

**National Ethics Advisory Committee**  
**Kāhui Matatika o te Motu**  
**Annual Report 2012**

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

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## Foreword

**E nga lwi, e nga mana, e nga reo. E nga karangatanga maha, tenei te mihi. Tenei te mihi i runga i ā tātou mate kua wheturangitia. Rātou kua piki ake ki Paerau ki te huihuinga o te Kahurangi, moe mai rā. Hoki mai ki ā tātou te hunga ora e pīkau nei nga mahi mo ā tātou whānau. Tēnā tātou katoa.**

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.

Much of NEAC's work over the past year has focussed on re-establishing itself as a working committee and advancing outstanding projects, following a temporary lull in activity due to circumstances outside the Committee's control. NEAC saw the appointment of five new members, and recruitment

of new secretariat staff. A new NEAC website was developed and published. NEAC held discussions about its governance policy – the duties and responsibilities of members and the Committee. Members and secretariat staff attended a number of meetings in 2012 to promote NEAC and its work. NEAC also continued its work on projects in the areas of advance care planning, Māori research ethics and harm in industrial action.

The remainder of NEAC's work this year has been as a result of the Health Select Committee inquiry into New Zealand's clinical trials environment and the Government's response to that inquiry. NEAC published revised *Ethical Guidelines for Intervention Studies* and *Ethical Guidelines for Observational Studies*, to align with the Ministry of Health's new procedural rules for Health and Disability Ethics Committees (HDECs). NEAC also began working with the Ministry of Health on a project for monitoring the changes to HDECs. And NEAC began a high-level environmental scan of 'cross-sectoral' arrangements for the ethical review of health and disability research and related activity.

With much of its outstanding work nearing completion, toward the end of the year NEAC held discussions on work programme development. NEAC considered possible projects for both the short term and in the longer term.

On behalf of NEAC, I am pleased to present this annual report for 2012.



Victoria Hinson  
**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 (the Minister). Its statutory functions, under section 16 of the New Zealand Public Health and Disability Act 2000 (the Act), 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 Act 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.

Five new members were appointed in 2012; Ms Nola Dangen, Dr Julian Crane, Dr Maureen Holdaway, Dr Fiona Imlach Gunasekara and Dr Wayne Miles. Dr John McCall finished his term in May. Dr Lorna Dyall and Dr Diana Sarfati finished their terms in June. Dr Fa'afetai Sopoaga finished her term in August.



# National Ethics Advisory Committee's work programme in 2012

## 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 July 2012, NEAC published revised *Ethical Guidelines for Observational Studies* and revised *Ethical Guidelines for Intervention Studies*. The guidelines were amended by NEAC to align with the Ministry of Health's new procedural rules for Health and Disability Ethics Committees (HDECs). These guidelines set out the established standards that all researchers must meet when undertaking health and disability research. NEAC also began working with the Ministry (the Ministry) on a project for monitoring the changes to HDECs.

NEAC consulted the Minister on its resource document *Māori Research Ethics: An overview*. NEAC began a high-level environmental scan of 'cross-sectoral' arrangements for the ethical review of health and disability research and related activity.

## **Services ethics**

NEAC prepared draft consultation advice on the ethical challenges that health professionals face in advance care planning. NEAC also undertook preliminary consultation with a range of health professionals to help inform the development of its draft advice.

NEAC continued discussions 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. NEAC launched limited consultation on its draft paper exploring how the principle of 'do no harm' applies to industrial action.

# Research ethics work in 2012

## Revising NEAC research guidelines

### Objectives

NEAC's objectives for work in this area were to amend the *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies* to align them with the revised Standard Operating Procedures (SOPs) for HDECs, as directed by the Government in its response to the Health Select Committee Inquiry into New Zealand's clinical trials environment. The review did not fundamentally change the existing NEAC ethical standards set out in the guidelines.

### Background

A key finding from the Select Committee's Inquiry on Clinical Trials was the need for a clearer division of responsibilities for various aspects of the ethical review process. The Ministry is responsible for process related guidance. The Government requested NEAC streamline ethical standards that apply to HDECs.

### Key progress in 2012

NEAC revised the *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies*. These were subject to a brief targeted consultation including individual researchers and members of the public. NEAC revised both sets of guidelines to remove process guidance, and ensure that policy previously included in the Operational

Standard for Ethics Committees is now included in the guidelines. The revised guidelines were published in July 2012. The 2012 revision aimed to provide consistency with the SOPs. The guidelines were updated to remove process guidance, and ensure that policy previously included in the Operational Standard for Ethics Committees is now addressed by these guidelines. A more comprehensive review of the guidelines is planned for 2015.

The promotion of the revised guidelines was used to further clarify NEAC's role and achievements, and to engage with stakeholders about NEAC's future work programme.

## **Cross-sectoral review of research ethics arrangements**

### **Objectives**

NEAC's objective for work in this area was to undertake a high-level environmental scan of 'cross-sectoral' arrangements for the ethical review of health and disability research and related activity. The environmental scan will be developed through a comprehensive review of current research ethics guidance documents and literature, and consulting with the research community and members of the public. The environmental scan will help identify gaps and inconsistencies with the current arrangements that might be addressed. This will ultimately culminate in recommendations to the Minister. The review will also help to inform the scope and focus of NEAC's 2015 review of *Ethical Guidelines for Intervention Studies* and the *Ethical Guidelines for Observational Studies*.

## **Background**

NEAC did a review of New Zealand's processes for ethical review for health and disability in 2003. After this review NEAC reported to the Minister recommending that NEAC scope the task of developing a governance framework for health and disability research ethics in New Zealand. In its advice to the Minister in 2010 in relation to the Health Committee's Inquiry into New Zealand's clinical trials environment, NEAC recommended a review of the 'cross-sectoral' ethics committee arrangements.

## **Key progress in 2012**

NEAC researched cross-sectoral arrangements in New Zealand, Australia and the United Kingdom. The Secretariat completed a first draft of an environmental scan of cross-sectoral ethics arrangements for health and disability research and related activity in New Zealand.

## **Monitoring of Health and Disability Ethics Committees (HDECs)**

### **Objectives**

NEAC's objectives for work in this area were to assist the Ministry's aim to measure the quality of HDEC review based on the four core outcome measures of robustness, efficiency, transparency and consistency, as well as obtain data to inform a planned 2015 review of NEAC's ethical guidelines for research.

## **Background**

A number of changes have been made to the HDEC review process since 1 July 2012. These include introducing new SOPs and an online application system, replacement of the seven previous HDECs with four new HDECs and the reduction in committee membership from 12 to eight.

## **Key progress in 2012**

NEAC agreed with the Ministry to work in an advisory capacity in its monitoring programme. NEAC provided initial feedback to the Ministry about what might constitute an effective monitoring programme and will maintain a watching brief as the programme is implemented.

## **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**

In 2009, NEAC supported a writing group 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.

### **Key progress in 2012**

NEAC had a second peer review of the document completed, following a number of revisions to ensure the document was up-to-date. NEAC also consulted the Minister on its resource document *Māori Research Ethics: An overview*.

# Services ethics work in 2012

## Harm and industrial action

### Objective

NEAC's objective for work in this area was 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

The harm and industrial action project aims to promote discussion and encourage dialogue between key stakeholders about how the ethical principle of 'do no harm' might apply 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 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 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 2012**

The NEAC 'do no harm' subcommittee continued 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.

NEAC published a paper summarising its position on how the ethical principle of 'do no harm' applies during industrial action. Limited consultation on the paper with representatives of health and disability workers and employers was launched in late November 2012 for a period of 11 weeks.

## **Advance care planning**

### **Objective**

NEAC's objective for work in this area was to develop draft advice on the ethical challenges that health professionals face in Advance Care Planning (ACP).

### **Background**

In November 2011, NEAC agreed it was timely to contribute to growing interest and momentum in the area of ACP. ACP is a voluntary process of discussion and shared planning for future health care between a person and health professionals. At present, ACP is primarily offered in the context of oncology services, aged care and services for people with long term health conditions.

### **Key progress in 2012**

The NEAC Advance Care Planning subcommittee held preliminary consultation meetings with a range of health care professionals. The subcommittee developed draft advice primarily aimed at health professionals that aimed to provide solutions to ethical challenges that they face in ACP work. The health care professionals that took part in the preliminary consultation provided comment on the draft advice.

NEAC developed draft advice after meeting with a range of health professionals in 2012 to discuss the ethical challenges in ACP. Case studies are used to highlight common ethical challenges that arise. The draft advice does not consider euthanasia or assisted dying, or resource allocation.

## Other work in 2012

### Work programme development

#### Objectives

NEAC's objectives for work in this area were to revisit its process for work programme development and to scope the 2013/14 and longer-term programme development, including existing projects and possible new projects that have been already identified by NEAC.

#### Background

Traditionally NEAC has chosen projects based on proposals by individual members and in conjunction with consultation with the Minister. There is no formal process set out in the Terms of Reference or previously established by the Committee that provides guidance to members about developing NEAC's work programme.

#### Key progress in 2012

NEAC discussed work programme development at its December meeting. Members identified four issues for NEAC to research and scope in 2013:

- ethical aspects of an alternative recruitment strategy for cancer trials in New Zealand
- ethical issues facing disability support services and its consumers

- ethical issues in organ allocation
- ethical issues in dementia care.

## **Promotion work**

### **Objective**

NEAC's objectives for work in this area were to promote the role of NEAC and its work programme, particularly the revised *Ethical Guidelines for Intervention Studies* and *Ethical Guidelines for Observational Studies*.

### **Background**

NEAC agreed it was important to promote and clarify NEAC's role, function and responsibilities. It agreed that the promotion of the revised guidelines would further clarify NEAC's role and achievements and provide an opportunity to engage with stakeholders about NEAC's future work programme.

### **Key progress in 2012**

NEAC members and secretariat staff attended a number of events to promote the role of NEAC and its work to key target audiences. This included meeting with Institutional Ethics Committees, HDECs and the Medical Council of New Zealand.

## **New website**

### **Objective**

NEAC's objective for work in this area was to update its website to comply with the Ministry's new committee website template.

### **Key progress in 2012**

The NEAC website was reviewed, updated and then published in December 2012.

## **Discussions about committee governance**

### **Objective**

NEAC's objective for work in this area was to review the duties and responsibilities of members and the Committee.

### **Background**

At NEAC's February 2012 meeting, members had a discussion on reaching a shared understanding about how members should work. This included members' confidentiality obligations, declaring and managing conflict of interests, and responding to the media.

### **Key progress in 2012**

NEAC had a series of discussions on governance policy in 2012. NEAC produced governance policy text to be incorporated into NEAC's Terms of Reference when it is next reviewed and updated.

## 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 Chair of a Complaints Assessment Committee for the Veterinary Council of New Zealand and as a professional conduct committee layperson member for the New Zealand Psychologists Board.

### **Robin Olds – deputy chair, Health Research Council nominee**

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 in October 2012.

### **Martin Wilkinson – deputy chair (from November 2012), ethicist**

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.

Martin was appointed deputy chair in November 2012.

## **Julian Crane – health researcher**

Julian Crane is a general physician by training and director of the Wellington Asthma Research Group and a co-director of the Health Research Council's Housing and Health Research Programme at the University of Otago Wellington.

Julian's main research interests are asthma and allergic disease, the effects of housing on respiratory health and more recently studies of smoking cessation. Julian has also been involved in the International Study of Asthma and Allergy in Childhood (ISAAC) research collaboration.

Julian was appointed in July 2012.

## **Nola Dangen – lawyer**

Nola Dangen is a lawyer having graduated with a LLB from University of Auckland.

Nola spent many years in private practice, as a partner in a medium/large law firm, a smaller law firm, and then in sole practice until 2005 when she sold her practice and since 2006 has practised as a locum lawyer/consultant lawyer assisting lawyers in times of need.

Nola's fields of practice are in contract law, commercial law, property law, building and construction law, wills, trusts and estate law – in fact almost any law except litigation.

Nola spent many years assisting in the governance of law within both the New Zealand Law Society and the Auckland District Law Society, and is presently vice president of the Independent Law Society based in Auckland.

Nola was appointed in June 2012.



### **Adriana Gunder (QSM) – general layperson**

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/accessability issues and is involved with disability organisations. She is a Board Member of New Zealand Red Cross, President of the Mission Bay-Kohimarama Resident's Association. She is also involved with other charities like the Cancer Society and SPCA just to mention a few. Adriana is a Justice of the Peace.

Adriana has been appointed to the Health Professional Disciplinary Tribunal (2010–present).

Adriana was reappointed in October 2012.

### **Andrew Hall – community/consumer**

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 2012.

## **Maureen Holdaway – health researcher**

Maureen is the deputy director for the Research Centre for Māori Health and Development, Massey University and a registered nurse with extensive experience in primary health care.

Maureen has worked in the health and education sectors for many years. Her key areas of research expertise are in Māori and indigenous health development, primary health care, and health workforce development.

Maureen has collaborated on national and international studies focusing on indigenous health and development and is a named investigator on two core programme grants for the Centre, and a named investigator on a number of individual Health Research Council grants, and significant collaborations within Massey University and with other universities and health service providers both nationally and internationally.

Maureen was appointed in June 2012.

## **Fiona Imlach Gunasekara – epidemiologist**

Fiona is currently a senior research fellow at the Wellington Department of Public Health, University of Otago. She completed a PhD in epidemiology in 2007. Her research interests include socioeconomic and health inequalities, poverty, alcohol and methods for longitudinal data analysis. She has previously worked in the health informatics sector, and in a number of health-related agencies.

Fiona is a fellow of the New Zealand College of Public Health Medicine and completed a Bachelor of Medicine and Surgery and a Masters of Public Health at the University of Auckland.

Fiona was appointed in October 2012.

## **Robert Logan – health professional**

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 recently retired as Chief Medical Officer at Hutt District Health Board and as a Crown monitor at Whanganui 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 2012.

## **Wayne Miles – health professional**

Wayne is director of Awhina Research and Knowledge, Waitemata District Health Board and a clinical associate professor at the Department of Psychological Medicine, University of Auckland. He has had extensive experience as a psychiatrist, as a clinical leader and as a clinical researcher.

Wayne has been a Health and Disability Ethics Committee member for seven years and is a member of the Health Research Council College of Experts. He chairs the Royal Australian and New Zealand College of Psychiatrist Community Liaison Committee and is a New Zealand Medical Association Board member. Past roles have included president of the Royal Australian and New Zealand College of Psychiatrists and chair of the Council of Medical Colleges in New Zealand.

Wayne was appointed in December 2012.

## **Jacob Te Kurapa – community/consumer**

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 is currently the project coordinator assisting the Education and Te Reo Strategy for Murupara and the people of Ngati Manawa.

Jacob worked in health as the 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 the chairperson of the Murupara Community Board and was the youngest elected representative during his nine-year term (2001–2010) in Office to the Whakatane District Council.

Jacob is a current member of the Medical Council of New Zealand, and a former member of the Health Practitioners Disciplinary Tribunal. He holds a number of positions in Murupara including the chair of a local charitable trust, the chair of the newly established Murupara Area School and he is also a Justice of the Peace.

Jacob is married to Melanie and they have three young children.

## **Outgoing members in 2012**

### **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.

### **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.

## **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.

# **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 2012 comprised:

- Olivia Stapleton, senior analyst
- Helen Martin, group administrator
- Stella Li, analyst (from July 2012)
- Chris Wilson, analyst (from May 2012)

Helen Colebrook, senior advisor at the Ministry of Health, also provided secretariat support.

## 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 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.

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. The National Ethics Advisory Committee members should have a commitment to work for the greater good of the committee.
2. There is an expectation that members will make every effort to attend all the National Ethics Advisory Committee meetings and devote sufficient time to

become familiar with the affairs of the committee and the wider environment within which it operates.

3. Members have a duty to act responsibly with regard to the effective and efficient administration of the National Ethics Advisory Committee and the use of committee funds.

## **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.

## 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 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 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 and guidelines 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 and guidelines 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 of and experience.

Every question before any meeting shall generally be determined by consensus decision-making. Where a consensus cannot be reached a majority vote will apply. Where a decision cannot be reached through consensus and a majority vote is made, the Chairperson shall have the casting vote.

Subject to the provisions set out above, the National Ethics Advisory Committee may regulate its own procedures.

## **Reporting requirements**

The National Ethics Advisory Committee is required to:

- keep minutes of all committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made

- prepare an annual report to the Minister of Health setting out its activities and comparing its performance to its agreed work programme and summarising any advice that it has given to the Minister of Health. 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 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.