

**National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**  
**Annual Report 2011**

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

Citation: National Ethics Advisory Committee – Kāhui Matatika o te Motu. 2012. *National Ethics Advisory Committee – Kāhui Matatika o te Motu Annual Report 2011: Tenth Annual Report to the Minister of Health*. Wellington: Ministry of Health.

Published in September 2012 by the  
Ministry of Health  
PO Box 5013, Wellington 6145, New Zealand

ISBN: 978-0-478-39320-0 (print)  
ISBN: 978-0-478-39347-7 (online)  
HP 5533

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



## Foreword

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

NEAC is an independent advisor to the Minister of Health, and operates independently of the Ministry of Health and its work. 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. NEAC works to a broad definition of ethics – identifying what matters and how best to act accordingly – and its credible membership, collaborative relationships and open, inclusive and thorough processes are all important contributors to its policy advice.

NEAC saw a number of significant changes in 2011, including the appointment of a new chair and three new members, and recruitment of new secretariat staff. After the formation of the new Committee, NEAC as a whole took the opportunity to review its vision and goals, working arrangements and work programme.

In 2011, NEAC provided advice in relation to the Health Committee's inquiry into New Zealand's clinical trials environment, and played a role in supporting and developing the system of health and disability ethics committees following that inquiry.

It continued its work on projects in the areas of Māori research ethics, advance care planning and harm in industrial action.

It prepared a final draft of the resource document *Māori Research Ethics: An overview*, which incorporated comments from a peer review process.

It explored a number of options about how best to encourage engagement and discussion between consumers, non-governmental organisations, health professionals and other community members with an interest in advance care planning, and agreed to develop advice setting out the guiding ethical principles for the implementation of advance care planning across the health sector.

NEAC also began consulting with relevant organisations to discuss the interpretation of the ethical principle of 'do no harm' and how to ensure that the application of the right to strike is consistent with this principle.

On behalf of NEAC, I am pleased to present this annual report for 2011.

A handwritten signature in blue ink that reads "Victoria Hinson".

Victoria Hinson  
**Chair**  
**National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**

# Contents

Foreword	iii
Introduction to the National Ethics Advisory Committee	1
National Ethics Advisory Committee's work programme in 2011	2
Research ethics work in 2011	3
Services ethics work in 2011	5
National Ethics Advisory Committee members	6
National Ethics Advisory Committee secretariat	11
Contact details for the National Ethics Advisory Committee	12
Appendix A: Terms of Reference for the National Ethics Advisory Committee	13



# 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. Its 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 Act 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 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.

There were a number of changes to NEAC's membership in 2011. Robin Wray's term as chair and as a member of NEAC finished, and Victoria Hinson was appointed as chair in June. Three new member appointments were made: Dr Fa'afetai Sopoaga, Dr Adriana Gunder and Dr Diana Sarfati. Mr Andrew Hall, Dr Robert Logan and Dr Robin Olds (now deputy chair) were reappointed.

Geoff Fougere (deputy chair), Ann Richardson and Libby Smales finished their terms in September. Jo Manning finished her term in December.

# National Ethics Advisory Committee's work programme in 2011

## Overview

A consideration of ethics involves identifying what matters and how best to act accordingly. NEAC works to this definition of ethics, producing 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.

### Research ethics

In 2011, NEAC contributed to the Ministry of Health's review of standard operating procedures and the national application form for health and disability ethics committees (HDECs) in New Zealand. It also reviewed work to streamline its ethical standards applying to health and disability research, to ensure a good fit with the Ministry's updated operating procedures.

NEAC incorporated comments from a peer review process into its draft resource document *Māori Research Ethics: An overview*. It prepared a final draft of this document for consideration by the full Committee.

### Services ethics

NEAC explored a number of options about how best to encourage engagement and discussion between consumers, non-governmental organisations, health professionals and other community members with an interest in advance care planning. On balance, NEAC agreed to develop advice setting out guiding ethical principles for the implementation of advance care planning across the health sector.

NEAC commenced an initial consultation with regulatory authorities, membership organisations and unions to discuss the interpretation of the ethical principle of 'do no harm' and how to ensure that the application of the right to strike is consistent with this principle.



## Health and disability ethics committees

### Objectives

NEAC's objectives for work in this area were to support and develop the system of HDECs in New Zealand and provide direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector.

### Background

In February 2010, the Health Committee initiated an inquiry into improving New Zealand's environment to support innovation through clinical trials (the inquiry), and sought NEAC's views on these matters. NEAC provided advice and analysis to the Minister in September 2010; this covered three areas of the inquiry's terms of reference:

- streamlined ethics approvals systems
- benefit to New Zealand patients through clinical trials
- removal of unnecessary barriers to clinical trials conduct.

The Minister forwarded NEAC's advice to the Health Committee to inform its inquiry. NEAC's full analysis, which forms the basis of the Minister's advice, is available at [www.neac.health.govt.nz](http://www.neac.health.govt.nz).

In September 2011, the Government responded to the inquiry. In its response, the Government directed the Ministry of Health to develop new procedural guidance to replace the current, fragmented rules for HDECs with effect from 1 July 2012. This direction included developing standardised operating procedures for HDECs. At the same time, the Government directed NEAC to streamline the ethical standards that apply to health and disability research.

### Key progress in 2011

NEAC explored how it could further address issues arising from the impact on the research community of the changes to HDECs, including through contributing to advice on what constitutes adequate peer review of research and developing plans to further explore research ethics governance arrangements in New Zealand.

The Ministry of Health briefed NEAC on revisions to the standard operating procedures and national application form for HDECs. NEAC provided informal comments to the Ministry on this matter at its November 2011 meeting.

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

### **Objectives**

NEAC's objectives for work in this area were 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 and development.

### **Background**

NEAC's Māori health and disability research ethics project is a 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).

In 2009, NEAC supported a writing group (including members of Pūtaiora) to develop a framework for addressing Māori ethical issues within the context of decision-making by ethics committee members. This framework, *Te Ara Tika – Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members*, was published by the Health Research Council in 2010, and was appended to its *Guidelines for Researchers on Health Research Involving Māori*.

NEAC's output for this project is a resource document, *Māori Research Ethics: An overview*. It summarises and discusses current issues in Māori research ethics, and is intended to provide useful information and practical assistance for health and disability researchers, research institutions and others involved in health and disability research with Māori. It was prepared to accompany the publication *Te Ara Tika – Guidelines for Māori Research Ethics*. The draft resource document was peer-reviewed in 2010.

### **Key progress in 2011**

NEAC incorporated comments from the peer review process into the draft resource document and prepared a final draft of the document for consideration by the full Committee.

## Harm and industrial action

### Objective

NEAC's objectives for work in this area were to determine ethical standards across the health and disability sector on the application of the professional ethical principle of 'do no harm' to industrial action.

### Background

In November 2009, the Minister of Health agreed that NEAC should explore the application of the professional ethical principle of 'do no harm' to industrial action.

The 'Code of good faith for public health sector' (Schedule 1B of the Employment Relations Act 2000 – the most relevant legal provision applicable to this matter) requires district health boards (DHBs) to provide for patient safety during industrial action. This includes developing contingency plans to maintain life-preserving services (such as crisis interventions, care required for therapeutic services and urgent diagnostic procedures) to prevent serious threats to life or permanent disability.

NEAC's view is that the life-preserving services provisions in the Code of good faith do not exclude all potential harm to patients and health and disability service consumers that might be caused by the withdrawal or withholding of services during industrial action. For example, during industrial action there may be scenarios whereby:

- an urgent diagnostic procedure is withheld where the likelihood of a serious diagnosis is small but not negligible
- significant harms occur to patients because services are withdrawn or withheld for conditions that do not amount to a serious threat to life or permanent disability.

NEAC's established view is that it is appropriate to consider whether the interpretation and application of the current life-preserving services provisions ensure that any withholding or withdrawal of service through industrial action also adheres to the 'do no harm' principle.

### Key progress in 2011

The chair of NEAC and Public Health Medicine Registrar (Canterbury DHB) Dr Matthew Reid commenced an initial consultation with medical regulatory authorities, membership organisations, unions, and employers to discuss the interpretation of the ethical principle of 'do no harm' and how to ensure that the application of the right to strike is consistent with this principle. Meetings were held with the Medical Council of New Zealand, the New Zealand Medical Association and the Office of the Health and Disability Commissioner.

## Advance care planning

### Objective

NEAC's objectives for work in this area were to develop and promote ethical guidelines for the implementation of advance care planning in New Zealand.

### Background

In November 2009, the Minister of Health agreed to a NEAC project on advance care planning. The original agreed purpose of NEAC's work in this area was 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.

### Key progress in 2011

NEAC undertook a considerable amount of scoping work for this project in 2011 to consider how best to encourage engagement and discussion between consumers, non-governmental organisations, health professionals and other community members with an interest in the area. This included options for hosting a conference on advance care planning in New Zealand. Throughout this process NEAC developed constructive relationships with key stakeholder groups, including the National Advance Care Planning Cooperative.

After careful consideration about how NEAC could contribute to this area, within the parameters of NEAC's statutory function and role, the Committee agreed to develop advice setting out guiding ethical principles for advance care planning.

## National Ethics Advisory Committee members

### Victoria Hinson – chair

Victoria Hinson is a consultant with extensive experience of New Zealand legislative policy analysis and development. Since moving to New Zealand in 1992, she has worked with a variety of government departments and agencies across a range of areas, including accident compensation, disability, occupational health and safety, human rights and criminal law.

Victoria holds a Bachelor of Arts in international relations and Russian/Russian area studies from the American University in Washington, DC, as well as a Juris Doctor degree from Northwestern University's School of Law in Chicago. She is a licensed American attorney and a member of the Illinois Bar. Victoria has previously served on the Dental Council of New Zealand, including as deputy chair, and currently acts as a professional conduct committee layperson member for the New Zealand Psychologists Board.

Victoria was appointed chair on 2 June 2011.

### Robin Olds – deputy chair

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.

Robin was reappointed as a member, and appointed as deputy chair, in October 2011.

### **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 that focused on gambling as an emerging health issue for Māori.

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

### **Adriana Gunder**

Adriana Gunder has a Doctoral Degree in biological sciences and a Post-Doctoral Degree in biophysics. She was involved in biological and medical research for many years, mainly in Italy and the United Kingdom.

Adriana had polio when she was an infant; as a consequence, she feels strongly about disability and accessibility issues, and is involved with disability organisations. She is also involved with community and charities organisations (the Red Cross, the Cancer Society, Rotary and the Mission Bay-Kohimarama Residents Association). Adriana is a Justice of the Peace. She is also currently a member of the Health Practitioners Disciplinary Tribunal and the Ethics Committee on Assisted Reproductive Technology.

Adriana's term began in October 2011.

### **Andrew Hall**

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

Andrew is software manager for Dynamic Controls, the world's largest supplier of wheelchair and scooter control systems. Previously he was chief executive of the New Zealand Spinal Trust, a consumer support and service-providing organisation. He is also a trustee of the Ben Lei'a Trust and the Sporting Futures Charitable Trust.

Andrew was reappointed in October 2011.

### **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.

Robert was reappointed in October 2011.

### **John McCall**

John McCall is the McKenzie professor of clinical science at the Dunedin School of Medicine, University of Otago. He is also a practising general surgeon at the Southern District Health Board. He previously worked in the New Zealand Liver Transplant Unit.

John has been involved in a range of laboratory and clinical research activities, including gastrointestinal cancer, transplant immunology and liver disease. He is a member of the Health Research Council of New Zealand's Data Monitoring Core Committee.

### **Diana Sarfati**

Diana is currently director of the Cancer Control and Screening Research Group at the University of Otago's Wellington School of Medicine. Prior to this she was a senior research fellow at the Department of Public Health, Wellington School of Medicine. Diana is currently a member of the New Zealand Cancer Registry Clinical Advisory Group, the Health Research Council's Public Health Assessing Committee and the National Bowel Cancer Working Group, to name a few such positions. She is also a former member of the Bowel Cancer Screening Taskforce. Diana is a fellow of the New Zealand College of Public Health Medicine, and completed a Master of Public Health (1998) and a Bachelor of Medicine and Surgery (1991) at the University of Otago.

Diana's term began in October 2011.

### **Fa'afetai Sopoaga**

Fa'afetai (Tai) Sopoaga is associate dean (Pacific) in the Division of Health Sciences at the University of Otago. She is a public health specialist and a trained general practitioner. Tai is a member of the Pacific Research Foundation Board and the Dunedin Youth Wellness Trust Board, and a Medical Advisor to Pacific Trust Otago. She completed a Bachelor of Medicine and Bachelor of Surgery at the University of Otago (1992), and is a fellow of the New Zealand College of Public Health Medicine and the Royal New Zealand College of General Practitioners.

Tai is Samoan, and has wide connections and involvement with the Pacific community in New Zealand and the region.

Tai's term began in October 2011.

### **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 health promotions team leader and the community action youth and drugs service coordinator; a position dedicated to finding alternative and positive solutions for young people in Murupara and the surrounding districts.

Jacob is currently chair of the Murupara Community Board, and was the youngest elected representative during his nine-year term (2001–2010) in office at the Whakatane District Council. Jacob is a former member of the Health Practitioners Disciplinary Tribunal. He holds a number of positions in Murupara, including chairing a local charitable trust, and he is also a Justice of the Peace. Jacob is married to Melanie and they have three young children.

## **Martin Wilkinson**

Martin Wilkinson is an associate professor in political studies at the University of Auckland. He works mainly in applied ethics, with special research interests in transplantation and public health. His book *Ethics and the Acquisition of Organs* was published in November 2011 in the Oxford University Press series 'Issues in Biomedical Ethics'. He was chair of the Bioethics Council from 2006–2009.

## **Outgoing members in 2011**

### **Robin Wray – chair**

Robin Wray has worked in his 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 for 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.

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

Robin's term as chair finished in January 2011.

### **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.

Geoff's term as a member and as deputy chair finished in September 2011.

### **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.

Joanna's term ended in December 2011.

### **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.

Ann's term ended in September 2011.

### **Elizabeth Smales**

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

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

Libby has been medical director of Cranford Hospice in 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.

Libby's term ended in September 2011.



## **National Ethics Advisory Committee secretariat**

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

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

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

The NEAC secretariat in 2011 comprised:

- Barbara Burt, senior analyst (until September 2011)
- Vanessa Roberts, analyst (until May 2011)
- Olivia Stapleton, senior analyst (from December 2011)
- Helen Martin, group administrator (from November 2011)

Helen Colebrook, senior analyst at the Ministry of Health, provided secretariat support from July 2011.

## Contact details for the National Ethics Advisory Committee

Contact details for NEAC:

Phone	64 4 496 2000
Email	<a href="mailto:neac@moh.govt.nz">neac@moh.govt.nz</a>
Postal address	PO Box 5013, Wellington 6145
Website	<a href="http://www.neac.health.govt.nz">www.neac.health.govt.nz</a>

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

### The role of the committee

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

The National Ethics Advisory Committee's statutory functions are to:

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

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

- consult with any members of the public, persons involved in the funding or provision of services and other persons that the committee considers appropriate before providing advice on an issue (section 16(4) refers)
- at least annually, deliver to the Minister of Health a report setting out its activities and summarising its advice on the matters referred to it under section 16 of the Act by the Minister of Health
- provide timely and sound advice to the Minister of Health on the membership and operation of its Sub-Committee on Appeals, including advice on those member categories that cannot be filled from the National Ethics Advisory Committee's membership, and will therefore require a wider nominations process. The National Ethics Advisory Committee may make nominations as part of this wider process.

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

- provide advice on priority issues of national significance as requested by the Minister of Health
- provide advice to the Minister of Health regarding ethical issues concerning emerging areas of health research and innovative practice. The advice is to include the National Ethics Advisory Committee's rationale for its advice and any relevant evidence and/or documentation
- provide advice to the Minister of Health regarding aspects of ethical review in New Zealand, including the setting of principles and guidelines in relation to each of the different types of health research and innovative practice. The advice is to include the National Ethics Advisory Committee's rationale for its advice and any relevant evidence and/or documentation
- develop and promote national ethical guidelines for health research and health and disability support services (the guidelines should address how to conduct different types of health research (including ethical issues relating to Māori health research) and innovative practice in an ethical manner and should establish parameters for, and provide guidance on, the ethical review of such types of health research and health and disability support services)
- monitor and review the operation of the health and disability ethics committees for the purposes of providing direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector
- undertake its tasks in a manner consistent with the principles of the Treaty of Waitangi
- develop guidelines on conducting observational studies in an ethical manner and establish parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of research).

## Composition of the committee

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

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

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

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

## Terms and conditions of appointment

Members of the National Ethics Advisory Committee are appointed by the Minister of Health for a term of office of up to three years. The terms of office of members of the National Ethics Advisory Committee will be staggered to ensure continuity of membership. No member may hold office for more than six consecutive years unless an additional period of up to 12 months is confirmed to allow for continuity of projects. Unless a person sooner vacates their office, every appointed member of the National Ethics Advisory Committee shall continue in office until their successor comes into office. Any member of the National Ethics Advisory Committee may at any time resign as a member by advising the Minister of Health in writing.

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

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

## Chairperson

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

## Duties and responsibilities of a member

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of the National Ethics Advisory Committee. This is intended to aid

members of the National Ethics Advisory Committee by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the National Ethics Advisory Committee and its members.

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

## **General**

1. National Ethics Advisory Committee members should have a commitment to work for the greater good of the committee.
2. There is an expectation that members will make every effort to attend all the National Ethics Advisory Committee meetings and devote sufficient time to become familiar with the affairs of the committee and the wider environment within which it operates.
3. Members have a duty to act responsibly with regard to the effective and efficient administration of the National Ethics Advisory Committee and the use of committee funds.
4. Members of the National Ethics Advisory Committee are not obliged to accept nomination to the Sub-Committee on Appeals.

## **Conflicts of interest**

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

## **Confidentiality**

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

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

## Working arrangements

The National Ethics Advisory Committee will agree a work programme with the Minister of Health. The National Ethics Advisory Committee will be serviced by permanent staff, sufficient to meet the Committee's statutory requirements, who 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 wellbeing 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 wellbeing of society
- iii. collaborate with researchers to ensure the interests, rights, dignity, welfare, health and well-being of participants and consumers are protected
- iv. give due consideration to community views
- v. consistent with section 4 of the New Zealand Public Health and Disability Act 2000 and He Korowai Oranga, recognise and respect the principles of the Treaty of Waitangi
- vi. operate in accordance with the *Operational Standard for Health and Disability Ethics Committees*
- vii. operate in accordance with any guidelines issued or approved by the Director-General of Health.

## **Composition and membership**

### **Guiding principle**

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

### **Minister to appoint members**

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

### **Member numbers**

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

## **Lay/non-lay membership**

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

- currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist or pharmacist)
- involved in conducting health or disability research or who is employed by a health research agency and who is in a sector of that agency which undertakes health research; or
- construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

At any time, the SCA shall have one member who is a lawyer and one member with expertise in ethics (for example, a teacher of ethics, philosopher, theologian, or community-recognised person such as a Māori elder). In addition, it is important that the SCA's composition also includes individuals possessing a knowledge and understanding of consumer and community issues and perspectives.

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

## **NEAC/non-NEAC membership**

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

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

## **Whole committee requirements**

At any time, consistent with the requirements of the New Zealand Public Health and Disability Act's requirements for District Health Boards and with the requirements of the Operational Standard, the SCA shall have at least two Māori members, who should have an awareness of te reo Māori and an understanding of tikanga Māori. All members of the SCA are expected to have knowledge of the principles of partnership, participation and protection and their application to ethical review.

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

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

## **Terms and conditions of appointment**

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

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

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

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

## **Chairperson**

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

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

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

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

### **General**

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

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

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

### **Conflicts of interest**

SCA members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the SCA and its members and will ensure it retains public confidence.

SCA members attend meetings and undertake SCA activities as independent persons responsible to the SCA as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. The SCA should not, therefore, assume that a particular group's interests have been taken into account because a SCA member is associated with this group.

When SCA members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or from undertaking an activity consistent with the SCA's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the SCA who has any involvement in any proposal under appeal shall not take part in the SCA's assessment of that proposal. The member may be present to answer questions about a proposal but should take no part in the discussion surrounding the consideration of the proposal or any decision relating to the proposal. This will allow proposals to be considered in a free and frank manner. The SCA must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

## **Confidentiality and information sharing**

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

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

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

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

## **Committee meetings**

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

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

The minutes of all meetings shall be publicly available.

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

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

## **Quorum**

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

## **Decision-making process**

### **Decisions**

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

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

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

In relation to appeals involving issues for Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend an SCA meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

On occasion, individual members may wish to abstain from some or all of the decision-making process because of strong personal moral or religious reasons. Such abstentions shall not affect the appeal process.

### **Communication of decisions**

All decisions of the SCA will be communicated to:

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

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

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

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

### **Expert advice and consultation**

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

### **Training for members**

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

### **Records**

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

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

### **Fees and allowances**

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

## **Servicing and administration of the SCA**

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

The contact address for the SCA will be:

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

Email: [appeals\\_neac@moh.govt.nz](mailto:appeals_neac@moh.govt.nz)