National Ethics Advisory Committee Kāhui Matatika o te Motu Annual Report 2009

Eighth Annual Report to the Minister of Health

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Citation: National Ethics Advisory Committee – Kāhui Matatika o te Motu. 2010. *National Ethics Advisory Committee – Kāhui Matatika o te Motu Annual Report 2009: Eighth Annual Report to the Minister of Health.* Wellington: Ministry of Health.

Published in October 2010 by the
Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN: 978-0-478-36633-4 (print)
ISBN: 978-0-478-36634-1 (online)
HP 5184

This document is available on the National Ethics Advisory Committee – Kāhui Matatika o te Motu website:
http://www.neac.health.govt.nz

neac
National Ethics Advisory Committee
Kāhui Matatika o te Motu

Foreword

This annual report summarises for the calendar year 2009 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. They 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. A consideration of ethics involves identifying what matters and how best to act accordingly. NEAC works to this broad definition of ethics, and this helps its work not to be identified with any particular sector interest or group.

In 2009, NEAC completed and published its Ethical Guidelines for Intervention Studies. Evidence from clinical trials is a fundamental driver of innovation, patient safety and improved care. In general, it is at least as safe and beneficial for patients to receive care in a clinical trial as it is outside a clinical trial, because care in such trials is more systematically planned, delivered, monitored and followed up. Clinical trials can bring treatments to clinics before they would otherwise be introduced. Additionally, healthcare organisations that are active in clinical research generally practice excellent patient care and have high retention of key clinical staff. The Guidelines constitute 'nationally consistent ethical standards' for the purposes of section 16 of the New Zealand Public Health and Disability Act 2000, and applicable ethical standards for the purposes of Right 4(2) within the Code of Health and Disability Services Consumers'

Rights 1996. They contribute to the high quality and safe conduct of clinical trials.

In 2009, NEAC responded to requests from the Minister of Health for advice on the retention and use of Guthrie cards, and on draft guidelines on tissue typing prepared by the Advisory Committee on Assisted Reproductive Technology.

NEAC agreed two new projects with the Minister of Health in 2009, in the areas of advance care planning, and harm and industrial action.

In summary, in 2009 NEAC completed a large project on a topic that matters to the quality and safety of patient care nationwide, and started two projects in other key areas, while continuing to provide timely and useful advice to the Minister on issues of interest. In these ways, NEAC continued to contribute to the positive health of all New Zealanders.

On behalf of NEAC, I am pleased to present this annual report for 2009.

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

NEAC is designed to effectively contribute to good health outcomes for New Zealanders. The Minister of Health appoints the members of NEAC, who come from a range of professions and backgrounds, and bring expertise in ethics, clinical leadership and health service provision, health and disability research, public health, epidemiology, law, Māori health and consumer advocacy.

National Ethics Advisory Committee's work programme in 2009

Overview

A consideration of ethics involves identifying what matters and how best to act accordingly. NEAC works to this definition of ethics, and produces work that is both principled and practical, and that is not identifiable with one sector group or interest. NEAC agrees its work programme with the Minister of Health.

Services ethics

At the request of the Minister, in 2009 NEAC provided advice on the retention and use of Guthrie cards and on draft guidelines on tissue typing prepared by the Advisory Committee on Assisted Reproductive Technology (ACART).

Towards the end of 2009, NEAC agreed two new services ethics projects with the Minister of Health, in the areas of advance care planning, and harm and industrial action.

Research ethics

In 2009, NEAC released its *Ethical Guidelines for Intervention Studies*, establishing ethical standards for such studies. It also carried out further work in the areas of Māori health and disability research ethics.

Services ethics work in 2009

Retention and use of Guthrie cards

The screening test in the Newborn Metabolic Screening Programme (NMSP) involves taking blood samples from babies' heels (the heel prick test) and storing them on blood-spot cards known as Guthrie cards. The primary purpose of the procedure is to screen New Zealand babies for 28 metabolic disorders. Guthrie cards are currently stored indefinitely in a secure facility, or, if requested, the card is returned to the family after testing.

Ethical issues in the retention and use of Guthrie cards

Process

In 2009, the Ministry of Health briefed the Minister on its review of the policy and legislative framework governing the NMSP. The Minister of Health then requested NEAC's comments on issues related to the retention and use of Guthrie cards.

NEAC's comments focused on two issues:

1. whether Guthrie cards should continue to be stored indefinitely, or instead should be destroyed after 16 years when no longer required for the primary purpose of the NMSP
2. whether Guthrie cards should be able to be used for any secondary purposes, such as research.

Public availability of NEAC's comments

The Minister is considering these issues. NEAC's comments are not yet publicly available.

Advance care planning

In November 2009, the Minister of Health agreed to the initiation of a NEAC project on advance care planning. The purpose of the project is to develop a resource to help people identify their wishes regarding future situations in which they may become incapacitated and unable to make their own decisions, and to facilitate those wishes being met.

Harm and industrial action

In November 2009, the Minister of Health also agreed to the initiation of a NEAC project on the application of the professional ethical principle of 'do no harm' to industrial action.

NEAC's preliminary work suggests that:

- the 'do no harm' principle is applicable to industrial action
- adherence to the 'do no harm' principle would constrain industrial action
- adherence to the Code of Good Faith (Schedule 1B of the Employment Relations Act 2000 – the most relevant legal provision applicable to this matter) might not guarantee adherence to the 'do no harm' principle.

A project plan will be developed and implemented in 2010.

ACART draft guidelines on tissue typing

ACART has drafted *Guidelines on the use of pre-implantation genetic diagnosis with human leukocyte antigen (HLA) tissue typing*. These draft guidelines cover situations in which parents seek health professionals' help to conceive a child who is 'tissue-matched' to an existing child who is seriously sick, so that the sick child can be treated using cord blood or other tissue from the planned child.

Process

ACART consulted the Minister of Health on its draft guidelines on tissue typing in May 2009. The Minister then asked for NEAC's views on the guidelines.

NEAC drafted its comment, and then invited and received ACART's response. NEAC provided the Minister with its finalised comments and analysis at the end of August 2009.

Public availability of NEAC's comments

The Minister is considering these issues. NEAC's comments are not yet publicly available.

Research ethics work in 2009

Intervention studies

Summary of the intervention studies project

What matters	Providing safe and high-quality health and disability services. Adding to health care knowledge.
NEAC contribution	Encouraging the ethical conduct of quality intervention studies to improve health care. Minimising risk and harm related to intervention studies. Building public confidence in intervention studies and their contribution to health and disability services.
NEAC output	*Ethical Guidelines for Intervention Studies* (NEAC 2009), available in hard copy and electronically at www.neac.health.govt.nz

Ethical issues in intervention studies

In an intervention study, the investigator intentionally alters one or more treatments or other health-related interventions (for example, a new blood pressure medicine) to study the effects of doing so. The effects studied typically concern treatment safety, treatment effectiveness, or both.

Intervention studies comprise the main source of reliable information on the effectiveness and safety of interventions, particularly new interventions. Intervention studies have been important contributors to the large improvements in medical care over recent decades.

In general, participants in intervention studies face greater potential for harm than do participants in other kinds of studies, such as observational studies or tissue studies. To minimise this potential for harm and to maximise potential benefit, it is important that intervention studies are scientifically and ethically sound.

NEAC's *Ethical Guidelines for Intervention Studies*

Aims of the *Guidelines*

The main aims of establishing these *Guidelines* as ethical standards are to:

- assist researchers to identify and address the ethical issues in their studies
- contribute to better health outcomes for New Zealanders by further developing best practice in intervention studies.

The *Guidelines* address ethical issues in study design and conduct, from developing a study question at the outset through to communicating study results and enabling post-study access to interventions.

Features of the *Guidelines*

The *Guidelines* bring together in one document, and build on, the best current national and international guidance on intervention studies. They also address New Zealand-specific issues (such as compensation for injury). The *Guidelines* operate alongside NEAC's well-functioning *Ethical Guidelines for Observational Studies* (NEAC 2006).

Project process

NEAC published and launched *Ethical Guidelines for Intervention Studies* in November 2009. The *Guidelines* were generated through a thorough and inclusive process.

NEAC identified ethical issues in intervention studies through a literature review, committee discussion, and discussions with key informants from across the health and research sectors. This process confirmed that existing New Zealand guidance did not

address all significant issues, and was not always up to date with best practice on the issues that it did address.

To address these issues, NEAC commenced work on a consideration of the ethics of intervention studies, comprising a discussion document and draft guidelines. It had this work peer-reviewed by experts in clinical trials, medical law and public policy. It also received comment from key public agencies and individuals, including the Ministry of Health, PHARMAC, Medsafe, the Health Research Council and the chairs of health and disability ethics committees. NEAC also briefly outlined its work to, and received helpful comment from, other sector groups, including the national group of District Health Board chief medical advisors, the Health and Disability Commissioner, the Health and Disability Commissioner's director of advocacy, and the National Health Committee. In general, the feedback was positive. Some improvements were suggested, and the work substantially revised accordingly.

NEAC then published *Ethics of Intervention Studies: Discussion Document* and *draft Ethical Guidelines for Intervention Studies,* and carried out a six-week public consultation. It also invited health and disability ethics committees to provide feedback over a 10-week period.

Submissions were received from a range of stakeholders, including interested individuals, patient and consumer advocacy groups, research groups, professional and provider organisations, ethics committees, the Ministry of Health, ACC and commercial research organisations.

Following public consultation, NEAC commissioned further peer review from experts in clinical research, research law, medical ethics and biostatistics.

In response to public consultation and this further peer review, NEAC further revised its *Guidelines* into their final form.

Implications of establishing *the Guidelines*

NEAC considers that its processes in developing the *Guidelines* have been thorough and robust, and that the sector response to publication has been positive.

NEAC has liaised with the Ministry of Health throughout the development process, and intends to continue this work. For example, the Ministry may wish to make consequent updates to its *Operational Standard for Ethics Committees* (Ministry of Health 2006).

NEAC believes its *Guidelines* comprise applicable ethical standards under Right 4(2) of the Code of Health and Disability Services Consumers' Rights, which states:

> 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards'.

Public availability of NEAC's work on intervention studies

NEAC's *Ethical Guidelines for Intervention Studies* are available at www.neac.health.govt.nz. Also available on NEAC's website is a bibliography of works consulted during the development of the *Guidelines* and a media release from the NEAC chair. NEAC's annual reports 2004–2008 contain further information about NEAC's work on intervention studies.

Māori health and disability research ethics

Summary of the Māori health and disability research ethics project	
What matters	Improving the quality of research in the area of Māori health. Assisting Māori communities to contribute to Māori health development. Better addressing Māori ethical issues in research.
NEAC contribution	Encouraging discussion and dialogue on Māori ethical issues among Māori communities, researchers and others.
NEAC output	A resource document outlining existing elements of Māori research ethics and potential areas for development. 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 Pūtaiora (comprising Māori members of health and disability ethics committees). Support for sector development of a guideline or framework on Māori research ethics for ethics committees and researchers.

Māori research ethics

The Māori research workforce is growing in numbers and demonstrating increased levels of skill, and a considerable body of literature now exists about Māori research and Māori research ethics. This literature draws on tikanga Māori and mātauranga Māori as ethical bases to guide practice: to indicate what is fair, true and just; and to protect the interests and wellbeing of groups and individuals. Addressing issues and concerns pertaining to Māori research will improve the ethical review system for all researchers and participants.

Project aims

NEAC's work on 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 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 Pūtaiora (comprising Māori members of health and disability ethics committees). This partnership has encouraged discussion on ethical issues among Māori communities, researchers, and other people and organisations involved in research ethics.

In 2009, NEAC continued its work, in consultation with its project partners, on a draft Māori research ethics resource document. The document outlines existing elements of Māori research ethics and potential areas for development. It is intended as a resource for the project partners, to support their future work.

NEAC also supported a writing group (including members of Pūtaiora) to develop a draft framework on Māori research ethics for ethics committees and researchers. NEAC's draft Māori research ethics resource document has been used by the writing group in its development of the draft framework.

NEAC's Māori research ethics resource document will be made available in 2010.

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 policy experience includes previous membership of the National Health Committee and Public Health Advisory Committee, plus contracted work over many years on prioritisation issues concerning medicines and other health services.

Andrew's practical experience in clinical ethics and health research ethics includes membership of the Health Research Council of New Zealand's Data Monitoring Core Committee for New Zealand-led clinical trials. In addition, he has previously been a member of university, regional and national ethics committees.

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 analysis of political and organisational change and public policy, particularly in the health sector.

Geoff's policy experience includes previous membership of the National Health Committee and chairing of the Public Health Advisory Committee.

Lorna Dyall

Lorna Dyall (Ngāti Maniapoto) is a senior lecturer at Te Kupenga Hauora Māori, Faculty of Medical and Health Sciences, Auckland University. Her teaching and research focuses on improving Māori health and wellbeing. Her particular current areas of interest are positive ageing, gambling and Māori health workforce development.

Lorna has worked widely in Māori health in the public sector, within the Department of Health, Wellington Area Health Board and Te Puni Kōkiri. Lorna holds a master's degree in public policy, a post-graduate diploma in community health and a PhD which focused on gambling as an emerging health issue for Māori.

Lorna was awarded a Queen's Service Medal for Māori health in June 2009.

Lorna's term began in May 2009.

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. He is also a practising m edical 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 on 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.

Michael's term finished in December 2009.

Andrew Hall

Andrew Hall sustained a spinal cord injury in 1983 as a 19-year-old Massey University student. 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. He has also 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 published articles and books on ethics and lectured on ethics at universities in the United States and New Zealand. He helped introduce and teach medical ethics at the University of Auckland Medical School during the 1970s.

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

John's term finished in May 2009.

Barbara Holland

Barbara Holland 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 associated 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.

Barbara's term finished in May 2009.

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.

Te Kani's term finished in May 2009.

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

Robin was a 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 working in the areas of information and capacity building and chronic disease prevention for the public health service of the Canterbury District Health Board. She is particularly interested in public health, epidemiology and cancer screening.

Ann obtained her undergraduate and postgraduate qualifications in medicine and public health in New Zealand and was a clinical research fellow in the Cancer Epidemiology Unit at the University of Oxford. She has also 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 currently 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 branch of the 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.

Jacob Te Kurapa

Ko Mataatua te Waka; Ko Manawaru te Maunga; Ko Ohinemataroa te Awa; Ko Mataatua te Marae; Ko Ngati Tawahaki te Hapu; Ko Tuhoe te Iwi; Ko Hakopa Te Kurapa taku ingoa. Tihei Mauri Ora!

Jacob Te Kurapa is currently the youngest elected member of the Whakatane District Council. He is also chair of the Murupara Community Board.

Jacob has worked as a community action youth and drugs service coordinator: a health promotion position dedicated to finding alternative and positive solutions for young people in Murupara and the surrounding districts.

Jacob has wide-ranging governance experience, including roles with a school board of trustees, a community health provider, a community development and economic provider and a number of charitable trusts.

Jacob's term began in May 2009.

Robin Wray

Robin Wray has worked in various communities for 40 years, principally in the fields of social welfare, health and education. During his career, he has been a social worker in Auckland and Whakatane, a trustee of the Eastbay Energy Trust, a trustee of the Auckland Regional Migrants Services Trust and a councillor for Waiariki Polytechnic.

Robin has also been involved in various health organisations in the Bay of Plenty region over the past 10 years. He has been the chair of the Bay of Plenty District Health Board, Eastbay Health and the Bay of Plenty Bio-Medical Ethics Committee respectively.

Robin is currently a judicial justice of the peace sitting in the Auckland, North Shore and Waitakere District Courts. He is an active Rotarian, a past president and Paul Harris Fellow. He is a board member of the Rural Education Activities Programme Inc (REAP) in Whakatane and is on the REAP Aotearoa New Zealand national executive. He lives in Auckland, and has a dairy farm in the Eastern Bay of Plenty.

Robin's term began in May 2009.

National Ethics Advisory Committee Secretariat in 2009

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 2009 comprised:

- Barbara Burt – senior analyst
- Vanessa Roberts – analyst.

Contact details for the National Ethics Advisory Committee

Phone	+64 4 496 2000
Email	neac@moh.govt.nz
Postal address	PO Box 5013, Wellington 6145
Website	www.neac.health.govt.nz

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

The Ethical Review System

GO DO

Goals, **O**bjectives, and **D**esired **O**utcomes

Goals	
Facilitate research and innovative practice that contribute to knowledge and improved health outcomes. Protect participants in health and disability research and innovative treatment. Find a balance that minimises risks and maximises benefits arising from health and disability research. Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review system for health and disability research.	
Objectives	**Desired outcomes**
Accountable	Public accountability requirements are defined. Ethical reviews meet internationally recognised standards. Ethical reviews take into account relevant legislation.
Enabling	Research participants/subjects are protected. Quality research is facilitated. Review processes are clear about jurisdiction and coverage. Awareness of ethical practice among all stakeholders is developed. Good communication with affected communities is demonstrated. Local input is achieved. Positive relationships with all stakeholders are developed. System review mechanisms are in place.

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

GO DO is a 'nationally consistent ethical standard', determined in accordance with s.16 of the New Zealand Public Health and Disability Act 2000. For background information, see *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand* (NEAC 2003), available at www.neac.health.govt.nz

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 is activities in an open and ethical manner. The National Ethics Advisory Committee has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference.

General

1. 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 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 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 New Zealand Public Health and Disability Act 2000 requirements for District Health Boards 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 6145

Email: appeals_neac@moh.govt.nz