

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

**National Advisory Committee on Health and Disability Support Services
Ethics**

December 2003

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Foreword

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. As required by its Terms of Reference, and the work programme it agreed with the Minister of Health in 2002, NEAC has in 2003 given priority to its review of the system of ethical review of health and disability research in New Zealand. The Committee presented its findings and recommendations from this review to the Minister in December 2003.

In conducting its review, NEAC used a wide range of methods to involve and draw upon the experience and expertise of stakeholders in the health and disability sectors – laypeople and professional, Māori and non-Māori. The Committee believes its recommendations rest upon the strong foundations of a fair and robust review process.

In addition, the NEAC review drew upon an opinion from the Crown Law Office. It benefited from advice, experience and comment from the Health Research Council and the Health Research Council Ethics Committee. The Ministry of Health supported the work of NEAC's secretariat, and respected the statutory independence of NEAC's ministerial advisory function. The Committee also had excellent professional support from its secretariat and contractors.

Many people made valuable contributions to the review, some at more than one point. NEAC acknowledges and warmly thanks all these members of ethics committees, research communities, public bodies, and other interested communities, as well as potential research participants. The Committee learnt a great deal from these diverse and insightful contributions. It believes they reflect widespread commitment to research ethics, and to high quality processes of ethics committee review. At the review's conclusion, there remained significant diversity of stakeholder opinion on some key issues on which NEAC had agreed to make recommendation to the Minister. The Committee worked hard to reflect convergences of view where these could be identified, and divergences where these remained; and on each issue to reflect the main reasons that stakeholders gave for their views. In light of these stakeholder insights, and its own reflections, NEAC strove to base its recommendations to the Minister on the strongest arguments.

NEAC's review focused on processes for ethics committee review of national and multi-centre studies, options for second opinion and appeal, and observational studies and audit. Stakeholders also offered insight into many wider issues. NEAC anticipates that in future it will be in a position to address these issues through its work to develop a Māori ethical framework for health research, and through future review of the *Operational Standard for Ethics Committees* (2002). NEAC also believes further work on governance issues in ethics would be valuable.



Andrew Moore
Chair

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Summary of the Work Programme for 2003

Review of ethical review system

On 20 November 2002 the Minister of Health agreed to a work programme set out by the National Ethics Advisory Committee (NEAC). The programme gave priority to four matters relating to the Recommendations of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region (Gisborne Inquiry).

1. 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 health research).
2. Consider the application of second opinion and appeals processes and recommend their appropriate use for ethics committees.
3. Review the current processes for the ethical review of national and multi-centre research.
4. Review the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

NEAC combined these four key areas into a review of processes for the ethical review of health and disability research in New Zealand. In this review NEAC used a wide range of methods to involve stakeholders in the health sector and in the disability sector – including Māori and non-Māori, lay people and professionals. It drew upon their experience and expertise to gain an understanding of the current ethical review system, and to develop, consider, and make recommendation on options for the future of the ethical review system. The review's structure and methods are set out below.

Processes of the review

In the first stage of the review NEAC examined the current ethical review system, obtaining information and input from the following sources:

- an initial letter sent to a wide range of individuals and organisations, which informed them of the review and invited comment and participation in the review process
- a legal opinion from the Crown Law Office on actual and possible second opinion and appeal processes
- a questionnaire survey sent to all current regional ethics committee members and a sample of researchers, including Māori researchers currently funded by the Health Research Council
- interviews with individual stakeholders
- a literature survey of recent material published in New Zealand and internationally on issues covered in the review.

The information gathered in this stage of the review was analysed and used in the development of two discussion documents. Where relevant it was also carried forward to the final report to the Minister of Health.

In the second stage of the review NEAC developed the options for the future of the ethical review system. The process included the following consultation:

- input from stakeholders in the development of goals, objectives, and desired outcomes for ethical review processes
- interviews with individual stakeholders
- group meetings with stakeholders

- release and distribution of more than 600 copies of two discussion documents, for comment over a six-week consultation period, with the result that:
 - System of Ethical Review of Health and Disability Research in New Zealand received 84 submissions
 - Ethical Review of Observational Research, Audit and Related Activities received 72 submissions
- two cross-sectoral consultation workshops, one in Christchurch and one in Auckland, to discuss review issues and test options with key stakeholders
- two consultation meetings with chairs of health and disability ethics committees, one focusing on perceptions of the current system of ethical review, and one on review process and goals, objectives and desired outcomes for a system of ethical review
- one consultation meeting with members of regional health and disability ethics committees, which focused on options contained in NEAC's discussion documents
- one consultation meeting with staff and the Chair of the Health Research Council.

Advice to the Minister of Health, December 2003

NEAC provided a full report outlining its advice to the Minister of Health on 12 December 2003. The advice includes recommendations on guidelines for the ethical conduct of observational studies and parameters for their ethical review; the application of second opinion and appeal processes in the ethics committee setting; processes for the ethical review of national and multi-centre research; the operation of ethics committees and the impact of their decisions; and the matter of whether ethics committees should be established on a statutory basis.

The report will be available on the NEAC website when the Minister has completed her consideration of it.

Further work

NEAC's current review of the operation of ethics committees has focused on certain areas, namely, the review of national and multi-centre studies, second opinion and appeal processes, and observational studies. However, the work undertaken for this review has canvassed a range of other issues relating to the operation of the current system for ethical review of health and disability research, on which stakeholders have provided important feedback. NEAC anticipates that it will be in a position to address some of these other matters in its future review of the *Operational Standard for Ethics Committees*.

NEAC is also responsible for the development of a Māori framework for ethical review.¹ As background work for this project, NEAC has completed interviews with key informants. The Committee has agreed that the second stage of this background work will be a document on national and international work being done in the area of indigenous ethical frameworks. Information relevant to the future development of a Māori framework has also been gathered by NEAC in the course of its current review.

NEAC and the Minister of Health have not yet agreed on a work programme for its work on a Māori framework for ethical review, or for its future work on the *Operational Standard*.

¹ Hon Annette King, letter to NEAC, 20 November 2002.

Membership of the Committee

Dr Andrew Moore – Chairperson

Dr Andrew Moore is a senior lecturer and Acting Head of the Department of 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 has also been a member of the human subjects ethics committee at the University of Otago.

In addition, Andrew is a member of the National Health Committee and of the Health Research Council's Data and Safety Monitoring Board for clinical trials.

Dr Allison Kirkman – Deputy Chairperson

Dr Allison Kirkman is a senior lecturer in Sociology in the School of Social and Cultural Studies 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 Human Ethics Committee at Victoria University. Prior to this, she was a member of the standing committee of the Human Ethics Committee as well as the convenor of the School of Social and Cultural Studies subcommittee of the Human Ethics Committee.

As well as being the immediate past president of the Sociological Association of Aotearoa (NZ), Allison is currently convenor of its Standing Committee on the Code of Ethics.

Professor Michael Ardagh

Professor Michael Ardagh (MBChB, PhD, FACEM, DCH) is 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 PhD 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, FAFPHM). Having undertaken vocational training in public health medicine, he is now a public health physician working for the Waitemata District Health Board. He also has an academic appointment as a senior lecturer in public health for the Department of Community Health, University of Auckland.

Dale is a member of the National Cardiovascular Advisory Committee, which is currently writing the new cardiovascular health strategies. He is also a member of the Māori National Cardiovascular Committee. He has a keen interest in Māori health, epidemiology, cardiovascular disease and health informatics. Dale has recently been awarded a Harkness Fellowship in health policy. He will be working from Mount Sinai Hospital in New York for the first six months of 2004.

Dale has tribal affiliations to Ngāti Hine and Ngā Puhi.

Dr Anne Bray

Dr Anne Bray has been involved for many years in a wide 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 on the law and ethics, as well as serving 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. She is the mother of one son.

Fiona has a PhD in social and developmental psychology from the University of Otago. After lecturing 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 in representing 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 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.

In 2003 Philippa was due to complete a postgraduate Diploma of Professional Ethics at the University of Auckland.

Professor Donald Evans

Professor Donald Evans was elected a member of the Academy of Humanitarian Research, Moscow in 1996 and was a longstanding member of the governing body of the Institute of Medical Ethics.

Donald has conducted research projects for the Department of Health on the Ethical Review of Multi Centre Research, United Kingdom and on the training of ethics committee members, a practice that he pioneered in the United Kingdom. He has acted as a consultant to the Council for International Organizations of Medical Sciences on the development of guidelines for ethical review in developing countries. He is currently co-leading a World Health Organization project on the development of ethical review of human participant research in South East Asia, South America and Africa.

Donald has served for many years as a chairperson, member and consultant of many ethics committees including those of the British Medical Association, the Royal College of Nursing, the Health Research Council of New Zealand, the Association of Clinical Research Contractors, and the University of Otago. He was a member of the Independent Biotechnology Advisory Council for its duration. Currently he chairs the Otago Regional Ethics Committee and is a member of the Canadian Institute of Health Research Stem Cell Oversight Committee.

Donald conducts training of ethics committee members in New Zealand and various Asian countries. He was appointed Professor and Director of the Centre for Bioethics Research, University of Otago in 1997 and was recently appointed Visiting Professor at the Medical University of Dalian, China.

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 with 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 Co-Director of the AIDS Epidemiology Group, which 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 is a member of its Scientific Advisory Group.

In 1987/88 Charlotte was a medical advisor to Judge Cartwright for the Cartwright Inquiry and has subsequently published articles on related 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, which produced guidance notes for health researchers and ethics committees.

Professor Neil Pearce

Professor Neil Pearce has recently established the Centre for Public Health Research, Massey University Wellington Campus, of which he has been appointed Director. The Centre is conducting public health research in a wide range of areas including respiratory disease, cancer, diabetes, Māori health, Pacific health, and occupational and environmental health research.

Since completing his PhD in epidemiology in 1985, Neil has been engaged in a diversity of public health research activities, focusing on both occupational epidemiology and asthma. His many research projects include the identification of the role of the asthma drug fenoterol in the New Zealand asthma mortality epidemic, the management of asthma in the community and, more recently, the causes of the increase in asthma prevalence in New Zealand and worldwide.

Neil was a member of the Health Research Council Public Health Research Committee and the Māori Health Committee from 1991 to 1996. From 1994 to 1996 he was also a member of the Council and Chair of the Public Health Research Committee.

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 PhD 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 United Kingdom.

As an academic, Martin teaches, researches and has published widely on disability. As a disabled person, he 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), serves on the Regional Committee for DPA, Palmerston North and is a committee member of the Manawatu Autistic Association.

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, 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 issues related to mental health and other types of civil litigation.

As a member of the Pacific Peoples Focus Group at the Ministry of Justice for the last three to four years, Mele has advised project leaders of the Tongan perspective and the general Pacific perspective. Other Pacific Island community groups in which she has been involved include the National Council of Tongan Women, the Tongan Women's Association and the Auckland Pacific Island Community Radio Trust.

Mele is a member of TaPasefeka Health Trust, a major provider of comprehensive health services in South Auckland and Auckland. She is also a faculty member of the New Zealand Law Society litigation skills programme, and a member of the Pacific Lawyers Association. Mele is a member of the Commission of Title D in the Anglican Church as the second representative of Tikanga Polynesia.

Terms of Reference

The role of the Committee

The National Advisory Committee on Health and Disability Support Services Ethics ('the National Ethics 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 Committee is established by and accountable to the Minister of Health.

The National Ethics 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 Committee is also required to:

- consult with any members of the public, persons involved in the funding or provision of services, and other persons that the Committee considers appropriate before providing advice on an issue (section 16(4) refers)
- at least annually, deliver to the Minister of Health a report setting out its activities and summarising its advice on the matters referred to it under section 16 of the Act by the Minister of Health.

In undertaking its functions, the National Ethics 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 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 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
- provide a second opinion in relation to decisions of health and disability ethics committees, the National Ethics Committee on Assisted Human Reproduction and any other ethical review committee established by the Minister of Health under section 16(3) of the Act.

In response to the recommendations of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region, the first task of the National Ethics Committee will be to:

- review the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand

- 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)
- consider the application of second opinion and appeal processes and recommend their appropriate use for ethics committees.

Composition of the Committee

The National Ethics Committee shall consist of not more than 12 members appointed by the Minister of Health ('the Minister'). The National Ethics 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 Committee shall have at least two Māori members, one of whom shall be a person with Māori research/ethics background.

The Director-General of Health will appoint an advisor to the National Ethics 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 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 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 Committee shall continue in office until their successor comes into office. Any member of the National Ethics Committee may at any time resign as a member by advising the Minister of Health in writing.

Any member of the National Ethics 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 Committee, or discharge any member of the National Ethics Committee or appoint new members to the National Ethics 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 Committee to be its Chairperson. The Chairperson will preside at every meeting of the National Ethics 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 Committee. This is intended to aid members of the National Ethics Committee by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect the National Ethics Committee and its members.

As an independent statutory body, the National Ethics Committee has an obligation to conduct its activities in an open and ethical manner. The National Ethics 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 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 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 Committee and the use of Committee funds.

Conflicts of interest

4. 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 Committee and its members and will ensure it retains public confidence.
5. 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 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.
6. 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.
7. A member of the National Ethics 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 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

8. The public has a right to be informed about the issues being considered by the National Ethics Committee. The National Ethics Committee should have procedures in place regarding the release of information and processing requests for information.
9. Individual members must observe the following duties in relation to Committee information. These provisions ensure that the National Ethics Committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.
 - Meetings of the National Ethics 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 Committee.
- Members must publicly support a course of action decided by the National Ethics 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 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 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 Committee will agree a work programme with the Minister of Health. The National Ethics 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 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 Committee must make reasonable attempts to consult with:

- health and disability ethics committees
- the National Ethics 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 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 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.

The National Ethics 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 Committee or the Chairperson of the National Ethics Committee decides.

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

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

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

Reporting requirements

The National Ethics Committee is required to:

- keep minutes of all Committee meetings which outline the issues discussed and include a clear record of any decisions or recommendations made
- prepare an annual report to the Minister of Health setting out its activities and comparing its performance to its agreed work programme and summarising any advice that it has given to the Minister of Health. The report is to include the National Ethics 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 Committee out of the Committee's allocated budget allocated and consistent with the Memorandum of Understanding between the National Ethics Committee and the Ministry of Health.

Fees and allowances

Members of the National Ethics Committee are entitled to be paid fees for attendance at meetings. The level of attendance fees is 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 Committee members.

Secretariat to the National Advisory Committee on Health and Disability Support Services Ethics at December 2003

Barbara Burt – Senior Analyst

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