Guidelines for Injuries Caused as a Result of Participation in a Clinical Trial and the Role of Ethics Committees</i>).<sup>11</sup></p> <p>In the context of the evaluation of investigational products, a clinical trial means the systematic study of investigational products (medicines or devices) in humans for the collection of information. Studies conducted to discover or verify the effects of and/or identify any adverse reactions to those products; studies of the absorptions, distribution, metabolism and excretion of a product (Phase I/II); studies to ascertain the efficacy and safety of a product (Phase III); and quality of life data and/or pharmacoeconomic studies (Phase IV) all lie within this definition.</p>
Compensation	Payment or medical care provided to participants injured in research. This does not refer to payment (remuneration) for participation in research.
Competence	<p>Technically, a legal term used to denote capacity to act on one's own behalf, the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.</p> <p>Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (for example, writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.</p>

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<sup>11</sup> Ministry of Health and Accident Rehabilitation and Compensation Insurance Corporation. 1993. *Guidelines for Injuries Caused as a Result of Participation in a Clinical Trial and the Role of Ethics Committees*. Wellington: Ministry of Health and Accident Rehabilitation and Compensation Insurance Corporation.

Confidentiality	The obligation on persons to whom private information has been entrusted not to use or divulge the information without permission for any purpose other than that for which it was originally given. This includes protecting the identity of individual research participants in addition to any information they may provide throughout the course of their participation.
Consumer	Any person on or in respect of whom any health care procedure is carried out. Under the Code of Health and Disability Services Consumers' Rights, this includes a person entitled to give consent on behalf of that consumer.
Disability	Includes psychiatric, intellectual, sensory or physical disabilities. This definition has been guided by the current legal and administrative definitions but is not limited by these. Some definitions limit disability to that which is of 'at least six months' duration' or that which 'means that the person is likely to need support for an indefinite period'. In consideration of ethics, there are issues, such as the treatment of infants with disabilities and individuals with intermittent disability, that may be excluded by rigid definitions.
Disability research	Includes any research whose primary focus of inquiry is children or adults with disabilities, their family members, their caregivers, or services provided for them. Research that may include some people with disabilities, simply by virtue of their membership of a population, is not included. Children who are identified as 'at risk' of disability would be included.
Economic harm	That which adversely affects the economic interests of a person. Economic harm may result from loss of income or employment. Economic harm may also occur in relation to insurance coverage or premium charges.
Ethical approval	Approval granted by a properly constituted ethics committee which reflects that a proposal is deemed to be ethical.
Ethics	The study of morals and values; that is, the study of right and wrong, justice and injustice, virtue and vice, good and bad, and related concepts and principles.
Ethics committee	A generic term used to refer to all ethical review bodies constituted and operating in accordance with this Operational Standard and any guidelines, standards, or advice issued by the National Ethics Committee.
Hapū	The sub-tribe component of a tribe to which a consumer or family/whānau may indicate their connection or affiliation.

Harm	That which adversely affects the interests or welfare of an individual or a group; the amount of harm, conservatively estimated, which is, from the consumer's or human subject's perspective, an ethically acceptable addition to harm that they would experience were they not part of the innovative practice or research project. Harm extends to physical, psychological, economic and social harm. Harm includes discomfort, anxiety, pain, fatigue, embarrassment and inconvenience.
Hauora	Spirit of life, health, vigour. The Māori view of health is distinct from the mainstream view, yet it does share some of the characteristics of 'health'. Several authors have described models to assist in interpretation (Durie MH 1998; Henare 1998; Pere 1997).
Health information	Health information includes information: <ul style="list-style-type: none"> <li>• about the health of that individual, including his or her medical history</li> <li>• about any disabilities that individual has, or has had</li> <li>• about any health services or disability services that are being provided, or have been provided, to that individual</li> <li>• provided by that individual in connection with the donation, by that individual, of any body part or any bodily substance of that individual or derived from the testing or examination of any body part, or any bodily substance of that individual or</li> <li>• about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.</li> </ul>
Human tissue and bodily substances	Includes the substance, structure, and texture of which the human body or any part or organ is composed and which is removed or separated from that human body; includes cells, blood, blood components, waste products, hair or nail clippings.
Incapacity	A person's mental status in terms of their inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice; often used as a synonym for incompetence.
Incompetence	Technically, a legal term meaning inability to manage one's own affairs; often used as a synonym for incapacity.
Inducement	Where a payment is large enough or service provided extensive enough to persuade prospective participants to consent to participate in research against their better judgement.
Informed consent	A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

Innovative practice	<p>A planned deviation from the currently accepted practice of a New Zealand body of health professionals involving an untested or unproven clinical intervention intended to be used on an ongoing basis. Innovative practice includes the application of known procedures in new or novel circumstances in which they have not previously been tested. It may involve new delivery practices by health practitioners, new devices, new investigative procedures, or clinical management options.</p> <p>A non-controversial practice generally accepted within a health profession overseas may not constitute an innovative practice provided it is accepted by the New Zealand body of health professionals and the particular health practitioner can demonstrate appropriate qualifications and possession of relevant experience and expertise to undertake the practice safely. Practices new to New Zealand that may be considered to impact on the views or interest of society (such as work in the fields of genetics, cloning, assisted human reproduction and xenotransplantation) should, however, be considered innovative practice.</p>
Intellectual disability service	<p>A service providing food, shelter and professional care (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include hospitals, community residential services for people with an intellectual disability, residential schools for persons with intellectual or physical disabilities, and acute mental health services.</p>
Investigational product	<p>Any investigational medicinal product or device, reference product or placebo being tested or used as a reference in a clinical study.</p>
Investigator	<p>Any qualified individual who actually conducts all or part of an investigation, be it a research project or a innovative practice (see also ‘principal investigator’).</p>
Iwi	<p>A tribe with a common ancestor, canoe and region(s).</p>
Kaupapa Māori	<p>Literally means the <i>Māori</i> way or agenda, a term used to describe traditional <i>Māori</i> ways of doing, being and thinking, encapsulated in a <i>Māori</i> world view or cosmology.</p>
Koha	<p>Donation, present or gift.</p>
Justice	<p>That which concerns fairness or equity, often divided into three parts:</p> <ul style="list-style-type: none"> <li>• procedural justice, concerned with fair methods of making decisions and settling disputes</li> <li>• distributive justice, concerned with the fair distribution of the benefits and burdens of society</li> <li>• corrective justice, concerned with correcting wrongs and harms through compensation or retribution.</li> </ul>

Lay person	<p>A lay person is a person who is not:</p> <ul style="list-style-type: none"> <li>• currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist)</li> <li>• an officer of, or someone otherwise employed by, any health board, health authority, the Ministry of Health, or medical school</li> <li>• involved in conducting health or disability research or who is employed by a health research agency and who is in a sector of that agency which undertakes health research; or</li> <li>• construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.</li> </ul>
Medical device	<p>A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopaedic pins or other orthopaedic equipment.</p>
Medicinal product	<p>Any substance or combination of substances that has a therapeutic, prophylactic or diagnostic purpose.</p>
Minimal risk	<p>A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.</p>
Monitoring	<p>An ethics committee's review of ongoing research or innovative practice; the collection and analysis of data as the experimental or research project progresses to assure the appropriateness of the research, its design and subject protection. Such monitoring may take a variety of forms, including review of annual reports, formal review of the informed consent process, establishment of a data safety monitoring committee, a periodic review by an independent third party of the documents generated by a research project, a review of the impact of the research on a population, a review of reports of adverse events, or a random audit of particular processes.</p>
Multi-centre research	<p>Research conducted simultaneously by several investigators at different centres, with identical methods and following the same protocol. The aim of such research is to collect data as rapidly as possible for unified analysis leading to a single report.</p>

Principal investigator	The qualified health professional and/or researcher with primary responsibility for the design and conduct of a particular investigation, be it a research project or innovative practice.
Privacy	Control over the extent, timing and circumstances of sharing oneself (physically, behaviourally or intellectually) with others. Privacy implies a zone of exclusivity where individuals and groups are free from the scrutiny of others.
Proposal	A document that provides the background, rationale and objectives of the innovative practice or research project and describes its design, methodology, organisation and the conditions under which it is to be performed and managed. The proposal should also provide the eligibility requirements for prospective participants and controls, the treatment regime(s), anticipated benefits and risks of harm and the proposed methods of analysis that will be performed on the collected data.
Rangatahi	Youth, Young Person.
Region of authority	The region of coverage designated to a health and disability ethics committee from time to time by the Director-General of Health.
Remuneration	Payment for participation in a research project.
Research	A systematic investigation designed to develop or contribute to generalisable knowledge. References to research in this document include both health and disability research. 'Research' includes the evaluation of clinical practice to determine its safety and efficacy.
Research participant	Any person actively participating in an experiment, the recipient of any physical, psychological, behavioural or social intervention or manipulation, or a provider of information.
Respect for persons	This has two fundamental aspects: (1) respect for the autonomy of those individuals who are capable of making informed choices and respect for their capacity for self-determination; and (2) protection of persons with impaired or diminished autonomy; that is, those who are incompetent or whose voluntariness is compromised.
Risk	The function of the magnitude of a harm or injury (physical, psychological, social or economic) and the probability of its occurrence as a result of participation in innovative practices or research studies. Both the probability and magnitude of possible harm may vary from minimal to significant.

Serious adverse effect	<p>Any event that suggests a significant hazard, contraindication, side-effect or precaution. With respect to human clinical experience, a serious adverse event includes any event that:</p> <ul style="list-style-type: none"> <li>• results in death</li> <li>• is life-threatening</li> <li>• requires hospitalisation or prolongation of existing hospitalisation</li> <li>• results in persistent or significant disability/incapacity</li> <li>• is a congenital anomaly/birth defect.</li> </ul>
Social harm	That which adversely affects the social interests of a person. Social harm most commonly results from loss of privacy and may involve discrimination or ostracism of a person.
Sponsor	An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of a clinical trial. The sponsor can be a pharmaceutical or therapeutic device company, a contract research organisation, or a funding organisation, such as the HRC.
Te Reo Māori	Māori language.
Tikanga Māori	Māori custom.
Therapeutic intent	The research physician's intent to provide some benefit to improving a participant's condition (for example, prolongation of life, shrinkage of a tumour, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected.) This term is sometimes associated with Phase I drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the consumer's condition as well as assessing the safety and pharmacology of a drug.
Voluntary	Free of coercion, duress, or undue inducement; used in the health and disability care and research contexts to refer to a consumer's or participant's decision to receive health or disability care or to participate (or continue to participate) in a research activity.
Whānau	Customary Māori extended family.

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