

National Ethics Advisory Committee
Kāhui Matatika o te Motu
Annual Report 2016

Fifteenth Annual Report to the Minister of Health

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Foreword

**E ngā iwi, e ngā mana, e ngā reo. E ngā karangatanga maha, tēnei te mihi.
Tēnei te mihi i runga i ā tātou mate kua whetūrangitia. 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 ngā 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's view of ethics involves identifying what matters, explaining how the sector can act, and encouraging ethical decision-making.

A main focus for NEAC this year has been the review of our ethical guidelines for researchers. We have continued work on drafting chapters with a particular emphasis on strengthening Māori research ethics and clearly differentiating ethical standards from descriptive or contextual information.

In May NEAC provided advice to the Associate Minister of Health on what people with dementia and their families need, what the wider community can do, and how the health and social support workforce needs to behave. We received a positive response from the Minister who agreed that work was needed across the range of areas covered by NEAC's recommendations.

We would like to thank the many organisations and individuals who contributed to our work this year. Your input helps us to ensure that our work is useful and addresses the issues that you consider important.

This year we farewelled two members who have made a significant contribution to project leadership and NEAC governance over many years: Victoria Hinson and Martin Wilkinson. We welcomed one new member, Monique Jonas.

We have continued to be exceptionally well supported by the secretariat over a period of change in 2016 with two staff leaving and one joining the secretariat.

On behalf of NEAC, I am pleased to present this annual report for 2016.

Neil Pickering
Acting 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 2016	2
Research ethics work in 2016	3
Services ethics work in 2016	7
Other work in 2016	8
National Ethics Advisory Committee members	9
National Ethics Advisory Committee secretariat	13
Contact details for the National Ethics Advisory Committee	14
Appendix: Terms of reference for the National Ethics Advisory Committee	15

Introduction to the National Ethics Advisory Committee

Functions of the National Ethics Advisory Committee

The National Advisory Committee on Health and Disability Support Services Ethics – 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 on ethical issues of national significance in respect of health and disability matters (including research and health services)
- 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

The Minister appoints the members of NEAC, who come from a range of professions and backgrounds and bring expertise in ethics, clinical leadership, health service provision, health and disability research, epidemiology, law, Māori health and consumer advocacy.

Adriana Gunder, Fiona Imlach and Wayne Miles were reappointed in March. Neil Pickering was reappointed in July and became Deputy Chair in September 2016.

Monique Jonas, Ethicist was appointed in June 2016.

Martin Wilkinson finished his term in June and Victoria Hinson finished her term in October. Neil Pickering has been Acting Chairperson since Victoria's departure.

All Committee members are listed on pages 9 to 12.

National Ethics Advisory Committee's work programme in 2016

Overview

NEAC's view of ethics involves identifying what matters, how best to act on it, and encouraging ethical decision-making. NEAC works to this definition of ethics, producing work that is both principled and practical and not identifiable with any particular sector interest or group. NEAC agrees its work programme with the Minister.

Research ethics

This year NEAC has focused on reviewing the *Ethical Guidelines for Intervention Studies* (revised edition, NEAC 2012) and the *Ethical Guidelines for Observational Studies* (revised edition, NEAC 2012). This work includes integrating Māori ethical values and their application into the new guidelines. The guidelines review project will continue into 2017.

NEAC developed a draft diagram to help researchers navigate the ethics landscape and a research continuum of activity from research to clinical practice as part of the cross-sectoral ethics arrangements work.

NEAC continues to receive regular updates on operational matters and emerging issues for the Health and Disability Ethics Committees (HDECs) and assisted with member training in March.

Services ethics

In May, NEAC provided advice to the Minister: *NEAC's Advice on Dementia to the Associate Minister of Health*. This advice recognised that while much is already being done, New Zealand can do better to ensure people with dementia are valued and supported to maintain their independence, and recognise and support families so they can provide the best support and care available.

Research ethics work in 2016

Review of ethical guidelines for researchers

Objective

NEAC is undertaking a comprehensive review of its *Ethical Guidelines for Intervention Studies* and *Ethical Guidelines for Observational Studies*. As agreed with the Ministry of Health, the review will also incorporate and update the Ministry's 2007 *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*.

The main objectives of the review are to ensure the guidelines are fit for purpose and consistent with other relevant guidance. The guidelines will also be updated to address ethical issues associated with developments in research methods and emerging topics.

Background

NEAC's ethical guidelines for intervention and observational studies set out the ethical requirements that must be met when undertaking health and disability research, whether or not that research requires review by an ethics committee. The guidelines are primarily aimed at researchers but they are also used by ethics committees, research sponsors and for training and educating researchers.

The observational guidelines were first published in 2006 and the intervention guidelines in 2009. Both documents were amended in July 2012 to align with the Ministry of Health's new procedural rules for HDECs. However, no fundamental changes were made at that time and NEAC publicly committed to a full review in 2015.

In 2015, NEAC developed a high-level structure and initial draft of the new guidelines. The main structural changes are combining the observational and intervention guidelines into a single document and making a clear distinction between ethical standards and guidance. The new guidelines will have a greater focus on Māori research ethics and improving Māori health and wellbeing (see next section).

NEAC convened a four-member peer review panel to provide robust critique of the new guidelines as they are developed.

Progress in 2016

In 2016, NEAC continued work preparing a draft ready for consultation. Early in the year, NEAC members provided detailed feedback on chapters covering ethical principles, research development and design, research conduct and communicating research results.

Draft chapters were also developed on intervention research, use of health information, and biobanking and human tissue.

NEAC members met with stakeholders to discuss specific parts of the new guidelines. In April, members met with biobanking experts and these discussions informed draft guidance on human tissue and biobanking. Members also attended the HDEC Chairs meeting in May to discuss chapters on ethical principles, research development and design, research conduct and communicating research results.

A summary of the guidelines review project was included in the conference packs for the New Zealand Association of Clinical Research 12th Conference in August. Wayne Miles, NEAC member attended and had informal discussions with participants about NEAC's new guidelines.

Later in the year, NEAC agreed a structure for content in the new guidelines to clearly differentiate descriptive or contextual information from the standards, the mandatory/minimum standards from best practice, and case studies or other examples showing how the standards may be applied. Members reviewed a re-draft of the chapter on research development and design at their last meeting in December.

At this meeting, members also agreed an approach for addressing vulnerability; sources of vulnerability will be discussed rather than vulnerable groups. This will help to ensure researchers consider what might make a person vulnerable in relation to their research project. It may also mean that groups of people are not unnecessarily excluded from research because of their perceived vulnerability.

Māori research ethics in NEAC's new guidelines

Objective

NEAC's objective for this part of the guidelines review is to strengthen the focus on Māori research ethics and improving Māori health and wellbeing.

Background

In 2009, NEAC supported work to develop *Te Ara Tika – Guidelines for Māori Research Ethics: A framework for researchers and ethics committee members*, published by the Health Research Council of New Zealand in 2010.

To assist in developing the framework, NEAC prepared a resource document, *Āhuatanga ū ki te tika me te pono mō te Rangahau Māori – Māori Research Ethics: An Overview* (November 2012), that summarises and discusses issues in Māori research ethics.

NEAC's discussion document on cross-sectoral ethics arrangements included a section on Māori and health research. Consultation in 2015 found there was strong support for integrating Māori ethical ideas and frameworks into the core principles of general research guidelines. NEAC is considering how best to do this for its new research guidelines as part of the guidelines review.

Progress in 2016

In April, NEAC agreed a proposed approach for incorporating Māori values and their application in the new guidelines. A section will describe what the Treaty of Waitangi means for research and reinforce the view that all research will impact on Māori. Māori ethical values (tika, manaakitanga, whakapapa and mana) will sit alongside values from the Western bioethical framework (beneficence, non-maleficence, autonomy and justice). Links to additional resources and examples of Māori values in practice will be provided.

At Ngā Pae o te Māramatanga in November, NEAC member Kahu McClintock talked about Māori values for the guidelines, how to increase their visibility throughout the guidelines, and minimum standards to ensure research contributes to improving Māori health and

wellbeing. The presentation is the start of a process of engagement with Māori researchers with focused workshops planned for 2017.

Cross-sectoral ethics arrangements

Objective

NEAC's objective for this work was to identify the gaps, overlaps, inconsistencies and areas that lack clarity in the current arrangements for ethical review of health and disability research. This will ultimately result in advice to the Minister on current issues and how these may be addressed.

This work has been useful for informing NEAC's concurrent review of its ethical guidelines for intervention and observational studies.

Background

New Zealand has a complex health and disability research ethics environment, involving a range of organisations and stakeholders. There is significant potential for the many sources of ethics committee standards and accountabilities to produce overlaps, inconsistencies and related practical issues. The research community has also expressed concern about the absence of a comprehensive framework for all research bodies.

In 2015, NEAC completed its consultation process on the cross-sectoral ethics arrangements. Much of the feedback is directly informing content in NEAC's new ethical guidelines for research. NEAC's priority for further work on cross-sectoral ethics arrangements is increasing clarity in the current ethics landscape.

Progress in 2016

In 2016, NEAC developed a draft diagram to help researchers navigate the ethics landscape and a research continuum of activity from research to clinical practice.

In July, NEAC sought feedback from stakeholders on the diagram and research continuum. Feedback suggested that the draft diagram was too busy, and it was not possible to have an easy to read flow diagram because of the complexity of processes. A diagram showing relevant organisations in the research ethics landscape, their roles and responsibilities, and how they relate to each other could be useful.

In October, NEAC advised the Associate Minister of Health on the progress of this work and feedback received, and noted that the Committee had agreed the guidelines work was more important and priority would be given to that work until it was completed.

Monitoring Health and Disability Ethics Committees

Objective

NEAC's objective was to assist the Ministry to measure and monitor the extent to which changes to HDECs contribute to improving the system of ethical review for health and disability research.

Background

A number of changes have been made to the HDEC's review process since 1 July 2012. These include: introducing new standard operating procedures and an online application system, replacing the seven previous HDECs with four new HDECs and reducing committee membership from 12 to 8.

In order to help mitigate concerns about the potential impact of these changes, the Minister of Health asked the Ministry to work with NEAC on monitoring and reviewing the changes.

Progress in 2016

A member of the HDEC Secretariat attended most NEAC meetings to provide an update on operational matters and emerging issues.

NEAC members assisted with the training for new HDEC members in March.

Services ethics work in 2016

Dementia

Objective

NEAC's objective for work in this area was to produce practical guidance for families, whānau and friends on the ethical values for living well with dementia and provide advice to the Minister on what needs to change for people with dementia and their families.

Background

New Zealand has an ageing population and an increasing number of people with dementia. The majority of people with dementia live at home and, for most, care is provided by family and friends. Ethical values are important for providing good support and care, and ensuring people live well with dementia.

Between 2013 and 2015, NEAC met with a wide range of stakeholders, including people with early stage dementia, family carers, Alzheimers New Zealand, the National Dementia Cooperative, health professionals, lawyers and educators. These meetings explored the ethical issues associated with caring for people with dementia, and the difficulties and concerns experienced by family members providing support.

In late 2015, NEAC sought stakeholder feedback on draft guidance for families, whānau and friends on relevant ethical values and what they mean in practice. NEAC also developed draft advice to the Associate Minister of Health on what else needs to be done to support people with dementia and their families.

Progress in 2016

In early 2016, NEAC's draft advice on dementia was sent out to stakeholders for feedback. The advice was then finalised and sent to the Associate Minister of Health in May.

NEAC's advice recommended the development of a dementia action plan with specific actions and measures of performance across central and local government, businesses and communities. It recommended this plan include actions to ensure a supportive community environment, planning ahead, good support for families, whānau and friends, quality health and social support services, and a skilled health and social support workforce.

In June, Hon Peter Dunne, Associate Minister of Health directed the Ministry of Health to give detailed and careful consideration to all of NEAC's recommendations on dementia as part of the consultation process for the Health of Older People Strategy.

In November, Wayne Miles (NEAC member) gave a presentation at the Alzheimers New Zealand conference on ethical issues associated with the use of electronic tracking for people with dementia.

Other work in 2016

Progress in 2016

NEAC members and secretariat staff attended a range of events in 2016.

- Big Health Data for Epidemiology workshop, January
- Power Up Our Future Health Symposium, April
- The Conversation: Supported Decision Making hui, April
- Omics-Based Technologies: Social and Cultural Workshop, May
- Regional Focus Group on New Zealand Health Research Strategy, June
- New Zealand Association of Clinical Research conference, August

Guest speakers at NEAC meetings included Nic Aagaard (Ministry of Health) who talked about ethical challenges posed by learning health care systems, and James Caldwell and Sheila Swan (Ministry of Health) who talked about the new therapeutic products regime.

NEAC members met with Dame Diane Robertson and John Whitehead from the Data Futures Partnership Working Group in July.

NEAC made submissions on Increasing Rates of Deceased Organ Donation and the New Zealand Health Research Strategy.

A shared electronic document space for NEAC members was set up in July. This site is used by members to access meeting papers, articles, current iterations of the new research guidelines and conference presentations.

National Ethics Advisory Committee members

Neil Pickering – Deputy Chairperson, Health Research Council of New Zealand nominee

Neil is a senior lecturer in the Bioethics Centre at the University of Otago. He has published on a range of ethical issues and has been a member of a number of research projects both in New Zealand and in his previous job in the United Kingdom. His primary area of research is philosophy of mental health, and his book *The Metaphor of Mental Illness* was published by Oxford University Press in 2006 in their International Perspectives in Philosophy and Psychiatry series.

He was a member of the University of Otago Human Research Ethics Committee from 1999 to 2005. He was also on the Health Research Council of New Zealand Ethics Committee from 2005 to 2010 and was acting Chairperson from 2007 to 2008. He is currently a member of the editorial board of the *Journal of Bioethical Inquiry* and a member of the committee of the Australasian Association of Bioethics and Health Law.

Neil was appointed to NEAC in April 2013 and reappointed in July 2016. He was appointed Deputy Chairperson in September 2016 and has been Acting Chairperson since October 2016.

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 of New Zealand'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 Allergies in Childhood (ISAAC) research collaboration.

Julian was reappointed to NEAC in October 2015.

Adriana Gunder (QSM) – Community/consumer

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. Adriana has served on the Board of the New Zealand Red Cross (2012–2014), the New Zealand Health Practitioners Disciplinary Tribunal (2010–2015) and the Ethics Committee on Assisted Reproductive Technology (2010–2016).

Adriana is involved with community and charity organisations (Cancer Society, SPCA, CCS Disability Action and Friends of Madill's Farm) and is a Justice of the Peace. She is a current member of the Medical Sciences Council.

Adriana was awarded the Queen's Service Medal for service to the community in June 2012.

Adriana was reappointed to NEAC in March 2016.

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. She is a named investigator on two core programme grants for the centre, a number of individual Health Research Council of New Zealand grants and other research involving significant collaborations within Massey University and with other universities and health service providers, both nationally and internationally.

Maureen was reappointed to NEAC in October 2015.

Fiona Imlach – Epidemiologist

Fiona is currently a Team Lead Research at the Health Promotion Agency. She completed a PhD in epidemiology in 2007 at the University of Otago, Wellington. Her research interests include: socioeconomic and health inequalities, poverty, child health, alcohol and methods for longitudinal data analysis. She has previously worked as an academic, 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 reappointed to NEAC in March 2016.

Monique Jonas – Ethicist

Monique Jonas is a senior lecturer in ethics at the School of Population Health at the University of Auckland. She has a PhD in Medical Ethics from Kings College, London. Her research focuses upon the ethics of advice-giving and the ethical aspects of relationships between families and the state. She has published on topics such as individual funding requests, the harm principle and childhood, child nutrition guidelines, parental rights and surrogacy disputes, decision-making for seriously ill neonates and competence to consent. She has conducted workshops in research ethics with NHS and University Ethics Committees across the United Kingdom. She has been a member of New Zealand's National Health Committee.

Monique was appointed to NEAC in July 2016.

Kahu McClintock – Māori member

Kahu McClintock (Waikato/Maniapoto, Ngāti Mutunga and Ngāti Porou) is the Manager Research at Te Rau Matatini. Kahu has worked in the health and disability sector for over 20 years, with a special focus on Māori health research and child and adolescent mental health. Kahu holds a Dip Nursing (Psychiatric), Higher Dip Teaching, B Ed, M Phil (Māori), D Phil (Psychiatry).

Kahu was a Member of the Māori Health Committee, New Zealand Health Research Council from 2008 to 2014, and Chair of Ngā Kanohi Kitea Community Research Committee, New Zealand Health Research Council during that term. She is the lead for Te Rā o Te Waka Hourua.

Kahu was appointed to NEAC in July 2015.

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, The University of Auckland. He has had extensive experience as a psychiatrist, a clinical leader and a clinical researcher.

Wayne has been an HDEC member for seven years and is a member of the Health Research Council of New Zealand College of Experts. Past roles have included president of The Royal Australian and New Zealand College of Psychiatrists and Chairperson of the Council of Medical Colleges in New Zealand.

Wayne was reappointed to NEAC in March 2016.

Liz Richards – Community/consumer

Liz Richards is an independent director and trustee for the Tasman Bays Heritage Trust. Previous roles include Chair of the Top of the South Health Alliance, Chair of the Upper South A Health and Disability Ethics Committee and Deputy Chair of the Canterbury Community Trust and the Nelson Marlborough District Health Board. Liz has also been active in governance roles for a number of community organisations in the Nelson region.

Liz has worked in health promotion and public sector housing management as well as lecturing in housing studies at Salford University. She has a Professional Qualification of the Chartered Institute of Housing and an MA in Housing from the University of Central England in Birmingham.

Liz was appointed to NEAC in October 2015.

Hope Tupara – Health professional

Hope Tupara works from home, mostly in private contract research and as a practising midwife. She has a MA Midwifery and a PhD Public Health. She has published papers in the New Zealand College of Midwives Journal, the Cambridge Quarterly of Health Care Ethics and the American Journal of Bioethics.

Hope has a special interest in iwi development, the Māori Women's Welfare League and Whānau Ora.

Hope was appointed to NEAC in October 2015.

Dana Wensley – Lawyer

Dana Wensley has an LLB (Hons) from the University of Auckland, and a PhD (Medical Law and Ethics) from King's College London. She is interested in issues that transcend the traditional boundaries between law, medicine, and ethics, with a specialisation on regulatory responses to emerging genetic technologies. She has held posts as research fellow at the Human Genome Research Centre (University of Otago) and assistant editor of the *Bulletin of Medical Ethics* (London). She currently serves as consumer representative on the Hospital Advisory Committee of the Nelson Marlborough District Health Board.

Dana was appointed to NEAC in October 2015.

Outgoing members in 2016

Victoria Hinson – Chairperson, Community/consumer

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 Chairperson. She is currently Chairperson of a Complaints Assessment Committee for the Veterinary Council of New Zealand, as well as acting as a professional conduct committee layperson member for the New Zealand Psychologists Board.

Victoria was appointed as NEAC Chairperson in June 2011, and reappointed on 4 June 2014 for a further three years. She finished on NEAC in October 2016.

Martin Wilkinson – Deputy Chairperson, 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 Chairperson of the Bioethics Council from 2006 to 2009.

Martin was appointed NEAC Deputy Chairperson in November 2012. Martin's term ended in June 2016.

National Ethics Advisory Committee secretariat

Role of the National Ethics Advisory Committee secretariat

The NEAC secretariat provides dedicated analytical policy 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 2016 comprised:

- Beverley Braybrook, principal policy analyst
- Gillian Parry, senior policy analyst (to May 2016)
- Stella Li, policy analyst (to May 2016)
- Isabel Ross, policy analyst (from August 2016)
- Moana Tupaea, group administrator.

Contact details for the National Ethics Advisory Committee

Contact details for NEAC:

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

Appendix: Terms of reference for the National Ethics Advisory Committee

These terms of reference came into effect in December 2013.

1. 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.

Functions of the Committee

2. 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.
3. As part of its functions the 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) of the Act 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.
4. In undertaking its functions, the 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 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 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 on weighing up the harms and benefits of this type of research).

Composition of the Committee

5. The National Ethics Advisory Committee will have a maximum of 12 members appointed by the Minister of Health.
6. The Committee's membership must include:
 - two health professionals (one of whom must be a registered medical practitioner)
 - 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
 - two or more Māori members (one of whom must have a background in Māori research and/or ethics).
7. The membership must also have expertise in the following areas:
 - ethics
 - research (qualitative and quantitative)
 - epidemiology
 - law.

Terms and conditions of appointment

8. Members of the National Ethics Advisory Committee are appointed by the Minister of Health for a term of up to three years. The terms of members of the Committee will be staggered to ensure continuity of membership. No member may be appointed for more than six consecutive years unless an additional period of up to 12 months is confirmed to allow for continuity of projects.
9. Unless a person sooner vacates their office, every appointed member of the Committee will continue in office until their successor comes into office.
10. Any member of the Committee may at any time resign as a member by advising the Minister of Health in writing.
11. Any member of the 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.
12. The Minister may from time to time alter or reconstitute the Committee, or discharge any member of the Committee or appoint new members to the Committee for the purpose of decreasing or increasing the membership or filling any vacancies.

Chairperson and Deputy Chairperson

13. 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 Committee at which they are present. The Chairperson may appoint a member as Deputy Chairperson, in consultation with the Minister. The Deputy Chairperson may exercise the powers of the Chairperson in situations where the Chairperson is not present or is unable to act (eg, if the Chairperson has a conflict of interest).

Duties and responsibilities of a member

14. This section sets out the Minister of Health's expectations on the duties and responsibilities of a person appointed as a member of the National Ethics Advisory Committee. This is intended to aid members by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the Committee and its members.
15. As an independent statutory body, the Committee conducts its activities in an open and ethical manner, and operates in an effective and efficient way within the parameters of its functions as set out in its Terms of Reference.
16. Committee members should have a commitment to work in the best interests of the Committee.
17. Members are expected to make every effort to attend all the Committee meetings and devote sufficient time to become familiar with the affairs of the Committee and the wider environment within which it operates.
18. Members are expected to act responsibly with regard to the effective and efficient administration of the Committee and the use of Committee funds.
19. Members will:
 - be diligent, prepared and participate
 - be respectful, loyal and supportive
 - not denigrate or harm the image of the Committee.
20. The Committee as a whole will:
 - ensure that the independent views of members are given due weight and consideration
 - ensure fair and full participation of members
 - regularly review its own performance
 - act in accordance with the principles of the Treaty of Waitangi.

Conflicts of interest

21. 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. They must also be, and be seen to be, independent of the Minister of Health and the Ministry of Health. Proper observation of these principles will protect the National Ethics Advisory Committee and its members and will ensure it retains public confidence.

22. 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 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.
23. Members are required to declare any actual or perceived interests to the full Committee. The Committee will then determine whether or not the interest represents a conflict, and if so, what action will be taken.
24. The Chairperson will ask members to declare any actual or perceived interests at the start of each meeting.

Confidentiality

General

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

General meeting discussions

27. Key discussion points in meetings are recorded in the meeting minutes. Upon request, a member's dissenting views may be recorded in the meeting minutes.
28. Members must ensure that the confidentiality of Committee business is maintained. Members must be clear about what Committee matters are permitted to be discussed with people that are not Committee members and, in doing so, should be familiar with the information that is publically available about the Committee's work.
29. Meetings of the Committee, including agenda material and draft minutes, are confidential. Committee members must ensure that Committee documents are kept secure to ensure that the confidentiality of Committee work is maintained. Committee correspondence or papers can only be released with the approval of the Committee.
30. Members are free to express their own views within the context of Committee meetings, or as part of the general business of the Committee.
31. Members may communicate general meeting discussions with other Committee members that were not present during at the meeting.
32. At no time should members individually divulge details of Committee matters or decisions of the 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. 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.

'In committee' discussions

33. At no time will a Committee member discuss the conduct or performance of another member who is not present at the 'in committee' session.
34. The meeting minutes will note that an 'in committee' session took place. A record of 'in committee' discussions will be kept in the Chairperson's notes.
35. 'In committee' discussions can be communicated with other Committee members who were not present during the 'in committee' session. This can either be done formally by the Chairperson or informally by another Committee member.

Media policy

36. Only the Chairperson is authorised to comment publicly on the affairs and policies of the Committee, and where appropriate, the Chairperson will advise the Minister of Health in advance. The Chairperson may delegate comment to other Committee members.
37. Where the Chairperson has delegated comment to another Committee member, the member must publicly support a course of action decided by the Committee. If unable to do so, members must not publicly comment on decisions.
38. The Chairperson, members and Secretariat will not support any action or public statement that is derogatory or in any way damaging to the Committee.
39. Members have the right to comment to the media on any matter in their professional capacity, as long as they do not attribute the comment to the Committee or imply that they are speaking on behalf of the Committee. If a member is forewarned of being asked to comment to the media, they should advise the Committee accordingly. If a Committee member is not forewarned, they should advise the Chairperson immediately after making comment to the media.

Working arrangements

40. The National Ethics Advisory Committee will agree a work programme with the Minister of Health.
41. In carrying out its Terms of Reference, the 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 on 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

42. In meeting its obligations to consult before providing advice to the Minister, the National Ethics Advisory Committee will, where appropriate, make reasonable attempts to consult with:
- health and disability ethics committees
 - the Advisory Committee on Assisted Reproductive Technology
 - the Health Research Council Ethics Committee
 - any other Ethics Committee established by the Minister of Health
 - organisations that 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 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.
43. The Committee will ensure that stakeholders are provided with feedback following consultation, in line with good consultation practice.

Performance measures

44. The National Ethics Advisory Committee will be effectively meeting its tasks when it provides relevant and timely advice to the Minister of Health based on research, analysis and consultation with appropriate groups and organisations.
45. The Committee must:
- agree in advance to a work programme with the Minister of Health
 - achieve its agreed work programme
 - stay within its allocated budget.

Meetings of the Committee

46. Meetings will be held at such times and places as the National Ethics Advisory Committee or the Chairperson of the Committee decides.
47. At any meeting, a quorum will consist of six members. A quorum must include either the Chairperson or Deputy Chairperson. An effort will be made to ensure reasonable representation of community/consumer members and members with specialist knowledge and experience.
48. Every question before any meeting will 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 will have the casting vote.
49. Subject to the provisions set out above, the Committee may regulate its own procedures.

Reporting

50. The National Ethics Advisory Committee will:
- 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 (as per section 16(6) of the Act). The report is to include the 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.

Secretariat

51. The Ministry of Health will provide dedicated analytical policy and administrative support to the National Ethics Advisory Committee through Secretariat staff, consistent with the Memorandum of Understanding between the Committee and the Ministry of Health. Secretariat staff are Ministry employees and are funded through the Committee's allocated budget.

Fees and allowances

52. 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 Cabinet Office Circular CO (12) 6, *Fees framework for members appointed to bodies in which the Crown has an interest*.
53. 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.
54. The attendance fee for members is set at \$320 per day (plus half a day's preparation fee).
55. The Ministry of Health pays for actual and reasonable travel and accommodation expenses of the Committee members.