Annual Report
to the Minister of Health

National Advisory Committee on Health and

Disability Support Services Ethics

December 2004

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NATIONAL ETHICS ADVISORY COMMITTEE
NATIONAL ADVISORY COMMITTEE ON HEALTH AND DISABILITY SUPPORT SERVICES ETHICS
KĀHUI MATATIKA O TE MOTU

Mā te huruhuru ka rere te manu.

Feathers enable the bird to fly.

Foreword

On the Committee's behalf, I am pleased to present the third Annual Report of the National Advisory Committee on Health and Disability Support Services Ethics, December 2004. The Report sets out the Committee's activities and summarises its advice on the matters referred to it under section 16 of the New Zealand Public Health and Disability Act 2000. For ease of expression below, the Committee uses the short name by which it is known – the National Ethics Advisory Committee (NEAC). The Committee is also known by its Māori name, Kāhui Matatika o te Motu.

This Annual Report opens with the whakatauki (proverb) 'Mā te huruhuru ka rere te manu'. This can be translated as 'Feathers enable the bird to fly'. At year's end 2004, seven new health and disability ethics committees were established by the Minister of Health under the New Zealand Public Health and Disability Act 2000, on the basis of NEAC's advice that is summarised in this Report. These Committees are a support structure for ensuring that health and disability research in this country safeguards the best interests of research participants. Well-functioning ethics committees are amongst the feathers that enable the birds of health and disability research to fly. NEAC offers its best wishes to the new committees as they undertake their important public role on behalf of all New Zealanders.

This annual report includes NEAC's updated Terms of Reference, issued by the Minister of Health in December 2004, reflecting the establishment of its sub-committee on appeals.

In this annual report the committee also reflects on the contribution it can potentially make in future to wider sector

goals through its statutory role of providing advice on ethical issues of national significance in health and disability matters.

Andrew Moore
Chairperson
National Ethics Advisory Committee

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Introduction

The National Ethics Advisory Committee (NEAC), Kāhui Matatika o te Motu, is an independent advisor to the Minister of Health on ethical issues of national significance concerning health and disability matters.

NEAC's statutory functions are to:

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

The Committee works within the context of the New Zealand Public Health and Disability Act 2000, and the key strategy statements for the health sector.

Work Programme 2004

NEAC's agreed work programme in 2004 has focused on issues of ethics policy in health and disability research. This work, and the advice it has generated, is summarised below.

Projects

Review of the Ethical Review System 2003

In its Annual Report 2003, NEAC described the process of its inclusive and robust review of New Zealand's system of ethical review for health and disability. That Annual Report also included the Terms of Reference, issued by the Minister in December 2001, under which NEAC conducted its review.

The National Ethics Advisory Committee's December 2003 report to the Minister of Health, *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand*, is available in full text at www.newhealth.govt.nz/neac.htm. Its 25 recommendations cover processes for:

- the ethics committee review of national and multi-centre research
- the operation of ethics committees and the impact of their decisions
- the statutory basis for ethics committees
- ethical conduct of observational studies and parameters for their ethics committee review
- the application of second opinion and appeal processes in the ethics committee setting.

At the end of 2003, NEAC's review recommendations were under consideration by the Minister, and the Committee consequently did not summarise these in its Annual Report 2003. Subsequent to further advice from the Ministry of Health, the Minister announced her acceptance of NEAC's recommendations in May 2004, and the Ministry has now largely implemented these decisions.

A summary of NEAC's December 2003 recommendations is presented below, followed by a statement of the outcomes, and a commentary.

Recommendations

- That all health and disability ethics committees, and their review activities, be established on a direct statutory basis. This would provide an explicit and secure source of public authority, and a clear framework of public accountability. Ethics committees would be responsible to Parliament through the Minister of Health, and work to Terms of Reference and the *Operational Standard for Ethics Committees.* Members would be appointed by the Minister on the basis of a public nominations process, ensuring transparency.
- That a new national ethics committee be established, as the primary review body for all multi-centre and national research studies. 'National research' is conducted by investigators based in one centre, potentially or actually involving participants nationwide (for example, by telephone interview, or by access to a national database, or a national postal survey). 'Multi-centre research' is conducted simultaneously by several investigators based at different centres, with identical methods and following the same protocol.

- That every research proposal receive one ethics committee review. There is one national set of standards, and only one ethics committee review is required to check that each study would meet those standards if conducted at a suitable locality. Single-centre studies would continue to be reviewed by a single regional committee, while the national committee would review multi-centre and national studies. In light of the 'one study, one review' principle, the number of Health and Disability Ethics Committees should also be reviewed.
- That as part of the review of each national and multi-centre study, it should be checked that each proposed study locality is appropriate, with relevant local arrangements made. This checking process should remain an important responsibility of the organisation at each study locality, or of an ethics committee for any study where there is no such organisation.
- That a limited right of appeal be established from ethics committee decisions, to an appellate body that is a sub-committee of NEAC. Appeal would only be accessible when all other avenues for resolution have been exhausted.

In the light of independent advice from the Ministry of Health, the Minister accepted NEAC's recommendations in May 2004, with the following outcomes.

Outcomes

- A new Multi-Region Ethics Committee, established under section 11 of the New Zealand Public Health and Disability Act 2000, to review all proposals for national or multi-region research studies.

- Six new Regional Ethics Committees, established under section 11 of the New Zealand Public Health and Disability Act 2000, to review all proposals for single-region research studies. There are two committees in the northern region, one in the central region, two in the upper south region, and one in the lower south region. The jurisdiction of the six new Regional Ethics Committees covers the whole country and replaces that of the fifteen current Regional Ethics Committees.
- Establishment of a NEAC Sub-committee on Appeals, through which to hear appeals from ethics committee decisions, when all other avenues for resolution have been exhausted, including the obtaining of a second opinion from the Health Research Council Ethics Committee. Any appeal is to be by way of re-hearing rather than a hearing *de novo*, and is to focus only on specific alleged errors in the original decision. Where no such error is found, the Sub-committee on Appeals is bound to reaffirm the original decision.

In December 2004, the new ethics committees held their first meetings, and applications for review were transferred from the former committees to the new committees. Further information about the new system of ethics committee review, including operational detail, is contained in issues of the Ministry of Health newsletter *Ethical Review*.

Commentary

The new ethics committee arrangements retain the strengths of the former review system. The new system remains mainly regional while including some national elements, it preserves strong lay and Māori input, and it maintains its primary focus on protecting participants. Consultation with Māori remains an important researcher responsibility, to be reported through ethics committees. Checking that each proposed research locality is suitable and that the

appropriate local arrangements have been made remains the responsibility of the organisation(s) at each study locality, now to be done through the strengthened vehicle of 'locality assessment' (see below).

The change process has also strengthened and streamlined the ethics committee review system, as follows.

- The capacity of ethics committees to protect participants and to facilitate high quality research is strengthened. This is achieved through concentration of ethics committee expertise. For example, the committee's terms of reference require for the first time that there be a non-lay Deputy-Chair, and membership that includes two researchers, a pharmacist or pharmacologist, and a biostatistician. This expertise is an important check on research quality, and it also provides necessary specialised input into the key task of protecting participants. At the same time, half the membership must continue to be lay people, including a lay Chair.
- Ethics committee public accountability, recognition and independence are strengthened. This is achieved through the Minister of Health establishing the committees under section 11 of the New Zealand Public Health and Disability Act 2000, replacing the previous establishment by administrative decision of the Ministry of Health. As the influential *Declaration of Helsinki* notes, ethics committee independence is a matter of freedom from undue influence by the researcher or sponsor of each study. Parliament and the Minister are significantly more distant than the Ministry is from the sponsorship of research studies. Annual reporting to the Minister and Parliament now gives ethics committees stronger public recognition and accountability for their important work.

- The fairness of the ethics committee review process is now being strengthened, by establishing a limited right of appeal to an independent body (NEAC, through its Sub-committee on Appeals), for the rare cases where an applicant and ethics committee disagree and all other means of resolution are exhausted. As the Crown Law Office noted, (*Opinion to the National Ethics Advisory Committee on Second Opinion and Appeal Processes for Ethical Review*, 6 August 2003) "In general there should be a right of appeal against the findings of officials, tribunals, and other public bodies making decisions that affect important rights, interests and legitimate expectations of individuals". NEAC considers that Regional Ethics Committees make decisions that impact on researchers' (and subjects') important rights, interests and legitimate expectations.
- The ethics committee review process is now streamlined. This is achieved by ensuring there is 'one study, one review' against the country's one national set of ethical standards for health and disability research. The Multi-region Ethics Committee reviews each national or multi-region study, and each single-region study is reviewed by the Regional Ethics Committee in its region.

NEAC will maintain its interest in ethics committee review arrangements, and in their place within the wider system of ethical review.

Through NEAC's review, groups and individuals offered many insights into issues wider than those the Committee was specifically asked to address. NEAC followed up many of these matters through its projects in 2004. These work streams are summarised below.

Locality Assessment and Ethics Committee Review

In accepting NEAC's review recommendations in May 2004, the Minister also asked the Committee to address the issue of appropriate guidance on locality assessment and locality issues, including for single-centre studies.

With the main policy decisions about locality assessment already confirmed, NEAC's follow-up work developed points of detail, with further input from key stakeholders. In November 2004, the Committee completed this project, recommending:

- that the distinctive role of ethics committee review is to check that the investigator has ensured each proposed study would meet established ethical standards, if conducted at an appropriate locality or set of localities
- that the distinctive role of locality assessment is to check that the investigator has ensured each proposed study locality is appropriate for study conduct, with appropriate local arrangements made
- that there should be locality assessment process for single-region studies, as well as for national and multi-region studies
- that the locality assessment check should be made by the "locality organisation" at each study location; or, for any study where there is no locality organisation, by the ethics committee that reviews the proposal
- that ethics committee approval be conditional on receipt by the committee's administrator of favourable locality assessment.

The Minister accepted NEAC's advice in December 2004, and the Ministry of Health is now implementing it. This will include the Ministry convening a follow-up meeting of stakeholders from ethics committees, locality organisations,

and researchers, after the new arrangements have had some time in operation.

Ethical Guidelines for Observational Studies

As agreed with the Minister in May 2004, NEAC has undertaken further work on the ethics of observational studies, and parameters for their ethics committee review. In observational studies, the investigator does not control study variables, and only observes outcomes, by recording, classifying, counting, and analysing data. Many studies of this sort draw on health records.

On the basis of extensive Committee work and consultation in 2002–04, NEAC has developed proposed ethical guidelines for observational studies. These have several significant features. Firstly, they cover a broad range of activities that share ethically relevant characteristics: epidemiological observational research, clinical observational research, audit, and audit-related activities such as quality assessment and public health surveillance. Secondly, they are directed primarily to the investigators who perform these activities, and who consequently have the primary ethical responsibility for study conduct. Thirdly, they set out the circumstances, mainly related to risk for participants, in which observational studies require ethics committee review. In broad terms, most observational research requires ethics committee review, and most audit and related activity does not.

NEAC is completing consultation on its second discussion document in this area, titled *Ethics of Observational Research, Audit and Related Activities*. Following revision informed by this consultation process, NEAC intends to present advice to the Minister on proposed completed *Ethical Guidelines for Observational Studies* by April 2005.

Māori Framework For Health and Disability Research Ethics

In November 2002, the Minister asked NEAC to take responsibility for the development of a Māori Framework for health and disability research ethics, on completion of its review of the ethical review system. The project will encourage discussion on Māori ethical issues amongst Māori communities, health researchers and people and organisations involved in the ethics of health research. NEAC sees the project as a process to foster discussion and dialogue with the aim of clarifying issues, needs and options.

NEAC has agreed a project plan based on a background report, and is undertaking initial discussions with key stakeholders and securing further work on how the central issues have so far been addressed in New Zealand and other countries.

Governance Framework for Health and Disability Research Ethics

The Minister has agreed that NEAC scope the task of developing a governance framework for health and disability research ethics. New Zealand currently does not have a clear or complete framework of this sort. We can learn from the United Kingdom in this area. Such a framework would clarify responsibilities in the ethical conduct of research and related activity. For example, one theme from the *Gisborne Cervical Screening Inquiry Report* concerned differences of view and consequent difficulties over the appropriate ethics committee role to address legal issues in study conduct. See, for example, Duffy AP et al, *Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*, 2001, p.259. Background reports to NEAC in 2004 have also identified many other key areas of responsibility, such as checking for

scientific validity, and monitoring emerging study data on participant safety.

A completed governance framework would match:

- key areas of responsibility (eg, for study design, protocol review, legal issues, ethical review, scientific assessment, monitoring of study data, monitoring of protocol adherence, prospective safety assessment)
- key parties (eg, researchers, ethics committees, locality organisations, research funders, researcher employers, data monitoring committees)
- key roles (eg, addressing issues, checking that they have been satisfactorily addressed, checking that a 'satisfactoriness check' has been made)
- key powers or authorities (eg, discretion versus duty to perform the role in question).

NEAC is developing a 'governance framework' project plan through which to progress this work further.

Intervention Studies and Innovative Practice

In December 2004, the Minister agreed in principle to NEAC conduct of a project on the ethics of intervention studies and innovative practice. In an intervention study, the investigator intentionally alters one or more factors to study the effects of doing so. In health research, these factors or 'interventions' are typically treatments, medicines, or procedures, and the effects to be studied typically concern intervention safety or benefit. One definition of innovative practice is that it involves the application, outside the context of any intervention study, of an intervention that is not established practice.

As is well recognised internationally, it is within intervention studies that research participants are most vulnerable. It is

less well recognised, but equally important, that patients are similarly vulnerable in the context of innovative practice. It is consequently in these two areas that protection is most critical. There is a need for strengthened guidance in both areas. NEAC background work in the 'governance framework' area (see above), also identified a number of important areas of responsibility that are particular to intervention studies, such as the assessment of adverse event reports. The close relation between intervention research and innovative practice parallels the close relation between observational research and audit. For aspects of both these points, see *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters*, 1988, pp.61–66. NEAC anticipates that many insights from its project on observational studies will inform its project on intervention studies and innovative practice.

NEAC has developed a draft project plan through which to progress its work on intervention studies and innovative practice.

Background Work

Booking systems for elective services

In 2003, the Canterbury Regional Ethics Committee wrote to NEAC presenting ethical concerns about 'booking system' approaches for elective services. NEAC responded that the ethical issues had been considered in, and were in fact integral to, the policy decisions that underpin the current approach. It also agreed to look at work done subsequently on the ethical issues.

The Minister has noted the correspondence outlined above, and NEAC's follow-up actions. The Committee has also

contracted background work on the issues, and it will receive and consider this work in the new year.

Research use of tissue from stillborn babies or fetuses

The Minister requested in October 2004 that the Committee consider developing guidelines on research use of tissue from fetuses or stillborn children.

NEAC is in discussion with the Ministry of Health about the scope of, and best way to progress, work in this area.

Operational Standard for Ethics Committees

The Ministry of Health is currently updating the *Operational Standard for Ethics Committees* to reflect the recent changes to the system of ethical review.

NEAC has agreed that all advice it presents to the Minister will continue to note any implications there might be for the *Operational Standard* and whether further updating might be required.

Future Directions

The statutory functions of NEAC extend to ethical issues of national significance in respect of any health and disability matters, including research and health services. It is likely that the Committee's work over the next two years will continue to focus primarily in the area of research ethics. For the most part the discussion below maintains this same emphasis. In addition, the paragraphs below briefly discuss issues regarding services. The Committee intends to take further steps to identify and consider potential future work in both areas.

Sector goals, research, and ethics

NEAC regards research and related activity as the key generator of evidence that should underpin pursuit of sector goals: better health; reduced inequalities; increased participation and independence; and trust and security for New Zealanders (Ministry of Health, *Statement of Intent* 2004–05). To achieve this, and to sustain firm public support as it does so, research and related activity must meet high ethical standards. There are continuing opportunities for NEAC policy work on ethics to contribute to this. In so doing, the Committee is firmly committed to maintaining open, inclusive, and thorough processes through which to develop all its advice.

Māori and research ethics

There is an ongoing need to support processes for Māori to express and further develop Māori understandings of research – what questions it answers, how best to do it, who benefits from its results, and so on. As NEAC moves into 2005 its aim is to pursue the development of a Māori health and disability research ethics framework. Undertaking this will be an exciting journey for the Committee and it will be seeking to collaborate and co-operate with others who are also working in and/or interested in this field. In the future, parallel processes can also engage Māori and other understandings of research with one another, recognising both shared understandings and differences.

System accountability and performance

Through its 2003 review, NEAC generated a statement of "Goals, Objectives and Desired Outcomes of an Ethical Review System" (see Appendix). These goals include facilitation of high quality research and related activity for health gain, and protection of all participants in such activity. There is potential for the sector to develop measures of the system's performance based on this statement, and thereby to build further public accountability and quality assurance. The statement can also serve as a starting point for reflection on ethics policy for areas of health and disability beyond research.

Governance of research ethics

Within the ethical review system for research and related activity, as elsewhere, each person has responsibility for her or his own actions. For example, investigators are responsible for the ethics of their own research and related activity, and thus also for ethical self-review; and ethics committees are responsible for checking that investigators meet established ethical standards, and for providing public assurance of this. Other parties have key roles too. A clearer 'governance framework' statement is needed to express this network of responsibilities, and each particular role within it. NEAC has a current project in this area (see above).

A theme that came through NEAC's 2003 review from diverse stakeholders is that ethics guidance for research and related activity is best directed primarily to the investigators who conduct it, while also attending to the role of ethics committees and others with core responsibilities. A related theme is that such guidance is best built around the main kinds of research and related activity, including: observational research, audit, and related activities; and intervention research and innovative practice. These themes are reflected in NEAC's Terms of Reference, and they also inform current NEAC projects in observational studies, intervention studies, and innovative practice (see above). In addition, these themes will be reference points for any future Committee projects on research and related activity, and for any guidance it might in future develop for other areas of health and disability.

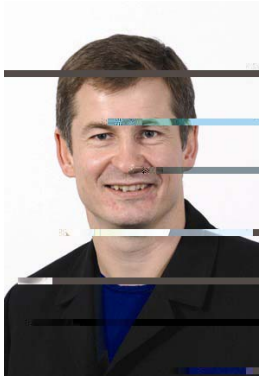
Disability ethics

NEAC is mindful of the need to ensure that the ideas and principles of the New Zealand Disability Strategy (*Whakanui Oranga: Making a World of Difference*) are reflected in the Committee's work. This includes the Strategy's objective to encourage and educate for a non-disabling society, and to include the perspectives of disabled people in ethical and bioethical debates. For example, there is scope for the wide range of disability research to be better understood and promoted, for the rights of disabled people to participate safely in health and disability research to be further supported, and for the experience and other expertise of disabled people to be expressed further, including through additional membership of ethics public bodies.

Conclusion

The National Ethics Advisory Committee will continue to approach its work and its planning in light of reflection on the wider contribution it can make though exercise of its statutory function regarding ethical issues of national significance in health and disability matters.

Membership of the Committee



Dr Andrew Moore – Chairperson

Dr Andrew Moore is a Senior Lecturer in Philosophy at the University of Otago, where his teaching, research and community service activities focus on ethics, political philosophy and bioethics.

Andrew's practical experience in clinical ethics and health research ethics includes previous health and disability ethics committee memberships at the Otago regional level and with the National Ethics Committee on Assisted Human Reproduction. He was also previously a member of the human subjects ethics committee at the University of Otago. In addition, he is presently a member of the Health Research Council's Data and Safety Monitoring Board for New Zealand led clinical trials.

Andrew's policy experience includes his membership of the National Health Committee and of the Public Health Advisory Committee.

Dr Allison Kirkman

Dr Allison Kirkman is a senior lecturer in sociology in the School of Social and Cultural Studies and Associate Dean (Students) in the Faculty of Humanities and Social Sciences at Victoria University of Wellington.

Allison's areas of expertise are in the sociology of gender, sexuality and health.

She has published recently on the importance of taking gender and sexuality into account when considering ethical issues in social science research.

Allison is the Convenor of the Victoria University of Wellington Human Ethics Committee and is also currently Convenor of the Standing Committee on the Code of Ethics for the Sociological Association of Aotearoa New Zealand.

Professor Michael Ardagh

Professor Michael Ardagh (MBChB, Ph.D., FACEM, DCH) is currently Professor of Emergency Medicine at the Christchurch School of Medicine and specialist Emergency Physician at the Christchurch Hospital Emergency Department. His duties involve a mix of patient care in the Emergency Department, supervision of junior medical staff, education and research.

Michael attained a Ph.D. in bioethics from the University of Otago in 2001, with a thesis exploring issues of ethics related to resuscitation.

Dr Dale Bramley

Dr Dale Bramley is a medical graduate of the University of Auckland (MBChB, MPH (Hons), FAFPHM). Having undertaken vocational training in public health medicine and as a qualified public health physician he is currently working as Manager of Health Gain for the Waitemata District Health Board, where he is responsible for the design and implementation of the strategic priorities of the District Health Board.

He also has an academic appointment as a senior lecturer in public health in the section on Epidemiology and Biostatistics at the University of Auckland.

Dale has a keen interest in Māori Health, Epidemiology, Cardiovascular Disease and Health Informatics. During July 2003–July 2004 Dale completed a Harkness Fellowship in Health Policy based at the Mount Sinai Medical Center in New York. The focus of his work was an international comparison of indigenous health disparities.

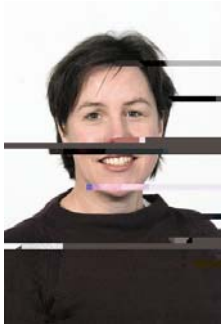
Dale has tribal affiliations to Ngāti Hine and Nga Puhi.

Dr Anne Bray

Dr Anne Bray has been involved for many years in a large range of activities and organisations concerned with people with disabilities.

Her primary interest is in ethical issues and research with implications for disadvantaged groups and individuals.

Anne is the Director of the Donald Beasley Institute, an independent disability research institute in Dunedin. She has also undertaken academic study in the law and ethics, and served as a member of the previous National Ethics Committee, and the National Health Committee.



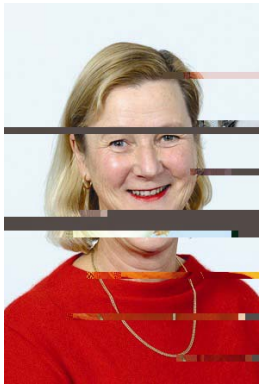
Dr Fiona Cram

Dr Fiona Cram is Māori with tribal affiliations to Ngāti Kahungunu. Fiona is the mother of one son.

Fiona has a Ph.D. in social and developmental psychology from the University of Otago and lectured in Social Psychology at the University of Auckland for seven years.

She was a Senior Research Fellow with the International Research Institute of Māori and Indigenous Education, University of Auckland.

In 2003 Fiona established her own research company, Katoa Ltd. Her research interests are wide ranging. They include kaupapa Māori research methodologies and ethics, Māori health research, evaluation research, qualitative and quantitative research methods, and community-based research training.



Philippa Cunningham

Philippa Cunningham is a barrister in private practice in Auckland with experience representing a number of clients with medico-legal problems. She is also a trained nurse.

Medical legal and ethical issues have been of interest to Philippa for many years, particularly since the Cartwright Inquiry in 1988, when she was one of the counsel assisting the Commissioner, Judge Cartwright.

She also chaired the Cartwright Evaluation Team set up by the Auckland Area Health Board to monitor implementation of the recommendations from the Cartwright Inquiry.

Philippa has had local body experience having served as a councillor, the Mayor of Mount Eden Borough, and a community board member in Auckland.

Philippa is also a member of the National Ethics Committee on Assisted Human Reproduction.

This year, Philippa will complete a post-graduate Diploma of Professional Ethics at the University of Auckland.

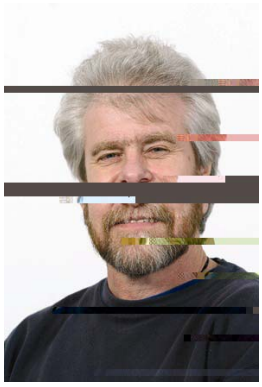
Dr Charlotte Paul

Dr Charlotte Paul is Associate Professor of Epidemiology at the Department of Preventive and Social Medicine, University of Otago Medical School.

Charlotte is an epidemiologist who has a background in medicine and public health.

She has extensive experience in conducting epidemiological research nationally, particularly in the areas of women's cancers and contraceptive safety. She is an advisor to the AIDS Epidemiology Group that is responsible for monitoring the HIV/AIDS epidemic in New Zealand. In addition she is a principal investigator in the Dunedin Multidisciplinary Health and Development Study in the area of sexual and reproductive behaviour, and a member of its Scientific Advisory Group.

In 1987/88 Charlotte was a medical advisor to Judge Cartwright for the Cervical Cancer Inquiry and has subsequently published articles on the ethical implications. She has been a member of the Otago Area Health Board Ethics Committee and the Health Research Council Ethics Committee. She chaired a working party for the Health Research Council on Privacy and Health Research that produced guidance notes for health researchers and ethics committees.



Dr Martin Sullivan

Dr Martin Sullivan is a senior lecturer in social policy and disability studies at the School of Sociology, Social Policy and Social Work, Massey University. After being awarded his Ph.D. on the sociology of paraplegia in 1997 he was made a Winston Churchill Fellow in 2000 for his work on the development of disability studies and the disability movement in the UK.

As an academic, Martin teaches, researches and has published widely on disability. As a disabled person, Martin has been actively involved in the disability movement for a number of years. He is currently chair of Advocacy Manawatu (a citizen advocacy group for disabled people) and serves on the Regional Committee for DPA, Palmerston North.

Mele Tuilotolava

Mele Tuilotolava is a Tongan New Zealander. She is married and has three sons.

Since 1989 Mele has worked in her own legal practice at Manukau City, focusing mainly on court work. She is a specialist criminal lawyer, family court lawyer, and counsel acting for children in matters of care and protection, youth justice and guardianship issues.

Mele is also involved with mental health related issues and other types of civil litigation.

She is a member of both the New Zealand Law Society and the Auckland District Law Society and has served on various committees within these societies.

Mele has been a member of the Pacific Peoples Focus Group at the Ministry of Justice advising project leaders of the Tongan and general Polynesian perspective; the National Council of Tongan Women; and the Tongan Women's Association. She is currently serving as Tikanga Polynesia member on the Commission for Title D in the Anglican Church and as a trustee on the Auckland Pacific Island Community Radio Trust and Ta Pasefika Health Trust, a funding trust to providers of comprehensive health services in the Auckland region.

Terms of Reference

The Role of the Committee

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

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

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

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

- consult with any members of the public, persons involved in the funding or provision of services, and other persons that the committee considers appropriate before providing advice on an issue (section 16(4) refers)

- at least annually, deliver to the Minister of Health a report setting out its activities and summarising its advice on the matters referred to it under section 16 of the Act by the Minister of Health
- provide timely and sound advice to the Minister of Health on the membership and operation of its Sub-Committee on Appeals, including advice on those member categories that cannot be filled from the National Ethics Advisory Committee's membership, and will therefore require a wider nominations process. The National Ethics Advisory Committee may make nominations as part of this wider process.

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

- provide advice on priority issues of national significance as requested by the Minister of Health
- provide advice to the Minister of Health regarding ethical issues concerning emerging areas of health research and innovative practice. The advice is to include the National Ethics Advisory Committee's rationale for its advice and any relevant evidence and/or documentation
- provide advice to the Minister of Health regarding aspects of ethical review in New Zealand, including the setting of principles and guidelines in relation to each of the different types of health research and innovative practice. The advice is to include the National Ethics Advisory Committee's rationale for its advice and any relevant evidence and/or documentation

- develop and promote national ethical guidelines for health research and health and disability support services (the guidelines should address how to conduct different types of health research [including ethical issues relating to Maori 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.

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

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

Terms and Conditions of Appointment

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

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

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

Chairperson

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

Duties and Responsibilities of a Member

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of the National Ethics Advisory Committee. This is intended to aid members of the National Ethics Advisory Committee by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the National Ethics Advisory Committee and its members.

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

General

1. The National Ethics Advisory Committee members should have a commitment to work for the greater good of the committee.

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

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

4. Members of the National Ethics Advisory Committee are not obliged to accept nomination to the Sub-Committee on Appeals.

Conflicts of interest

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

2. Members attend meetings and undertake committee activities as independent persons responsible to the committee as a whole. Members are not appointed as representatives of professional organisations and groups. The National Ethics Advisory Committee should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.

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

4. A member of the National Ethics Advisory Committee who has a proposal before the committee, or who has an involvement in a proposal, such as a supervisory role, shall not take part in the National Ethics Advisory Committee's assessment of that proposal. The member may be present to answer questions about a proposal but should be asked to leave the meeting while the remaining members consider the proposal. This will allow proposals to be considered in a free and frank manner.

Confidentiality

1. The public has a right to be informed about the issues being considered by the National Ethics Advisory Committee. The National Ethics Advisory Committee should have procedures in place regarding the release of information and processing requests for information.

2. Individual members must observe the following duties in relation to committee information. These provisions ensure that the National Ethics Advisory Committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.

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

Working Arrangements

The National Ethics Advisory Committee will agree a work programme with the Minister of Health. The National Ethics Advisory Committee will be serviced by permanent staff, sufficient to meet the committee's statutory requirements, that will be based in the Ministry of Health.

In carrying out its terms of reference, the National Ethics Advisory Committee must:

- provide the Minister of Health with advance notice of any media statements or reports to be published
- ensure its advice is published and widely available
- ensure that, in developing any advice, guidelines, or its views in relation to an appeal, an appropriate balance exists between protecting the rights and well-being of patients and research participants and facilitating health research and innovative practice
- ensure that, where appropriate, any advice or guidelines contain clear guidance regarding the application of ethical principles that is appropriate to the type of health research or innovative practice being considered (due regard should be given to the different nature of qualitative and quantitative approaches to research)
- ensure that any advice, guidelines, and views in relation to an appeal, comply with the laws of New Zealand
- ensure appropriate consultation has occurred in accordance with the requirements set out below.

Consultation

Where appropriate, the National Ethics Advisory Committee must make reasonable attempts to consult with:

- health and disability ethics committees
- the National Ethics Advisory Committee on Assisted Human Reproduction
- the Health Research Council Ethics Committee
- any other Ethics Committee established by the Minister of Health
- organisations known to the committee to represent affected patients or other groups of the community
- relevant whanau, hapu and iwi
- a reasonably representative sample of affected patients or members of the public or (if the National Ethics Advisory Committee thinks it more appropriate) a reasonably representative sample of people who would be entitled to consent on behalf of the affected patients or members of the public
- a reasonably representative sample of affected health researchers and/or affected health professionals
- relevant government bodies.

Performance Measures

The National Ethics Advisory Committee will be effectively meeting its tasks when it provides relevant and timely advice to the Minister of Health based in research, analysis and consultation with appropriate groups and organisations.

The National Ethics Advisory Committee must:

- agree in advance to a work programme with the Minister of Health
- achieve its agreed work programme
- stay within its allocated budget.

Meetings of the Committee

Meetings shall be held at such times and places as the National Ethics Advisory Committee or the Chairperson of the National Ethics Advisory Committee decides.

At any meeting, a quorum shall consist of six members. A quorum must include either the Chairperson or Deputy-Chairperson. An endeavour will be made to ensure reasonable representation of community/consumer members and members with specialist knowledge of and experience.

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

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

Reporting Requirements

The National Ethics Advisory Committee is required to:

- keep minutes of all committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made
- prepare an annual report to the Minister of Health setting out its activities and comparing its performance to its agreed work programme and summarising any advice that it has given to the Minister of Health. This report must also include details of the appeals heard by the Sub-Committee on Appeals. The report is to include the National Ethics Advisory Committee's rationale for its advice and any relevant evidence and/or documentation. This report will be tabled by the Minister of Health in the House of Representatives pursuant to section 16(7) of the Act.

Servicing of the Committee

The Ministry of Health will employ staff to service the National Ethics Advisory Committee out of the Committee's allocated budget allocated and consistent with the Memorandum of Understanding between the National Ethics Advisory Committee and the Ministry of Health.

Fees and Allowances

Members of the National Ethics Advisory Committee are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies. The Chairperson will receive $430 per day (plus half a day's preparation fee) and an allowance of two extra days per month to cover additional work undertaken by the Chairperson. The attendance fee for members is set at $320 per day (plus half a day's preparation fee). The Ministry of Health pays for actual and reasonable travel and accommodation expenses of the National Ethics Advisory Committee members.

Sub-Committee on Appeals

The National Ethics Advisory Committee will convene a Sub-Committee on Appeals (the SCA).

Whereas the main statutory function of the National Ethics Advisory Committee is to advise the Minister of Health on ethical issues of national significance regarding health and disability, the function of its Sub-Committee on Appeals is to review particular proposals at appeal.

The SCA will be responsible for hearing appeals from decisions of the following health and disability ethics committees:

- Regional Ethics Committees (RECs) established under section 11 of the New Zealand Public Health and Disability Act 2000
- the Multi-region Ethics Committee (MEC) established under section 11 of the New Zealand Public Health and Disability Act 2000.

Authority of the Sub-Committee on Appeals

An appeal may only be lodged with the SCA by the principal researcher identified in the application in question. The SCA may not hear any appeal that is lodged by any third party.

The SCA may only hear appeals in cases where a second opinion from the Health Research Council Ethics Committee has been sought (by either the original ethics committee or the researcher) and received, and the matter reconsidered by the original ethics committee. All appeals will be from the decision made by the original committee following the second opinion.

All appeals heard by the SCA will be by way of re-hearing, focussing on specific alleged errors of judgement or reasoning in the original decision.

In hearing an appeal, the SCA will have discretionary power to re-hear any part of the evidence that is relevant to these specific alleged errors of judgement or reasoning. The SCA will also have the power to receive further evidence and to call individuals involved in the reconsidered decision to give evidence in person.

In hearing an appeal, the SCA will be bound by the presumption that the original decision was correct. The SCA will affirm the decision being appealed against where:

i. the SCA is not satisfied that errors exist in the original decision

ii. the SCA is satisfied of the existence of such errors but considers the errors to be of insufficient importance to warrant reversing the original decision.

The SCA will reverse the original decision only where it is satisfied that the original decision contained errors of judgement of a sufficiently serious nature to warrant the reversal.

The SCA will in all cases either affirm or reverse the original decision.

Consequential amendments to the Operational Standard for Health and Disability Ethics Committees

These Terms of Reference have precedence over the Operational Standard for Health and Disability Ethics Committees on any point of conflict. Otherwise, the Operational Standard applies to the SCA.

Approvals

The SCA must be approved for all purposes required for the application in question.

Role of the Sub-Committee on Appeals

The primary role of the SCA will be to hear appeals from the decisions of the health and disability ethics committees named above.

The SCA will act so as to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy. In order to do this, the SCA shall:

i. foster an awareness of ethical principles and practices in the health and disability sector and research community;

ii. facilitate excellence in health research and innovative practice for the wellbeing of society;

iii. collaborate with researchers to ensure the interests, rights, dignity, welfare, health, and wellbeing of participants and consumers are protected;

iv. give due consideration to community views;

v. consistent with section 4 of the New Zealand Public Health and Disability Act 2000 and He Korowai Oranga, recognise and respect the principles of the Treaty of Waitangi;

vi. operate in accordance with the Operational Standard for Health and Disability Ethics Committees; and

vii. operate in accordance with any guidelines issued or approved by the Director-General of Health.

Composition and membership

Guiding principle

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

Minister to appoint members

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

Member numbers

The number of members of the SCA shall be at least 12, including a lay chairperson.

Lay/non-lay membership

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

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

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

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

NEAC/non-NEAC membership

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

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

Whole committee requirements

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

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

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

Terms and Conditions of Appointment

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

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

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

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

Chairperson

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

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

Duties and responsibilities of a member

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

General

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

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

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

Conflicts of interest

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

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

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

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

Confidentiality and information sharing

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

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

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

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

Committee meetings

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

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

The minutes of all meetings shall be publicly available.

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

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

Quorum

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

Decision-making process

Decisions

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

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

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

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

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

Communication of decisions

All decisions of the SCA will be communicated to:

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

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

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

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

Expert advice and consultation

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

Training for members

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

Records

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

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

Fees and Allowances

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

Servicing and administration of the SCA

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

The contact address for the SCA will be:

Sub-Committee on Appeals
National Ethics Advisory Committee
PO Box 5013
WELLINGTON
Email: appeals_neac@moh.govt.nz

Secretariat

Barbara Burt — Senior Analyst

Vanessa Waldron — Analyst

Marie Farquhar — Executive Assistant

To contact the National Advisory Committee on Health and Disability Support Services Ethics:

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Appendix A: Goals, Objectives and Desired Outcomes of an Ethical Review System[1]

Overall goals	
• Protection of participants in health and disability research and innovative treatment • Facilitation of research and innovative practice that contributes to knowledge and improved health outcomes • Finding a balance that minimises risks and maximises benefits arising from health and disability research • Recognise and respect the principles of the Treaty of Waitangi by enabling Māori to contribute to the ethical review of health and disability research	
Objectives	**Desired outcomes**
Accountable	• Public accountability requirements are defined • Ethical reviews meet internationally recognised standards • Ethical reviews take into account relevant legislation

[1] Based on Recommendation 1 of the National Ethic Advisory Committee's *Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand, Report to the Minister of Health*.

Enabling	• Research participants/subjects are protected • Quality research is facilitated • Review processes are clear about jurisdiction and coverage • Awareness of ethical practice among all stakeholders is developed • Good communication with affected communities is demonstrated • Local input is achieved • Positive relationships with all stakeholders are developed • System review mechanisms are in place
Informed	• Researchers consider ethical implications from the outset, eg, there is clarification of who will benefit from the research (participants, the public, etc.) • The perspectives of affected communities are included • Review processes are proactive and attend to emergent issues; and are responsive to change over time • Review processes apply appropriate expertise • Scientific and ethical standards are considered alongside each other where appropriate • Decision-making is consistent • Review capacity and relevant expertise is maintained and developed

Enabling Māori involvement	• A Māori ethical framework is developed and implemented • Consultation with Māori is collaborative, genuine, inclusive, and appropriate • Māori participation in the decision-making component of the system is facilitated • The potential for diversity of opinion across iwi and regions is recognised and respected • Māori research capability is facilitated
Fair	• Review processes are independent • Stakeholders have access to due process • Outcomes of processes are equitable • Applicants to review processes have the right of reply • Conflicts of interest are acknowledged and addressed
Efficient	• Time and resources are used productively • Reviews are timely • The *Operational Standard* is updated regularly, with participation from all stakeholders