

**National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**  
**Annual Report 2008**

**Seventh Annual Report to the Minister of Health**

2008

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<http://www.neac.health.govt.nz>



## Foreword

This annual report summarises for the calendar year 2008 the activities of the National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) and the advice NEAC gave on matters referred to it under section 16 of the New Zealand Public Health and Disability Act 2000.

NEAC's statutory functions are broad and strategic. These functions include advising the Minister of Health on ethical issues of national significance in respect of health and disability matters and determining nationally consistent ethical standards across the health system.

In 2008 NEAC completed substantial further work towards producing guidelines for intervention studies. These guidelines will parallel NEAC's successful *Ethical Guidelines for Observational Studies* (2006). Ethical guidance for intervention studies is an important area of NEAC's work because, in general, participants in intervention studies face greater potential for harm than do participants in other kinds of studies.

NEAC aims to contribute to better health outcomes and reduced health inequalities for New Zealanders by contributing to the development of best practice in intervention studies. NEAC's inclusive and thorough project processes involve expert peer review and public comment on its draft documents. These processes produce work that is both principled and practical.

In the context of NEAC's policy work on research ethics, NEAC views research and the evidence it produces as vital to the achievement of health sector goals: better health; reduced inequalities; increased participation and independence; and trust and security for New Zealanders. To be credible and sustain public support, such research must meet high ethical standards.

NEAC's *Ethical Guidelines for Intervention Studies* is likely to be published in 2009. In anticipation of this publication, it is worth reflecting on the design of New Zealand's current system of health and disability ethics committees. In line with NEAC's recommendations, the regionalised structure of the health and disability ethics committees was retained in the major reforms of 2005. Since 2005, the new process of locality assessment has demonstrated its ability to address 'local' issues in proposed research studies. A regionalised committee structure is no longer needed to address such issues. In addition, recent changes to the terms of reference for the health and disability ethics committees reflect the related point that a multi-regional structure is not essential for the competent review of multi-regional studies. NEAC's work is now showing that significant ethical issues are distinctive of clinical trials and other intervention studies. In light of these considerations, it may be timely to consider the merits of reconfiguring the jurisdiction of the health and disability ethics committees and non-lay membership categories. Such reconfiguration could result in some health and disability ethics committees specialising in intervention studies, whether single-region or multi-regional studies, and other health and disability ethics committees specialising in the other kinds of studies. Any review of these and other issues of ethics committee design and functioning would be best informed by the nationally consistent ethical standard that NEAC has determined on this matter: *Goals, Objectives, and Desired Outcomes of an Ethical Review System* (see Appendix A).

On behalf of NEAC, I am pleased to present this annual report for 2008.

A handwritten signature in black ink, appearing to read 'Andrew Moore', enclosed within a light grey rectangular border.

Andrew Moore

**Chair**

**National Ethics Advisory Committee**

**Kāhui Matatika o te Motu**



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# Introduction to the National Ethics Advisory Committee

## Functions of the National Ethics Advisory Committee

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) is an independent advisor to the Minister of Health. NEAC's statutory functions, under section 16 of the New Zealand Public Health and Disability Act 2000, are to:

- advise the Minister of Health on ethical issues of national significance in respect of health and disability matters
- determine nationally consistent ethical standards across the health sector
- provide scrutiny for national health research and health services.

NEAC works within the context of the New Zealand Public Health and Disability Act 2000 and key health and disability policy statements. Section 16(6) of the New Zealand Public Health and Disability Act 2000 requires that NEAC:

*at least once a year, deliver to the Minister a report setting out its activities and summarising its advice on the matters referred to it under this section.*

## **Membership of the National Ethics Advisory Committee**

The Minister of Health appoints the members of NEAC.

NEAC members have expertise in the fields of ethics; health, and disability research; health service provision and leadership; public health; epidemiology; law; Māori health; and consumer advocacy.

# National Ethics Advisory Committee's Work Programme in 2008

## Overview

Ethics involves identifying what matters and how best to act on this finding. NEAC uses this understanding of ethics to produce work that is both principled and practical.

NEAC agrees its work programme with the Minister of Health. NEAC's work on the ethics related to health and disability support services and research is varied and far-reaching. Important ethical issues to be considered across the health and disability system include quality and safety, workforce, health system design, and public health priorities.

NEAC's 2008 work programme focused on projects in the area of quality and safety, with follow-up work being carried out in other areas.

## Quality and safety work

In 2008, NEAC's projects in the area of quality and safety were:

- intervention studies
- health and disability research ethics governance
- Māori health and disability research ethics.

## **Follow-up work**

In 2008, NEAC's follow-up work was in the areas of:

- observational studies (quality and safety)
- innovative practice (quality and safety)
- pandemic planning (public health priorities).

## Quality and Safety Work in 2008

### Intervention studies project

Summary of the intervention studies project	
What matters	Providing safe and high-quality health and disability services.
NEAC contribution	Encouraging the ethical conduct of quality intervention studies to assist health care improvements.  Minimising any risk or harm related to intervention studies.  Building public confidence in intervention studies and their contribution to health and disability services.
NEAC output	<i>Ethics of Intervention Studies: Discussion document and draft ethical guidelines for intervention studies</i> (2008, available in hard copy and from the NEAC website ( <a href="http://www.neac.health.govt.nz">http://www.neac.health.govt.nz</a> )).

### Ethical issues in intervention studies

In an intervention study, the investigator intentionally alters one or more treatments or other health-related interventions to study the effects of doing so. The effects studied are typically about treatment safety, treatment effectiveness, or both. A clinical trial of a new blood pressure medicine is an example of an intervention study.

Intervention studies are the main source of reliable information on the effectiveness and safety of an intervention, particularly a new intervention. Intervention studies have been important sources for the large improvements in medical care over recent decades.

Ethical guidance for intervention studies is an important area of NEAC's work. In general, participants in intervention studies face greater potential for harm than do participants in other kinds of studies. Therefore, it is important that intervention studies are scientifically and ethically sound to minimise this potential for harm and to maximise potential benefit.

## **Project aims**

NEAC aims to contribute to better health outcomes and reduced health inequalities for New Zealanders by contributing to the development of best practice in intervention studies. In 2008, NEAC pursued these aims by:

- identifying ethical issues for intervention studies in New Zealand
- considering how ethical issues for intervention studies were currently addressed
- identifying which ethical issues for intervention studies needed to be addressed more effectively
- proposing options for addressing ethical issues for intervention studies effectively.

## **Project guidance**

In June 2008, NEAC published *Ethics of Intervention Studies: Discussion document and draft ethical guidelines for intervention studies*. These draft guidelines bring together the best national and international guidance from many sources, provide guidance to address New Zealand-specific features of ethical issues, and include new guidance where current national and international guidance does not fully address an ethical issue.

The draft guidelines give guidance about ethical issues in the process of designing and conducting a study: from the beginning stages of developing a study question to the communication of study results and post-study access to interventions.

## **Project process**

The Minister of Health agreed to NEAC's carrying out work on the ethics of intervention studies.

In early 2008, NEAC completed substantial further work towards producing guidelines for intervention studies. Experts in clinical trials, medical law, and public policy peer-reviewed NEAC's work into the ethics of intervention studies.

In June 2008, NEAC published *Ethics of Intervention Studies: Discussion document and draft ethical guidelines for intervention studies*. The draft guidelines were available for public consultation for six weeks. NEAC received submissions from a variety of stakeholders, including interested individuals, patient and consumer advocacy groups, research groups, professional and provider organisations, ethics committees, the Ministry of Health, and the research industry.

NEAC analysed the submissions, then revised the draft guidelines in light of suggestions made in the submissions. NEAC then sought further peer review of the revised guidelines, and made further appropriate changes to the guidelines as a result of that review.

Pending NEAC approval of the final guidelines in 2009, NEAC will present a report to the Minister of Health recommending the guidelines be implemented.

## Health and disability research ethics governance project

<b>Summary of the health and disability research ethics governance project</b>	
What matters	Facilitating good studies that are conducted to high ethical standards. Addressing ethical issues well.
NEAC contribution	Analysing existing sector guidance. Reviewing international research ethics governance arrangements. Interviewing key people in the health and disability research community.
NEAC output	To be decided.



## **Ethical responsibilities in research**

Governance arrangements for health and disability research ethics concern responsibility for the ethical design, review, and conduct of such research. The arrangements also cover the standards, processes, and structures to support and facilitate these responsibilities. It matters that good studies are facilitated and conducted to high ethical standards and that ethical issues are addressed well.

The responsibility for the ethical design, review, and conduct of research is exercised at many levels, including by researchers, ethics committees, bodies that establish ethical review processes, funding organisations, agencies that set standards, and government.

NEAC's 2003 review of the ethics committee system in New Zealand identified areas where responsibilities were unclear or inconsistent.

## **Project aims**

NEAC's research ethics governance project:

- examines the current governance arrangements for health and disability research ethics in New Zealand.

## **Project draft document**

In 2008, NEAC carried out significant further work on its background document *Health and Disability Research Ethics Governance Arrangements in New Zealand*. This background document examines New Zealand's current governance arrangements in relation to 'who is responsible for what' in the ethical design, review, and conduct of health and disability research. The document aims to identify things that are not addressed or done well in New Zealand's ethics governance arrangements.

The document considers issues in ethics standards, participant welfare, Māori research ethics, relationships with communities, locality issues, scientific validity, law, and adherence to study protocols.

NEAC will consult further with individuals and groups with an interest in this work before deciding the next steps in this project.

## **Project process**

NEAC analysed existing sector guidance, and identified gaps, overlaps, and broad options for future development and improving linkages between different pieces of guidance. NEAC also identified potential areas of responsibility that need to be addressed, held preliminary discussions with key people in the health and disability research community, and reviewed international approaches to health and disability research ethics governance.

## Māori health and disability research ethics project

<b>Summary of the Māori health and disability research ethics project</b>	
What matters	<p>Improving the ability of researchers to address Māori ethical issues.</p> <p>Improving the quality of research for Māori.</p> <p>Assisting Māori communities to contribute to Māori health development.</p>
NEAC contribution	Encouraging discussion and dialogue on Māori ethical issues among Māori communities, researchers, and others.
NEAC output	<p>A resource document that outlines existing elements of Māori research ethics and potential areas for development.</p> <p>A project partnership with the Health Research Council, Ngā Pae o te Māramatanga (Māori Centre of Research Excellence, based at the University of Auckland) and members of Pū Tai Ora (Māori members of health and disability ethics committees).</p> <p>Support for the development of a guideline or framework on Māori research ethics for ethics committees and researchers.</p>

## **Māori research ethics**

The Māori research workforce is growing in number and skill, so a considerable body of literature now exists about Māori research and Māori research ethics. This literature draws on tikanga Māori and mātauranga Māori as an ethical base to guide practice; to indicate what is fair, true, or just; and to protect the interests and wellbeing of groups and individuals. NEAC believes that addressing issues and concerns about research and Māori is an opportunity to improve the ethical review system for all researchers and participants.

## **Project aims**

NEAC's work into Māori health and disability research ethics aims to facilitate understanding of Māori research ethics; improve the quality of research for Māori, including the ability of researchers to assist Māori communities; and to contribute to Māori health development.

## **Project process**

NEAC is working in collaboration with Ngā Pae o te Māramatanga (the Māori Centre of Research Excellence, based at the University of Auckland), the Health Research Council of New Zealand, and Pū Tai Ora (Māori members of health and disability ethics committees). This partnership has been to encourage discussion and dialogue on ethical issues among Māori communities, researchers, and other people and organisations involved in research ethics.

In 2008, NEAC continued to develop and consult its project partners on a Māori research ethics issues paper. A draft issues paper was made available to Māori members of health and disability ethics committees. The paper outlines existing elements of Māori research ethics and potential areas for development. The paper is intended as a resource for the project partners to support future work.

NEAC also supported a writing group (including members of Pū Tai Ora) to develop a draft guideline or framework on Māori research ethics for ethics committees and researchers.

## Follow-up work in 2008

### Observational studies (quality and safety work stream)

#### Ethical issues in observational studies

Observational studies tell New Zealanders about the safety and effectiveness of health services, and provide vital evidence about New Zealanders' health and how best to protect and improve it. Observational studies use personal information for the public good, so they must meet high ethical standards to be effective.

In an observational study, the investigator observes and analyses information about health or disability but does not control the care or services that people receive. This type of study differs from an intervention study (see page 5) in which the investigator intentionally alters people's treatment or other care to study the safety and benefit of doing so. This difference means observational studies are relatively low risk to participants.

NEAC's *Ethical Guidelines for Observational Studies* (2006) aim to ensure high-quality studies, protect the interests of participants, and underpin public assurance of good study conduct. A two-page summary guidance sheet for easy reference is also available with the guidelines.

## **Reviewing the use of *Ethical Guidelines for Observational Studies***

In 2008, NEAC began reviewing comments it had received since the *Ethical Guidelines for Observational Studies* had been implemented in December 2006.

### **Further information**

For further information about the *Ethical Guidelines for Observational Studies*, see NEAC's 2006 and 2007 annual reports, which are available from NEAC's website (<http://www.neac.health.govt.nz>).

## **Innovative practice (quality and safety work stream)**

### **What is innovative practice?**

Innovative practice is practice that is a planned deviation from currently accepted practice.

Innovative practice involves applying known procedures in circumstances in which they have not previously been tested. Innovative practice may involve new delivery practices by health practitioners, new devices, new investigative procedures, or new clinical management options.

### **Ethical issues in innovative practice**

The ethical issues involved in innovative practice are similar to those for an intervention study. The potential benefit is great, but participants are also vulnerable to potential harm.

## **Project process**

NEAC reviewed the literature on ethical issues in innovative practice, undertook a stocktake of New Zealand and international policy and guidance on innovative practice, and interviewed relevant people.

In 2008, NEAC focused on its work on intervention studies. This work shares similarities with NEAC's work on innovative practice. NEAC has put on hold further work in innovative practice until it has finished its intervention studies work.

## **Pandemic planning (public health priorities work stream)**

### **Advice on ethical values for a pandemic**

An influenza pandemic would be likely to involve high levels of illness and death. Pandemic planning aims to prevent a pandemic when possible and to minimise the negative impacts of a pandemic when prevention is not possible. NEAC believes that considering ethical issues as part of pandemic planning will better equip people to react to a pandemic by helping them to act on shared values using common sense and imagination, even when time is severely limited.

NEAC's pandemic work, published as *Getting through Together: Ethical values for a pandemic* (2007), was based on wide consultation to confirm the shared values of New Zealanders that could assist with planning for and responding to a pandemic. *Getting through Together* also contains practical guidance for decision-makers who will be faced with overwhelming demand for health services. A summary statement of ethical values is also included in the Ministry of Health's *New Zealand Influenza Pandemic Action Plan* (2009).



NEAC's pandemic work has received recognition by the World Health Organization.

In 2008, NEAC responded to ongoing national and international interest in its work on pandemic ethics.

### **Further information**

For further information about NEAC's work in pandemic planning, see NEAC's 2006 and 2007 annual reports, which are available from NEAC's website (<http://www.neac.health.govt.nz>).

## Membership of the National Ethics Advisory Committee

### Andrew Moore – chair

Andrew Moore is an associate professor in the Department of Philosophy at the University of Otago. 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, Andrew is a member of the Health Research Council of New Zealand's Data Monitoring Core Committee for New Zealand-led clinical trials.

Andrew is a previous member of the National Health Committee and Public Health Advisory Committee.

## **Geoff Fougere – Deputy Chair**

Geoff Fougere is a senior lecturer in sociology in the Department of Public Health, Wellington School of Medicine (University of Otago). He also holds honorary appointments in sociology at the University of Canterbury and University of Auckland and is an external faculty affiliate of the Center on Organizational Innovation, Columbia University, New York. Geoff's teaching and research interests focus on the analysis of political and organisational change and public policy, particularly in the health sector.



Geoff is a member of the National Health Committee and chairs the Public Health Advisory Committee.

## **Barbara Beckford**

Barbara Beckford is the co-convenor of the Federation of Women's Health Councils Aotearoa and manages a Well Women's Centre. Barbara has a particular interest in the ethical issues around determining the public good and priorities in health care; how consumers are involved in consultation; and the processes, rights, and responsibilities that lie with individual and collective actions.



Barbara is a lay member of the Medical Radiation Technologists Board, has extensive involvement with national screening programmes, is a member of the National Quality Improvement Programme – Safe Medication Management steering group, and is a community representative on the West Coast District Health Board Hospital Advisory Committee and Community and Public Health Advisory Committee.

## **Michael Findlay**

Michael Findlay is a professor of oncology, the head of the discipline of oncology, the director of Cancer Trials New Zealand, and an honorary professor at the Auckland Cancer Society Research Centre at the University of Auckland. Michael is also a practising medical oncologist in the Auckland Regional Cancer and Blood Service.



Michael has published in the area of cancer research, particularly in the area of clinical trials in cancer of the gastrointestinal tract. He is the deputy-chairperson of the Australasian Gastro-Intestinal Trials Group and has been an active investigator for over a decade.

More recently, Michael's major focus has been in developing Cancer Trials New Zealand – an academic research organisation established to facilitate and support cancer research and the research environment to improve cancer outcomes in New Zealand.

## **Andrew Hall**

Andrew Hall sustained a spinal cord injury in 1983 as a 19-year-old at Massey University. After completing an agricultural economics degree at Lincoln University, Andrew undertook computer programming work in New Zealand and Australia. He has also farmed in Central Otago.



Andrew is the chief executive of the New Zealand Spinal Trust, a consumer support and service-providing organisation. He is the current chair of the National Spinal Cord Injury Group and a trustee of the Sporting Futures Charitable Trust.

## **John Hinchcliff**

John Hinchcliff is a retired vice-chancellor of the Auckland University of Technology and has served on the Auckland City Council. John 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.

## **Te Kani Kingi**

Te Kani Kingi is director of Te Mata o te Tau, the Academy for Māori Research and Scholarship, at Massey University, Wellington. Te Kani has extensive experience in Māori health research and has lectured in Māori health, health policy, Māori mental health, and the Treaty of Waitangi. He has served on health-related committees and continues to publish in the broad area of Māori health and Māori development. Te Kani has a particular interest in mental health, the measurement of health outcomes, and the development of culturally aligned outcome indicators.



Te Kani was born and raised in Poroporo (near Whakatane) and educated at St Stephen's School in South Auckland. He studied at Waikato and Massey Universities and has tribal affiliations to Ngāti Awa and Ngāti Pūkeko.



## **Robert Logan**

Robert Logan has extensive experience of the health sector through a variety of roles in clinical practice, management, and governance. Until recently, Robert chaired the National Health Committee, National Chief Medical Advisors Group, and Workforce Taskforce. He is currently chief medical advisor at Hutt District Health Board and a Crown monitor at Wanganui District Health Board.



Robert has been actively involved in research in New Zealand and overseas and has published papers on clinical uncertainty.

## **Joanna Manning**

Joanna Manning is an associate professor in 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 also the consumer representative on the Medical Practitioners' Disciplinary Committee for 10 years.

## **Robin Olds**

Robin Olds is chief executive of the Health Research Council of New Zealand.



Robin is a medical graduate of the University of Otago with postgraduate training in pathology and is a fellow of the Royal Australasian College of Pathologists. He has also researched molecular genetics of haemostatic disorders at Oxford University as a Nuffield Dominions Medical Fellow.

Robin has been the chair in pathology at the Dunedin School of Medicine where his research focused on molecular aspects of the major mood disorders, particularly manic depression. Robin was head of the Department of Pathology and had additional roles in the management of the medical curriculum.

## **Ann Richardson**

Ann Richardson is an epidemiologist and public health physician. She is particularly interested in public health, epidemiology, and cancer screening.



Ann is a public health physician in the areas of information and capacity building and chronic disease prevention for the public health service of the Canterbury District Health Board.

Ann obtained her undergraduate and postgraduate qualifications in medicine and public health in New Zealand, was a clinical research fellow in the Cancer Epidemiology Unit at the University of Oxford, and worked in the Department of Public Health and General Practice at the University of Otago Christchurch campus.

## **Elizabeth Smales**

Libby Smales is a palliative care physician who trained in London and San Francisco. She came to New Zealand in 1979.



Libby is shifting her focus from clinical to psychological practice and workshop facilitation. She has a private practice and works with people in crisis. She has wide experience of practising and teaching palliative care in New Zealand and overseas.

Libby has been medical director of Cranford Hospice, Hawke's Bay; president of Hospice New Zealand; honorary treasurer of the Asia Pacific Hospice Network; and president of the Hawke's Bay New Zealand Medical Association. She has also worked as a general practitioner, in family planning and as an assessor for the Accident Compensation Corporation, working with men and women who have been sexually abused.

# **National Ethics Advisory Committee Secretariat in 2008**

## **Role of the National Ethics Advisory Committee secretariat**

The NEAC secretariat provides dedicated analytical policy support and administrative support to NEAC. The NEAC secretariat is located in the Ministry of Health.

## **Membership of the National Ethics Advisory Committee secretariat**

The NEAC secretariat in 2008 comprised:

- Barbara Burt – senior analyst
- Vanessa Roberts – analyst
- Polly Atatoa-Carr – public health medicine registrar (fixed term)
- Gabrielle McDonald – public health medicine registrar (fixed term).

## Contact Details for the National Ethics Advisory Committee

National Ethics Advisory Committee:

Telephone 64 4 496 2000

Email [neac@moh.govt.nz](mailto:neac@moh.govt.nz)

Postal address PO Box 5013, Wellington 6145

Website <http://www.neac.health.govt.nz>

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

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) issued a statement entitled *Goals, Objectives, and Desired Outcomes of an Ethical Review System* in accordance with its statutory function to ‘determine nationally consistent ethical standards across the health sector’ (section 16 of the New Zealand Public Health and Disability Act 2000).

The ethical review system includes ethical aspects of self-review, peer review, ethics committee review, and specialist review of health and disability research and related activity. It applies established ethical standards to research and related activity. *Goals, Objectives, and Desired Outcomes of an Ethical Review System* states the established goals, objectives, and desired outcomes that are to be applied to the ethical review system itself.

For details of the inclusive public process that generated Goals, Objectives, and Desired Outcomes of an Ethical Review System, see NEAC’s Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand (2003), which is available from the NEAC website (<http://www.neac.health.govt.nz>).



## Goals, objectives, and desired outcomes of an ethical review system

<b>Overall goals</b>
<p>Facilitate research and innovative practice that contribute to knowledge and improved health outcomes.</p> <p>Protect participants in health and disability research and innovative treatment.</p> <p>Find a balance that minimises risks and maximises benefits arising from health and disability research.</p> <p>Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review system for health and disability research.</p>

<b>Objectives</b>	<b>Desired outcomes</b>
Accountable	<p>Public accountability requirements are defined.</p> <p>Ethical reviews meet internationally recognised standards.</p> <p>Ethical reviews take into account relevant legislation.</p>
Enabling	<p>Research participants/subjects are protected.</p> <p>Quality research is facilitated.</p> <p>Review processes are clear about jurisdiction and coverage.</p> <p>Awareness of ethical practice among all stakeholders is developed.</p> <p>Good communication with affected communities is demonstrated.</p> <p>Local input is achieved.</p> <p>Positive relationships with all stakeholders are developed.</p> <p>System review mechanisms are in place.</p>

Objectives	Desired outcomes
Informed	<p>Researchers consider ethical implications from the outset; for example, it is clear who will benefit from the research (participants, the public, and so on).</p> <p>The perspectives of affected communities are included.</p> <p>Review processes are proactive, attend to emerging issues, and are responsive to change over time.</p> <p>Review processes apply appropriate expertise.</p> <p>Scientific and ethical standards are considered alongside each other where appropriate.</p> <p>Decision-making is consistent.</p> <p>Review capacity and relevant expertise are maintained and developed.</p>
Enabling of Māori participation	<p>A Māori ethical framework is developed and implemented.</p> <p>Consultation with Māori is collaborative, genuine, inclusive, and appropriate.</p> <p>Māori participation in the decision-making component of the system is facilitated.</p> <p>The potential for diversity of opinion across iwi and regions is recognised and respected.</p> <p>Māori research capability is facilitated.</p>
Fair	<p>Review processes are independent.</p> <p>Stakeholders have access to due process.</p> <p>Outcomes of processes are equitable.</p> <p>Applicants to review processes have the right of reply.</p> <p>Conflicts of interest are acknowledged and addressed.</p>

<b>Objectives</b>	<b>Desired outcomes</b>
Efficient	Time and resources are used productively. Reviews are timely. Sector guidance is updated regularly, with opportunity for all stakeholders to participate.

## Appendix B: Terms of Reference for the National Ethics Advisory Committee

### 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 Public 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. No member may hold office for more than six consecutive years unless an additional period of up to 12 months is confirmed to allow for continuity of projects. 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 its 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. 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 National Ethics Advisory 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 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 National Ethics Advisory 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 members of 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 SCA 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 SCA**

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 SCA

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 well-being of society
- iii. collaborate with researchers to ensure the interests, rights, dignity, welfare, health and well-being 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 twelve, 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 or 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's 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 that 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 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 members of 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](mailto:appeals_neac@moh.govt.nz)