Fourth Annual Report to the Minister of Health

National Ethics Advisory Committee

Kāhui Matatika o te Motu

Citation: National Ethics Advisory Committee. 2006. *Fourth Annual Report to the Minister of Health: National Ethics Advisory Committee Kāhui Matatika o te Motu*. Wellington: Ministry of Health.

Published in July 2006 by the
Ministry of Health
PO Box 5013, Wellington, New Zealand

ISBN: 0-478-29983-4 (Book)
ISBN: 0-478-29986-9 (Internet)
HP 4268

This document is available on the NEAC website:
http://www.newhealth.govt.nz/neac

Foreword

This is the fourth annual report of the National Ethics Advisory Committee (NEAC). The report sets out NEAC's activities and summarises its advice on the matters referred to it under section 16 of the New Zealand Public Health and Disability Act 2000.

NEAC's development of advice to the Minister of Health is strengthened by its independence; credible membership; collaborative relationships; and open, inclusive and thorough processes.

NEAC's work to date has mainly concerned policy on research ethics. The first ethical question asked about research has often been: 'Do our people and values need to be protected against this research?'. Based on its work, however, NEAC's view is that this first ethical question should instead be: 'How can our people and values benefit from this research?'. For example, research and related activity can give us vital evidence about how to achieve better health and reduce inequalities. To play this key beneficial role, and to sustain public support, research and related activity must meet high ethical standards, including the protection of study participants. In 2005, NEAC's policy work on ethics continued to contribute to these outcomes.

A highlight of 2005 was NEAC's completion of its Ethical Guidelines for Observational Studies (the guidelines). In observational studies, investigators access health information to observe and study health outcomes, but they do not control participants' health care. The guidelines have several nationally and internationally significant features: they set out the full range and worth of observational studies; explain their relatively low-risk character; and systematically

specify which studies require ethics committee review, including the 'minimal risk' cases where such review is to take an expedited form. NEAC generated the guidelines using a thorough and inclusive process over three years and they reflect the valuable input of a wide range of stakeholders. NEAC is confident the guidelines will assist people in the sector working with these important studies.

With the agreement of the Minister of Health in November 2005, NEAC embarked on its first project on ethical issues of national significance that moves beyond policy on research ethics. In this new project, NEAC is considering ethical issues arising in the planning for an influenza pandemic. NEAC's experience in ethics policy work, capability in public health and emergency medicine ethics, legal capability and independence will help to ensure that ethical issues raised in such planning are addressed.

On NEAC's behalf I am pleased to present this annual report for 2005.

Andrew Moore
Chair
National Ethics Advisory Committee

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Introduction

The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health on ethical issues of national significance concerning health and disability matters. The committee's formal statutory name is the National Advisory Committee on Health and Disability Support Services Ethics. It is also known by its Māori name, Kāhui Matatika o te Motu.

NEAC's statutory functions are to:

- advise the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and services)
- determine nationally consistent ethical standards across the health sector
- scrutinise national health research and health services.

NEAC works within the context of the New Zealand Public Health and Disability Act 2000 and the key strategy statements for the health sector.

Work Programme 2005

NEAC's agreed work programme in 2005 continued to focus on issues of ethics policy in health and disability research. This work, and the advice it has generated, is summarised by project below under the following headings:

- Ethical Guidelines for Observational Studies
- Governance framework for health and disability research ethics
- Māori framework for health and disability research ethics
- Intervention studies and innovative practice
- Research use of tissue from stillborn babies or foetuses
- Pandemic planning
- Research use of imported embryonic stem cell lines.

In other background work in 2005 NEAC:

- advised the Minister of Health on the membership of the NEAC Sub-Committee on Appeals
- carried out work on booking systems for elective services
- provided comments to the Ministry of Health on the update of the Operational Standard for Ethics Committees
- continued to work on accountability and performance of the ethical review system.

Projects

Ethical Guidelines for Observational Studies

The Minister of Health asked NEAC to 'develop guidelines on conducting observational studies in an ethical manner and establish parameters for the ethical review of observational studies' (NEAC Terms of Reference, 2001). NEAC completed its Ethical Guidelines for Observational Studies (Guidelines) in July 2005, and the Minister approved them in December 2005. They will be published in 2006, together with a two-page summary guidance sheet for easy reference. The Guidelines will facilitate high quality studies, protect participants' interests and underpin public assurance of good study conduct. Publication of the Guidelines will also implement accepted recommendations of the Gisborne Cervical Screening Inquiry Report. (See AP Duffy, DK Barrett, MA Duggan. 2001. *Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*. Wellington: Ministry of Health.)

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

Observational studies are relatively low risk, because the investigators observe and analyse information about health or disability but do not control the care or services that people receive. They differ from intervention studies, in

which investigators intentionally alter people's care or services to study the safety and benefit of doing so.

The guidelines have several internationally significant features. One of these is their wide scope, covering observational research, audits and other activities related to observational research. Second, they are directed primarily to: investigators, who have ethical responsibility for good study conduct; ethics committees that review studies against established ethical standards; and other interested communities and individuals. Third, they are structured around the process of study conduct, from the formulation of the study question to the dissemination of the study's findings. Fourth, they set out the circumstances, mainly related to risk, in which observational studies require ethics committee review. They base review requirements on the principle that intensity of ethical scrutiny should be proportional to the level of risk of the activity. In many cases, ethics committee review may be expedited and sometimes no ethics committee review is required.

NEAC has generated the guidelines through a thorough and inclusive process over three years. This has included a questionnaire to ethics committee members and researchers, public consultation on two discussion documents, interviews and group meetings with key informants and public agencies, a cross-sector workshop, and an independent, peer-reviewed report. The guidelines reflect the valuable input of a wide range of stakeholders.

Governance framework for health and disability research ethics

In May 2004 the Minister of Health agreed that NEAC would scope the task of developing a governance framework for health and disability research ethics. New Zealand does not have a clear or complete framework of this sort. Such a framework would clarify responsibilities in the ethical conduct of research and related activity. For example, one theme from the Gisborne Cervical Screening Inquiry Report concerned differences of view and consequent difficulties over the appropriate ethics committee role in addressing legal issues in study conduct. (See AP Duffy, DK Barrett, MA Duggan. 2001. *Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*. Wellington: Ministry of Health, pp. 259–260.)

A completed governance framework would match:

- key areas of responsibility (eg, for study design, protocol review, legal issues, ethical review, scientific assessment, monitoring of study data, monitoring of protocol adherence, prospective safety assessment); with
- key parties (eg, researchers, ethics committees, locality organisations, research funders, researcher employers, data monitoring committees); with
- key roles (eg, addressing issues, checking issues have been satisfactorily addressed, checking that a 'satisfactoriness check' has been made); with
- key powers or authorities (eg, discretion compared with the duty to perform the role in question).

Within its project, NEAC is prioritising two issues. The first concerns who should have responsibility for addressing legal issues in study conduct. Lack of clarity in this area is a significant issue for health and disability research and for its ethical review. The second priority area concerns responsibilities for generating and co-ordinating key sector guidance. In this area, NEAC has commenced an overview and analysis of the range of current sector guidance, including identification of gaps, overlaps and broad options as to future development and linking of guidance.

Māori framework for health and disability research ethics

The Minister of Health asked NEAC to take responsibility for developing a Māori framework for health and disability research ethics. The project is designed to encourage discussion on ethical issues among Māori communities, health researchers and people and organisations involved in the ethics of health research. NEAC sees the project as a process to foster discussion and dialogue with the aim of clarifying issues, needs and options.

NEAC has agreed a project plan based on a background report, and is undertaking a stocktake on how the central issues have been addressed in New Zealand and other countries.

NEAC anticipates the outcomes of this project will align with the governance framework project, where responsibilities, roles, parties and authorities in research ethics are clarified.

NEAC is the lead agency in this project, working in collaboration with Ngā Pae o te Māramatanga and the Health Research Council of New Zealand.

Intervention studies and innovative practice

In December 2004, the Minister of Health agreed NEAC would conduct a project on the ethics of intervention studies and innovative practice. In an intervention study, the investigator intentionally alters one or more factors to study the effects of doing so. In health research, these factors or 'interventions' are typically treatments, medicines or procedures, and the effects to be studied typically concern intervention safety or benefit. A clinical trial of an influenza vaccine is an example of an intervention study. Innovative practice involves the application, outside the context of any intervention study, of an intervention that is not established practice.

As is well recognised internationally, it is within intervention studies that research participants are most vulnerable. It is less well recognised, but equally important, that patients are similarly vulnerable in the context of innovative practice. Consequently, it is in these two areas that protection is most critical and strengthened guidance is needed in both areas.

NEAC's work in the governance framework area (see above) has identified several important areas of responsibility that are particular to intervention studies, such as the assessment of adverse event reports. The close relation between intervention research and innovative practice also parallels the close relation between observational research and audit. NEAC anticipates that many insights from its project on observational studies will inform its project on intervention studies and innovative practice.

Research use of tissue from stillborn babies or foetuses

The Minister of Health in October 2004 requested that NEAC consider developing guidelines on the research use of tissue from stillborn babies or foetuses. Following discussion with the Ministry of Health about the scope of this work and the best way to progress it, NEAC did some initial project work in 2005. This work is ongoing.

Pandemic planning

In 2005 the Ministry of Health identified a need for an independent group to consider ethical issues arising in its planning for an influenza pandemic. Discussions and preliminary scoping of this work by the Ministry and NEAC resulted in mutual recognition that NEAC has the required attributes for the role, and in November 2005 the Minister of Health agreed to NEAC's involvement. Specifically, NEAC has the experience in ethics policy work, capability in public health and emergency medicine ethics, legal capability, independence, and statutory role to help ensure that ethical issues raised in this work have been addressed.

NEAC's first comment has been on the ethical issues concerning policy on the distribution of anti-viral medicine. NEAC advocated public engagement with the overall pandemic plan, including the interim anti-viral policy, to enable policy-makers to achieve 'consistency with communities' values' and 'acceptability to communities', which are important principles for prioritisation issues. Public consultation on the distribution policy for the national reserve of medication would also strengthen public information and understanding of the issues, including public understanding about the best use of privately held stocks of medication.

Research use of imported embryonic stem cell lines

In March 2005, the Minister of Health asked NEAC to develop interim guidance on research using imported embryonic stem cell lines. NEAC accepted this request and welcomed the opportunity to assist in clarifying the issues and developing practical advice. NEAC produced *Ethics of Human Embryonic Stem Cell Research*. This draft work gave background on stem cells and stem cell research, summarised New Zealand stem cell research policy, and discussed relevant policy instruments. After further discussions with the Ministry of Health it was agreed that the Ministry was best placed to develop guidance on research using embryonic stem cells. NEAC consequently passed its document to the Ministry to assist its work in this area.

Background work

Membership of Sub-Committee on Appeals

In May 2004 the Minister of Health agreed that a provision for a limited right of appeal to an independent body be established for the rare cases where an applicant and ethics committee disagree and all other means of resolution are exhausted.

In accordance with NEAC's terms of reference (reproduced in Appendix B) it advised the Minister of Health in 2005 on the membership of the NEAC Sub-Committee on Appeals (SCA).

Booking system for elective services

In 2003, the Canterbury Ethics Committee wrote to NEAC expressing concern about the implementation of the booking system for elective services in the Canterbury region. NEAC responded by undertaking background work on the issues raised. NEAC continued this background work in 2005 and will finalise it, with advice, in 2006.

Operational standard for ethics committees

In 2005, the Ministry of Health updated the *Operational Standard for Ethics Committees 2002,* with the assistance of the Health Research Council of New Zealand. The aim of this work was to reflect recent changes to the system of ethical review. NEAC made suggestions to the Ministry of Health regarding this update.

More generally, in all its advice to the Minister of Health, NEAC will continue to note any implications there might be for the Operational Standard.

System accountability and performance

Through its 2003 review, NEAC generated a statement of 'Goals, objectives and desired outcomes of an ethical review system' (see Appendix A), and this was agreed by the Minister of Health. These goals include facilitating high quality research and related activity for health gain and protecting all participants in such activity. There continues to be potential for the sector to develop measures of the system's performance based on this statement, thereby building further public accountability and quality assurance. The statement can also serve as a starting point for reflecting on ethics policy for areas of health and disability beyond research.

Committee Membership

Dr Andrew Moore – chair

Dr Andrew Moore is a senior lecturer in philosophy at the University of Otago, where his teaching, research and community service activities focus on ethics, political philosophy and bioethics.

Andrew's practical experience in clinical ethics and health research ethics includes previous health and disability ethics committee memberships at the Otago regional level and with the National Ethics Committee on Assisted Human Reproduction. He was also previously a member of the human subjects ethics committee at the University of Otago. In addition, he is a member of the Health Research Council of New Zealand's Data and Safety Monitoring Board for New Zealand led clinical trials.

Andrew's policy experience includes his membership on the National Health Committee and Public Health Advisory Committee.

Dr Allison Kirkman – deputy chair

Dr Allison Kirkman is a senior lecturer in sociology in the School of Social and Cultural Studies and Associate Dean (Students) in the Faculty of Humanities and Social Sciences at Victoria University of Wellington.

Allison's areas of expertise are in the sociology of gender, sexuality and health. She has published recently on the importance of taking gender and sexuality into account when considering ethical issues in social science research.

Allison is the convenor of the Victoria University of Wellington Human Ethics Committee and is the convenor of the Standing Committee on the Code of Ethics for the Sociological Association of Aotearoa New Zealand.

Professor Michael Ardagh

Michael Ardagh MBChB PhD FACEM DCH is professor of emergency medicine at the Christchurch School of Medicine, specialist emergency physician at the Christchurch Hospital Emergency Department and chair of the Emergency Care Foundation (a charitable trust dedicated to innovation, education and research into emergency care). His duties involve a mix of patient care in the Emergency Department, supervision of junior medical staff, education and research.

Michael attained a doctorate in bioethics from the University of Otago in 2001, exploring ethical issues related to resuscitation.

Barbara Beckford

Barbara Beckford is the co-convenor of the Federation of Women's Health Councils Aotearoa.

Barbara has extensive hands-on knowledge of health care in the community. She has been a patient advocate and chair of a regional health and disability ethics committee.

Barbara is a lay member of the Medical Radiation Technologists Board, the co-chair of the National Screening Unit Consumer Reference Group, a consumer representative on the Breast Screen Aotearoa Advisory Group, and a community representative on the West Coast District Health Board Hospital Advisory Committee and Community and Public Health Advisory Committee.

Dr Dale Bramley

Dr Dale Bramley MBChB MPH FAFPHM is a medical graduate of the University of Auckland.

Dale is a public health physician and manager of Health Gain for the Waitemata District Health Board. He has an honorary academic appointment as a senior lecturer in public health in Epidemiology and Biostatistics at the University of Auckland.

Dale has a keen interest in Māori health, epidemiology, cardiovascular disease and public health. From July 2003 to July 2004 Dale completed a Harkness Fellowship in Health Policy at the Mount Sinai Medical Centre in New York. The focus of his work was an international comparison of indigenous health disparities.

Dale has tribal affiliations to Ngāti Hine and Nga Puhi.

Dr Anne Bray (member until 31 December 2005)

Dr Anne Bray has been involved for many years in a large range of activities and organisations concerned with people with disabilities.

Anne's primary interest is in ethical issues and research with implications for disadvantaged groups and individuals.

Anne is the director of the Donald Beasley Institute, an independent disability research institute in Dunedin. She has also undertaken academic study in law and ethics, and served as a member of the National Ethics Committee and National Health Committee.

Dr Fiona Cram (member until 27 June 2005)

Dr Fiona Cram PhD is Māori with tribal affiliations to Ngāti Kahungunu. Fiona is the mother of one son.

Fiona's doctorate from the University of Otago is in social and developmental psychology. She has lectured in social psychology at the University of Auckland for seven years. Fiona was a senior research fellow with the International Research Institute of Māori and Indigenous Education at the University of Auckland.

In 2003 Fiona established her own research company, Katoa Ltd. Her research interests are wide ranging, including kaupapa Māori research methodologies and ethics, Māori health research, evaluation research, qualitative and quantitative research methods, and community-based research training.

Elisabeth Harding

Elisabeth Harding is the legal advisor and privacy officer at Counties Manukau District Health Board. Elisabeth trained and worked as a nurse for 17 years. She spent four years working for the Privacy Commissioner then worked in private practice. Working for the District Health Board brings her nursing and legal skills together.

Elisabeth has an ongoing interest in privacy issues related to the safe management of health information and led the privacy work stream in the Ministry of Health's WAVE project. She is a member of the Health Research Council's Ethics Committee.

Dr John Hinchcliff

Dr John Hinchcliff retired as vice-chancellor of the Auckland University of Technology and was elected to the Auckland City Council in 2004. He has published articles and books on ethics, lectured on ethics at universities in the United States and New Zealand, and helped introduce and teach medical ethics at the University of Auckland Medical School during the 1970s.

John has been head of the Department of Humanities at the Royal Melbourne Institute of Technology, chaplain at the University of Auckland and assistant professor of philosophy at Hampden Sydney University in Virginia.

John has also lectured on the ethics of business, technology, sport, politics and futures studies.

Joanna Manning

Joanna Manning is associate professor of the Faculty of Law at the University of Auckland.

Joanna is an academic lawyer, teaching and researching principally in the fields of medical law and ethics, and torts and accident compensation. She has published widely, particularly on issues relating to informed consent to medical treatment and the Code of Patients' Rights.

Joanna has a practical background in prosecution and civil litigation. She was the consumer representative on the Medical Practitioners' Disciplinary Committee for 10 years.

Professor Charlotte Paul

Charlotte Paul is professor of preventive and social medicine at the University of Otago Medical School in Dunedin.

Charlotte is an epidemiologist with a background in medicine and public health. She has extensive experience in conducting epidemiological research nationally, particularly in the areas of women's cancers and contraceptive safety. She is associate director of the AIDS Epidemiology Group that is responsible for monitoring the HIV/AIDS epidemic in New Zealand. In addition she is a principal investigator in the Dunedin Multidisciplinary Health and Development Study in the area of sexual and reproductive behaviour and a member of its Scientific Advisory Group.

In 1987/88 Charlotte was a medical advisor to Judge Cartwright for the Cervical Cancer Inquiry and has published articles on the ethical implications. She has been a member of the Otago Area Health Board Ethics Committee and the Health Research Council Ethics Committee. She chaired a working party for the Health Research Council of New Zealand on Privacy and Health Research that produced guidance notes for health researchers and ethics committees.

Dr Martin Sullivan

Dr Martin Sullivan PhD is a senior lecturer in social policy and disability studies at the School of Sociology, Social Policy and Social Work, Massey University. He was awarded his doctorate on the sociology of paraplegia in 1997 and was made a Winston Churchill Fellow in 2000 for his work on the development of disability studies and the disability movement in the United Kingdom.

As an academic, Martin teaches, researches and has published widely on disability. As a disabled person, Martin has been actively involved in the disability movement for several years and is chair of Advocacy Manawatu (a citizen advocacy group for people with disabilities).

Personnel 2005

Barbara Burt – senior analyst

Tanith Robb – analyst (part year)

Vanessa Waldron – analyst (part year)

Annabel Begg – public health medicine registrar

Marie Farquhar – executive assistant/personal assistant

Secretariat 2006

Barbara Burt — senior analyst

Vanessa Roberts – analyst

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Appendix A: Goals, Objectives and Desired Outcomes of an Ethical Review System

This table is based on Recommendation 1 from National Ethics Advisory Committee. 2004. *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand: Report to the Minister of Health*. Wellington: Ministry of Health.

Overall goals	
• Protect participants in health and disability research and innovative treatment • Facilitate research and innovative practice that contributes to knowledge and improved health outcomes • Find a balance that minimises risks and maximises benefits arising from health and disability research • Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review of health and disability research	
Objectives	**Desired outcomes**
Accountable	• Public accountability requirements are defined • Ethical reviews meet internationally recognised standards • Ethical reviews take into account relevant legislation

Enabling	• Research participants/subjects are protected • Quality research is facilitated • Review processes are clear about jurisdiction and coverage • Awareness of ethical practice among all stakeholders is developed • Good communication with affected communities is demonstrated • Local input is achieved • Positive relationships with all stakeholders are developed • System review mechanisms are in place
Informed	• Researchers consider ethical implications from the outset, for example, there is clarification of who will benefit from the research (participants, the public, etc) • The perspectives of affected communities are included • Review processes are proactive and attend to emergent issues and are responsive to change over time • Review processes apply appropriate expertise • Scientific and ethical standards are considered alongside each other when appropriate • Decision-making is consistent • Review capacity and relevant expertise is maintained and developed

Enabling Māori involvement	• A Māori ethical framework is developed and implemented • Consultation with Māori is collaborative, genuine, inclusive and appropriate • Māori participation in the decision-making component of the system is facilitated • The potential for diversity of opinion across iwi and regions is recognised and respected • Māori research capability is facilitated
Fair	• Review processes are independent • Stakeholders have access to due process • Outcomes of processes are equitable • Applicants to review processes have the right of reply • Conflicts of interest are acknowledged and addressed
Efficient	• Time and resources are used productively • Reviews are timely • The Operational Standard is updated regularly, with participation from all stakeholders

Appendix B: Terms of Reference

The Role of the Committee

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

The National Ethics Advisory Committee's statutory functions are 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)
- 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 Advisory Committee is also required to:

- 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)
- 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

- provide timely and sound advice to the Minister of Health on the membership and operation of its Sub-Committee on Appeals, including advice on those member categories that cannot be filled from the National Ethics Advisory Committee's membership, and will therefore require a wider nominations process. The National Ethics Advisory Committee may make nominations as part of this wider process.

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

- provide advice on priority issues of national significance as requested by the Minister of Health
- 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 Advisory Committee's rationale for its advice and any relevant evidence and/or documentation
- 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 Advisory Committee's rationale for its advice and any relevant evidence and/or documentation
- 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)

- 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
- undertake its tasks in a manner consistent with the principles of the Treaty of Waitangi
- 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 research).

Composition of the Committee

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

- two health professionals (one of whom must be a registered medical practitioner)
- 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)
- one epidemiologist
- 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)

- three community/consumer representatives (must not be health professionals, health researchers, or professional members)
- one member nominated by the Health Research Council of New Zealand.

At any time, the National Ethics Advisory 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 Advisory 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 Advisory 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 Advisory 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 six consecutive years. Unless a person sooner vacates their office, every appointed member of the National Ethics Advisory Committee shall continue in office until their successor comes into office. Any member of the National Ethics Advisory Committee may at any time resign as a member by advising the Minister of Health in writing.

Any member of the National Ethics Advisory 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 Advisory Committee, or discharge any member of the National Ethics Advisory Committee or appoint new members to the National Ethics Advisory 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 Advisory Committee to be its Chairperson. The Chairperson will preside at every meeting of the National Ethics Advisory Committee at which they are present. The Chairperson may from time to time appoint a new 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 Advisory Committee. This is intended to aid members of the National Ethics Advisory Committee by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the National Ethics Advisory Committee and its members.

As an independent statutory body, the National Ethics Advisory Committee has an obligation to conduct is activities in an open and ethical manner. The National Ethics Advisory 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 Advisory 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 Advisory 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 Advisory Committee and the use of committee funds.

4. Members of the National Ethics Advisory Committee are not obliged to accept nomination to the Sub-Committee on Appeals.

Conflicts of interest

1. 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 Advisory Committee and its members and will ensure it retains public confidence.

2. 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 Advisory 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.

3. 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.

4. A member of the National Ethics Advisory 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 Advisory 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

1. The public has a right to be informed about the issues being considered by the National Ethics Advisory Committee. The National Ethics Advisory Committee should have procedures in place regarding the release of information and processing requests for information.

2. Individual members must observe the following duties in relation to committee information. These provisions ensure that the National Ethics Advisory Committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.

    - Meetings of the National Ethics Advisory Committee, including agenda material and draft minutes, are confidential. Members must ensure that the confidentiality of committee business is maintained.

- Members are free to express their own views within the context of committee meetings, or the general business of the National Ethics Advisory Committee.
- Members must publicly support a course of action decided by the National Ethics Advisory Committee. If unable to do so, members must not publicly comment on decisions.
- At no time should members individually divulge details of committee matters or decisions of the National Ethics Advisory 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 Advisory 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.
- 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 Advisory Committee will agree a work programme with the Minister of Health. The National Ethics Advisory 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 Advisory Committee must:

- provide the Minister of Health with advance notice of any media statements or reports to be published
- ensure its advice is published and widely available
- 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
- 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)
- ensure that any advice, guidelines, and views in relation to an appeal, comply with the laws of New Zealand
- ensure appropriate consultation has occurred in accordance with the requirements set out below.

Consultation

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

- health and disability ethics committees
- the National Ethics Advisory Committee on Assisted Human Reproduction
- the Health Research Council Ethics Committee
- any other Ethics Committee established by the Minister of Health

- organisations known to the committee to represent affected patients or other groups of the community
- relevant whānau, hapū and iwi
- a reasonably representative sample of affected patients or members of the public or (if the National Ethics Advisory 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
- a reasonably representative sample of affected health researchers and/or affected health professionals
- relevant government bodies.

Performance measures

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

The National Ethics Advisory Committee must:

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

Meetings of the Committee

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

At any meeting, a quorum shall consist of 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 Advisory Committee may regulate its own procedures.

Reporting requirements

The National Ethics Advisory Committee is required to:

- keep minutes of all committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made
- 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. This report must also include details of the appeals heard by the Sub-Committee on Appeals. The report is to include the National Ethics Advisory 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 Advisory Committee out of the Committee's allocated budget allocated and consistent with the Memorandum of Understanding between the National Ethics Advisory Committee and the Ministry of Health.

Fees and allowances

Members of the National Ethics Advisory 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 Advisory Committee members.

Sub-Committee on Appeals

The National Ethics Advisory Committee will convene a Sub-Committee on Appeals (the SCA).

Whereas the main statutory function of the National Ethics Advisory Committee is to advise the Minister of Health on ethical issues of national significance regarding health and disability, the function of its Sub-Committee on Appeals is to review particular proposals at appeal.

The SCA will be responsible for hearing appeals from decisions of the following health and disability ethics committees:

- Regional Ethics Committees (RECs) established under section 11 of the New Zealand Public Health and Disability Act 2000
- the Multi-region Ethics Committee (MEC) established under section 11 of the New Zealand Public Health and Disability Act 2000.

Authority of the Sub-Committee on Appeals

An appeal may only be lodged with the SCA by the principal researcher identified in the application in question. The SCA may not hear any appeal that is lodged by any third party.

The SCA may only hear appeals in cases where a second opinion from the Health Research Council Ethics Committee has been sought (by either the original ethics committee or the researcher) and received, and the matter reconsidered by the original ethics committee. All appeals will be from the decision made by the original committee following the second opinion.

All appeals heard by the SCA will be by way of re-hearing, focusing on specific alleged errors of judgement or reasoning in the original decision.

In hearing an appeal, the SCA will have discretionary power to re-hear any part of the evidence that is relevant to these specific alleged errors of judgement or reasoning. The SCA will also have the power to receive further evidence and to call individuals involved in the reconsidered decision to give evidence in person.

In hearing an appeal, the SCA will be bound by the presumption that the original decision was correct. The SCA will affirm the decision being appealed against where:

i. the SCA is not satisfied that errors exist in the original decision

ii. the SCA is satisfied of the existence of such errors but considers the errors to be of insufficient importance to warrant reversing the original decision.

The SCA will reverse the original decision only where it is satisfied that the original decision contained errors of judgement of a sufficiently serious nature to warrant the reversal.

The SCA will in all cases either affirm or reverse the original decision.

Consequential amendments to the Operational Standard for Health and Disability Ethics Committees

These Terms of Reference have precedence over the Operational Standard for Health and Disability Ethics Committees on any point of conflict. Otherwise, the Operational Standard applies to the SCA.

Approvals

The SCA must be approved for all purposes required for the application in question.

Role of the Sub-Committee on Appeals

The primary role of the SCA will be to hear appeals from the decisions of the health and disability ethics committees named above.

The SCA will act so as to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy. In order to do this, the SCA shall:

i. foster an awareness of ethical principles and practices in the health and disability sector and research community

ii. facilitate excellence in health research and innovative practice for the wellbeing of society

iii. collaborate with researchers to ensure the interests, rights, dignity, welfare, health, and wellbeing of participants and consumers are protected

iv. give due consideration to community views

v. consistent with section 4 of the New Zealand Public Health and Disability Act 2000 and He Korowai Oranga, recognise and respect the principles of the Treaty of Waitangi

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 Director-General of Health.

Composition and membership

Guiding principle

The primary guiding principle for appointing members to the SCA is to ensure the most appropriate expertise, skills, knowledge and perspectives to hear appeals from the decisions of the MEC and the RECs.

Minister to appoint members

Members of the SCA will be appointed by the Minister of Health.

Member numbers

The number of members of the SCA shall be at least 12, including a lay chairperson.

Lay/non-lay membership

At least one half of the total membership shall be lay members. A lay member is a person who is not:

- currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist, pharmacist)
- 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
- construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

At any time, the SCA 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 the SCA's composition also includes individuals possessing a knowledge and understanding of consumer and community issues and perspectives.

The SCA's non-lay membership shall include two health researchers, two health practitioners, one biostatistician, and one pharmacist or pharmacologist.

NEAC/non-NEAC membership

Members will in the first instance be drawn from the membership of NEAC. All members of the National Ethics Advisory Committee, with the exception of the Chair and any NEAC member who is also a member of a Regional Ethics Committee, the Multi-region Ethics Committee or the Health Research Council Ethics Committee, shall be eligible for appointment to the SCA.

Where further members are required to meet the requirements for approval under these terms of reference and the relevant legislation, these further members will be drawn from outside of NEAC.

Whole committee requirements

At any time, consistent with the requirements of the New Zealand Public Health and Disability Act requirements for District Health Boards and with the requirements of the Operational Standard, the SCA 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 the SCA are expected to have knowledge of the principles of partnership, participation, and protection and their application to ethical review.

The SCA's membership should include expertise in the main kinds of health and disability research (eg, interventional, observational, kaupapa Māori, and social research), and in both quantitative and qualitative research methods.

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important that the SCA be comprised of people from a range of backgrounds and ethnicities.

Terms and conditions of appointment

Members of the SCA who are also members of NEAC will be appointed to both committees by the Minister of Health for a term of office of up to three years. Other members will also be appointed to the SCA for a term of office of up to three years. The terms of office of members of the SCA will be staggered to ensure continuity of membership. No member may hold office for more than six consecutive years.

Unless a person sooner vacates their office, every appointed member of the SCA shall continue in office until their successor comes into office. Any member of the SCA may at any time resign as a member by advising the Minister of Health in writing.

A member of both NEAC and the SCA may resign from the SCA and remain on NEAC. A member of both NEAC and the SCA who resigns from NEAC shall require specific Ministerial approval to continue serving on the SCA.

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

Chairperson

The Chairperson of the SCA shall also be a member of the National Ethics Advisory Committee.

The Chairperson of the SCA shall be chosen by the Minister of Health. The chairperson will preside at every meeting of the SCA at which they are present. The Chairperson may from time to time appoint a member as Deputy Chairperson to act in the place of the Chair when required.

Duties and responsibilities of a member

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

General

SCA members should have a commitment to protecting the interests of human participants while promoting and facilitating excellence in research and innovative practice.

There is an expectation that SCA members will make every effort to attend all SCA meetings and devote sufficient time to become familiar with the affairs of the SCA and the wider environment within which it operates.

Members have a duty to act responsibly with regard to the effective and efficient administration of the SCA and the use of SCA funds.

Conflicts of interest

SCA 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 SCA and its members and will ensure it retains public confidence.

SCA members attend meetings and undertake SCA activities as independent persons responsible to the SCA as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. The SCA should not, therefore, assume that a particular

group's interests have been taken into account because a SCA member is associated with this group.

When SCA 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 SCA's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the SCA who has any involvement in any proposal under appeal shall not take part in the SCA'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. The SCA must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

Confidentiality and information sharing

The SCA should assure all appellants that, subject to the Official Information Act 1982, the details of their appeals will be kept confidential.

It is desirable for the members of the SCA to have an opportunity to discuss issues arising from appeal with key contacts and support people prior to the consideration of proposals. This process should be encouraged. However, due to the need to protect any personal information and the commercial sensitivity of some applications, names, identifying details and written material should not be circulated or made known outside the SCA. The SCA will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing processes around information sharing.

Within the SCA, members with particular community expertise should be consulted and provide advice on the appropriate consultative process for all ethical issues concerning particular communities of interest.

Agendas and minutes, except for 'in committee' items should be available to the public. Subject to the Official Information Act 1982, copies of proposals under appeal will not be available to individuals outside the SCA without the prior approval of the researcher.

Committee meetings

Meetings of the SCA shall be held whenever an appeal or other related business is before the committee. Meetings shall be called by the Chairperson of the SCA.

Meetings of the SCA shall be open to the public. However, the SCA may exclude non-members from being present while it considers a decision.

The minutes of all meetings shall be publicly available.

Appellants may attend meetings, in person or by teleconference, to be available to talk to their proposal and answer any questions the SCA may have. The SCA should advise appellants that they may be asked to leave the meeting while the SCA considers its decision on the appeal.

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

Quorum

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.

Decision-making process

Decisions

Where possible, decisions of the SCA shall be made by consensus. If consensus cannot be reached within a reasonable period of time, as defined by the Chair, a decision may be made by simple majority vote. In such cases, the Chair of the SCA shall hold a casting vote.

Members of the SCA should be free to participate fully in discussion and debate. In particular, the chairperson should have skills in consensus decision-making and conflict resolution.

Issues of ethical review are often complex and can involve ethical dilemmas on which there is no consistent community view. Members of the SCA have a responsibility to identify underlying ethical principles.

In relation to appeals 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 SCA meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

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 appeal process.

Communication of decisions

All decisions of the SCA will be communicated to:

i. the principal investigator of the application in question
ii. the committee which made the original decision
iii. other RECs/MEC
iv. the National Ethics Advisory Committee
v. the Health Research Council Ethics Committee
vi. the Director-General of Health.

The reasoning behind the decision must be explained as clearly as possible.

Members will be expected to publicly support the decisions of the SCA.

Once the SCA has made and communicated its decision on the matter at appeal, the ethics committee that made the original decision will resume its full responsibilities in relation to the ethics committee application in question. The original committee will be bound by the decision of the SCA.

Expert advice and consultation

Where the chairperson or a quorum of SCA members believes there is insufficient expertise on the SCA to assess an application or an issue, the committee should seek additional expert advice.

Training for members

Training should be provided for new members and chairpersons within six months of appointment to the SCA.

Records

Information held by the SCA is subject to the Privacy Act 1993, the Official Information Act 1982, and the Archives Act 1957.

Records may only be accessed with the permission of the chairperson or the Director-General of the Ministry of Health. The secretariat of the SCA is responsible for maintaining and controlling access to the SCA's records.

Fees and allowances

Members of the SCA are entitled to be paid fees for attendance at meetings. The Chairperson's attendance fee is set at $430 per day (plus half a day's preparation fee). The attendance fee for members is set at $320 per day (plus half a day's preparation fee). The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies. The Ministry of Health pays actual and reasonable travel and accommodation expenses of the SCA members.

Servicing and administration of the SCA

The SCA will use the administrative resources of the National Ethics Advisory Committee.

The contact address for the SCA will be:

Sub-Committee on Appeals
National Ethics Advisory Committee
PO Box 5013
WELLINGTON

Email: appeals_neac@moh.govt.nz