

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

**National Ethics  
Advisory Committee  
Kāhui Matatika o te Motu**

2006

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National Ethics Advisory Committee

Kāhui Matatika o te Motu

## Foreword

Ethics involves identifying what matters and how best to act on it or live by it. This fifth annual report of the National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) outlines what matters in the Committee's work areas, and reports on how the Committee's activities and advice in 2006 contributed to these things.

NEAC's statutory functions are broad and strategic. They include roles to advise the Minister of Health on ethical issues of national significance on any health and disability matters, and to determine nationally consistent ethical standards across the health sector.

When NEAC began its work in 2002, it was asked to undertake a major project on health research. The final part of that work, on observational studies, is summarised in this annual report, alongside reports of other research ethics projects from the Committee's current work programme. There is still work to be done in research ethics, especially in terms of maximising the benefits of research for health and disability, and for wider social and economic development.

NEAC completed two other major pieces of work in 2006. One was a 'big picture' project on the hardy perennial topic of elective services. The other was a project on ethical values for a pandemic, centred on the theme of 'getting through together'. Both these projects are reported on in the pages that follow. Towards the end of 2006 the Committee also started an analysis of the links between the ethical principle of 'do no harm' and the practice of withdrawing labour through industrial action.

NEAC strives to produce work that is both principled and practical. Several things matter to this: an expert and credible membership, collaborative working relationships with key individuals and organisations, inclusive and thorough project processes, and a professional secretariat.

On behalf of the National Ethics Advisory Committee, I am pleased to present this annual report for 2006.

A handwritten signature in black ink, appearing to read 'Andrew Moore', with a stylized, cursive script.

Andrew Moore  
**Chair**  
**National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**

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# Introduction

The National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC) is an independent advisor to the Minister of Health. Its statutory name is the National Advisory Committee on Health and Disability Support Services Ethics.

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 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 policy statements for the health and disability sectors. Section 16(6) of the 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.*

The members of NEAC, appointed by the Minister, bring expertise in ethics, health and disability research, health service provision and leadership, public health, epidemiology, law, Māori health and consumer advocacy.

NEAC's 2006 work on health and disability focused on both services and research. In particular, the Committee completed work on elective services, pandemic planning and observational studies.

### Introduction

#### Services ethics projects

Central to NEAC's work on services ethics is an approach that sees issues and improvements through the eyes of a patient or, with public health initiatives, through the eyes of members of the public. In elective services, for example, improvement is needed at all the steps each patient must take on his or her pathway to getting an elective procedure. In a pandemic, to take a different example, we would all be vulnerable and usual services might not be available to everyone, so we all need to find practical ways to 'get through together'.

Even if issues are seen through the right eyes, shared values and practical guidance are still needed to help with the hard decisions. For example, NEAC's pandemic work *Getting Through Together* confirmed through wide consultation some shared values to help us care for ourselves, our whānau and our neighbours, plus practical guidance for decision-makers faced with overwhelming demand.

Another key element in services ethics is a clear focus on the outcomes that matter, including health gain and reduced inequalities.

NEAC's services ethics work is reported below in the areas of:

- elective services
- pandemic planning

#### Research ethics projects

NEAC's approach to policy and guidance on research ethics has two main features. First, it reframes issues in terms of research worth *and* research risk, in contrast to some traditional approaches that focus solely on protecting study participants from risk. Second, NEAC takes the relationship between investigator and participant to be central, and consequently recognises that investigators have the primary ethical responsibility for studies. NEAC's *Ethical Guidelines for Observational Studies* reflect both these features, by aiming to facilitate high-quality studies and by being directed to investigators, who have the main ethical responsibility for good study conduct.

Further principles guiding NEAC's policy work include recognising the important roles that others – including ethics committees and study sponsors – have in research ethics, and ensuring that the intensity of ethical scrutiny is in proportion to the level of research risk.

NEAC's research ethics work is reported below in the areas of:

- observational studies
- research ethics governance
- intervention studies and innovative practice
- Māori health and disability research ethics
- tissue research: stillborn babies and fetuses
- appeals in the ethical review system (follow-up work only)
- performance of the ethical review system (follow-up work only).



## Elective services

Summary	
What matters	Elective services that work better for New Zealanders.
NEAC contributions	A proposed strategic direction for elective services that is patient-centred, develops all steps on the electives pathway for patients, and addresses key sector contexts.
Output	NEAC advice to the Minister on the above themes, intended to inform further policy development and examination of the booking system approach.  For NEAC's <i>Report to the Minister of Health on Ethical Issues in Elective Services</i> , see: <a href="http://www.neac.health.govt.nz">http://www.neac.health.govt.nz</a>

### Ethical issues in elective services

Since the mid-1990s New Zealand has been implementing an internationally distinctive 'booking system' approach to elective services. Key principles underlying the booking system are clarity, timeliness and fairness. Ongoing review of the system will help to deliver elective services that work better for New Zealanders.

### NEAC advice on ethical issues in elective services

In September 2006 NEAC provided advice to the Minister of Health on ethical issues in elective services. The Committee took a whole-of-system approach to this work, considering the overall design of the electives pathway and its interaction with other parts of the New Zealand health system. This resulted in the identification and discussion of a number of ethical issues in elective services.

NEAC advised that there are potential ethical advantages in New Zealand's 'booking system' approach to elective services. To help secure these advantages, a key message in NEAC's advice is that the ongoing development of elective services should be more explicitly built around the patient-centred idea of the 'electives pathway'. Adoption of this idea would highlight the full set of steps during which things must work well for patients.

In particular, NEAC wishes to see the development of a tool to measure progress towards the ideal that every patient who has a primary care referral is offered a timely and appropriate specialised service. This is likely to require ongoing innovation in how, where, and by whom such specialised services are offered.

NEAC advised that some issues relating to the overall design of the electives pathway, and its interaction with other parts of the New Zealand health system, warrant further examination. These issues are:

- the 'first specialist assessment' step
- relations between elective services and acute services
- relations between public and private sectors.

NEAC's advice could also be used to inform ongoing Ministry of Health work in the following areas:

- equity of access
- quality and national consistency
- the centrality of the health professional–patient relationship
- the basis of prioritisation for elective services.

## Process

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 to these concerns by undertaking background work on the issues raised.

NEAC completed a scan of literature reporting on research and developments related to New Zealand's booking system approach to elective services. In July 2006 NEAC presented the direction of its thinking on elective services at a multi-specialty forum on elective services, and outlined its elective services project to a meeting of District Health Board chief medical advisors. The following month NEAC also outlined this work to a meeting of the National Health Committee. NEAC liaised with the Ministry's elective services group throughout the project.

In September 2006 NEAC provided advice to the Minister of Health on ethical issues relating to elective services. In conducting its work on elective services, NEAC has not consulted with patients, health sector stakeholders (beyond those stated above), or the wider public. The Committee consequently regards its findings as indicative rather than definitive. Wider sector and public input would be valuable for the further work suggested by NEAC on the electives pathway and its interaction with other parts of the health system.

For NEAC's *Report to the Minister of Health on Ethical Issues in Elective Services*, see: <http://www.neac.health.govt.nz>

## Pandemic planning

Summary	
What matters	<p>Minimising harm from any pandemic.</p> <p>Minimising inequalities in the impact of any pandemic.</p> <p>Getting through any pandemic together.</p>
NEAC contributions	<p>Identifying shared values to assist difficult decision-making.</p> <p>Providing practical guidance on some key 'hard issues'.</p> <p>Working with the Ministry of Health, the lead cross-government agency for this work.</p>
Output	<p>Accessible published work, developed through inclusive public consultation processes.</p>

### Ethical values for a pandemic

An influenza pandemic would be likely to lead to high levels of illness and death, in both New Zealand and other countries. Pandemic planning aims to prevent a pandemic wherever possible, and to minimise the negative impacts where prevention is not possible. Considering ethical issues in advance of any pandemic will better equip us to act on shared values using common sense and imagination, even when we have little time.

### NEAC advice on ethical values for a pandemic

NEAC's contribution to pandemic planning, *Getting Through Together: Ethical values for a pandemic*, was written to reflect the New Zealand context and aims to:

- highlight, for the public and all who are involved in pandemic planning, the fact that ordinary people can do extraordinary things, and that stating high expectations for ourselves and one another will help more of us to act in this way
- emphasise that when we are pulled in more than one direction by things that matter, we should get through as far as we can with an imaginative approach that maintains each of the things that matter (eg, thought and action that achieves *both* self-protection *and* help for our neighbours).

As was confirmed through consultation feedback, *Getting Through Together* identifies shared values and offers broad guidance in the areas of restrictive measures, the responsibilities of health professionals, prioritising health services, and neighbourliness/whānaungatanga. NEAC considers that community action expressing neighbourliness and whānaungatanga will be vital to managing a future pandemic.

*Getting Through Together* also includes a summary statement of ethical values for a pandemic, expressed in a common-sense style. Identifying the values that matter most gives us a shared basis for decision-making. The summary statement identifies values recognised in Māori tikanga alongside other values, and it recognises that our values can pull us in more than one direction. The values apply in many settings, and at all pandemic phases. Two hypothetical cases are used to examine some of the challenges we may face in a pandemic.

## Process

In 2006 NEAC undertook work to formulate guidance on ethical values for a pandemic. This project, informed by a public consultation and other work on pandemic ethics and decision-making, generated the report *Getting Through Together: Ethical values for a pandemic*. New Zealand is the only country to have considered ethical issues in pandemic planning through a process that has included national public consultation. NEAC's work has been strengthened on many points by the consultation feedback.

NEAC was invited to present its work in progress at the World Health Organization's Global Consultation on Addressing Ethical Issues in Pandemic Planning in October 2006. This provided an opportunity to test the Committee's work in a global setting, and to engage with the best work by others.

*Getting Through Together* will be published and launched in 2007. In keeping with its process values, NEAC welcomes further feedback on this report. When it has made any further improvements, the Committee will seek to have key parts of its work included in the next update of the Ministry of Health's *New Zealand Influenza Pandemic Action Plan*.

*Getting Through Together* is available at <http://www.neac.health.govt.nz>

## Observational studies

Summary	
What matters	Safe and high-quality health and disability services. Safe environments at home, work and leisure.
Benefits of observational studies	New generalisable knowledge of health and disability. Vital evidence about our health and how best to protect and improve it.
NEAC contributions	Building observational studies further into the culture and routines of the health and disability sector. Minimising any risk or harm related to such studies. Building public confidence in these contributions.
Output	NEAC's <i>Ethical Guidelines for Observational Studies: Observational research, audits and related activities</i> , available in hard copy and electronically at: <a href="http://www.neac.health.govt.nz">http://www.neac.health.govt.nz</a>

### Ethical issues in observational studies

Observational studies inform New Zealanders 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, they 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.

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 differs from an intervention study, in which the investigator intentionally alters people's treatment or other care to study the safety and benefit of doing so. This difference makes observational studies relatively low risk. The conduct of such studies also generally involves a reduced potential for conflict between the investigator role and the clinician role.

### NEAC's *Ethical Guidelines for Observational Studies*

NEAC published its *Ethical Guidelines for Observational Studies: Observational research, audits and related activities* (the Guidelines) in December 2006. The Committee's work in this area was conducted in the context of a privacy culture which developed in the 1990s and gave particular emphasis to privacy interests. The Committee focused on how best to address the Gisborne Inquiry findings, which noted that privacy concerns had impeded an essential audit of the National Cervical Screening Programme. Publication of the Guidelines implements accepted recommendations of the Gisborne Cervical Screening Inquiry Report. The Guidelines also addressed a long-standing national and international difficulty by developing a principled and practical distinction between research and audit, based on level of risk.

### *Aims of the Guidelines*

The main aims of publishing and launching the Guidelines are to:

- build a new consensus among investigators, ethics committees and the public, to secure the benefits of observational studies
- assist investigators to design and conduct high-quality studies
- address the risks associated with observational studies

- address the research/audit distinction associated with observational studies, in both principle and practice.

The above aims are achieved through the processes of producing and using the Guidelines, and through their specific features. Using the Guidelines will help ensure that observational studies meet high ethical standards and generate benefits for the sector and the wider community.

### ***Features of the Guidelines***

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, which 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 through to the dissemination of the study's findings. Finally, 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 in some cases no ethics committee review is required.

### **Process**

NEAC completed the Guidelines, which reflect the valuable input of a range of stakeholders, in 2005 (see the NEAC Annual Report 2005 for details). In 2006 NEAC helped the Ministry to complete required follow-up work to establish the expedited review process. NEAC published and launched the Guidelines in December 2006. NEAC will undertake a review of the Guidelines by the end of 2008.

*Ethical Guidelines for Observational Studies: Observational research, audits and related activities* is available in hard copy, and electronically at: <http://www.neac.health.govt.nz>

## Research ethics governance framework

### Ethical responsibilities in research

It matters that good studies are facilitated and conducted to high ethical standards, and that any ethical issues are well addressed. 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 some gaps, overlaps, unclear areas and inconsistencies in responsibilities for ensuring good studies are facilitated and issues are well addressed.

Key areas of responsibility include: ethical review, study design, adherence to study protocol, information issues, relationships with communities, participant welfare, locality issues, scientific assessment and legal issues. These key areas of responsibility should be matched with:

- key parties (eg, researchers, ethics committees, locality organisations, research funders, researcher employers, data monitoring committees)
- key roles (eg, addressing versus checking that issues have been satisfactorily addressed)
- key powers or authorities (eg, a discretion compared with a duty to perform the role in question).

### NEAC's aims

New Zealand does not have a complete framework to address 'who is responsible for what' in research ethics. A completed research ethics governance framework would promote high ethical standards in research design, conduct and review by more clearly identifying and matching the key areas of responsibility with the appropriate responsible parties. For example, it would fully address who is responsible for observing, reporting, assessing and acting on 'serious adverse events' in intervention studies, and it would clarify who should check that these things are done in a manner consistent with study practicalities and national and international standards.

### Process

Within its agreed governance framework project, NEAC began in 2006 an overview and analysis of existing sector guidance, including identifying gaps, overlaps and broad options for future development and linking of guidance.

## **Intervention studies and innovative practice**

### **Ethical issues in intervention studies and innovative practice**

#### ***What are intervention studies?***

In an intervention study, the investigator intentionally alters one or more treatments or other health-related factors to study the effects of doing so. The effects to be studied typically concern treatment safety or benefit for participants. A clinical trial of an influenza vaccine is an example of an intervention study.

Ethical guidance for intervention studies is an important area of NEAC's work, because this is a dynamic area of research, with great potential benefit alongside some vulnerability of participants to potential harm.

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

Innovative practice involves the use, outside any study, of an intervention that is not established practice. The introduction of a new surgical technique is an example of an innovative practice.

Innovative practice covers a dynamic set of activities, again with great potential benefit and also some vulnerability of participants to potential harm.

### **NEAC's aims**

NEAC aims to contribute to the high-quality conduct of intervention studies and innovative practice, and through this to add to better health outcomes and reduced inequalities. The project is doing this by identifying and addressing ethical issues in intervention studies and innovative practice.

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 relationship between intervention research and innovative practice also parallels the close relationship between observational research and audit. NEAC consequently anticipates that many insights from its project on observational studies (see above) will also inform its work on intervention studies and innovative practice.

### **Process**

The Minister of Health agreed to NEAC's conducting a project on the ethics of intervention studies and innovative practice. NEAC has scanned the existing guidance and carried out initial discussions with key informants. The Committee has also carried out a literature scan on ethical issues in innovative practice, a stocktake of New Zealand and international policy and guidance on innovative practice, and interviews with key informants.

NEAC is aiming to produce guidance parallel to its established *Ethical Guidelines for Observational Studies*. The Committee will also make recommendations to the Minister to attend to any matters the Guidelines cannot address.



## **Māori health and disability research ethics**

Māori have been developing their capacity to undertake research for a number of years, drawing on tikanga Māori and matauranga Māori as an ethical base. This has created new opportunities and challenges, but as yet there are few formal protocols or ethical guidelines to guide such research. There are also important linkages between Māori research ethics and wider frameworks and approaches.

### **NEAC's aims**

The project is designed to encourage discussion of ethical issues among Māori communities, health researchers and people and organisations involved in the ethics of health research. The project process is intended to identify issues and foster discussion and dialogue that will: assist the development of Māori health and disability research ethics; assist high-quality research participation of Māori; and, through this contribute to health gain and reduced inequalities.

### **Process**

In this project, NEAC is working in collaboration with Ngā Pae o te Māramatanga (Māori Centre of Research Excellence, based at the University of Auckland) and the Health Research Council of New Zealand.

## **Tissue research: stillborn babies or fetuses**

In recent decades new techniques in genetics and molecular biology have enabled major research advances in human development, and in understanding of disease cause and progression. With improvement in techniques has come an increased interest in using tissue from a range of sources, including from embryos, fetuses and stillborn babies.

NEAC is examining the issues that arise when people wish to use tissue from stillborn babies, or from fetuses following miscarriage or termination of pregnancy, for such research, along with related uses.

Central to this work is the potential use of this tissue, the legislative and ethical mechanisms that regulate its use in New Zealand, and the extent to which there are uses of tissue from fetuses and stillbirths that are not covered by these mechanisms. One significant issue is the consent process for sourcing and use of tissue from fetuses following a termination of pregnancy. There may also be increasing research demands for fetal stem cells and ovarian tissue for research and clinical use.

### **Process**

The Minister of Health asked NEAC to consider developing guidelines on the research use of tissue from stillborn babies or fetuses in October 2004. In 2006 NEAC considered a background report on the issues.

### Appeals in the ethical review system

In May 2004 the Minister of Health agreed that provision for a limited right of appeal to an independent body should be established for cases where an applicant and ethics committee disagree and all other means of resolution have been exhausted. The Ministry of Health continues to work on the establishment of an appeals body.

### Performance of the ethical review system

Through its 2003 review, NEAC generated a statement of *Goals, Objectives and Desired Outcomes of an Ethical Review System*, and this was agreed to in revised form 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. The statement is included in this annual report (see Appendix A), with minor amendment to keep it current and applicable.

## Committee Membership

### **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 and political philosophy.



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 previous membership of the National Health Committee and Public Health Advisory Committee.

### **Allison Kirkman – deputy chair**

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 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.

## **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, which provides advocacy for generic consumer interests, particularly at the policy level.



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.

## **Dale Bramley**

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



Dale is a public health physician and general manager of Clinical Support Services for the Waitemata District Health Board. He has an honorary academic appointment as a senior lecturer in public health in the section of 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 he completed a Harkness Fellowship in Health Policy at the Mount Sinai Medical Center in New York. The focus of his work was an international comparison of indigenous health disparities.

Dale has tribal affiliations to Ngāti Hine and Ngā Puhī.



## **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 before working in private practice. Working for the District Health Board combines her nursing and legal skills.



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.

## **John Hinchcliff**

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.

## **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 a number of health-related committees and continues to publish in the broad area of Māori health and Māori development. He has a particular interest in mental health, health outcome measurement, and the development of culturally aligned outcome indicators.



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

## **Joanna Manning**

Joanna Manning is 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 the consumer representative on the Medical Practitioners' Disciplinary Committee for 10 years.



## **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, which 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, which produced guidance notes for health researchers and ethics committees.

## **Martin Sullivan**

Martin Sullivan 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, he has been actively involved in the disability movement for many years and is chair of Advocacy Manawatu (a citizen advocacy group for people with disabilities).

## Secretariat 2006

Barbara Burt – senior analyst

Jamie Hosking – public health medicine registrar (fixed term)

Fiona Imlach – public health medicine registrar (fixed term)

Vanessa Roberts – analyst

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

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

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. GODO states 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 the GODO statement, see National Ethics Advisory Committee, *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand* (December 2003), available at: <http://www.neac.health.govt.nz>

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

Overall goals
<p>Facilitate research and innovative practice that contributes 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>

Objectives	Desired outcomes
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; eg, there is clarification of who will benefit from the research (participants, the public, etc).</p> <p>The perspectives of affected communities are included.</p> <p>Review processes are proactive and attend to emergent 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>
Efficient	<p>Time and resources are used productively.</p> <p>Reviews are timely.</p> <p>Sector guidance is updated regularly, with opportunity for all stakeholders to participate.</p>

## 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 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. 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 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 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](mailto:appeals_neac@moh.govt.nz)