

## **Terms of Reference**

### **National Ethics Advisory Committee (NEAC)**

#### **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 6 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 its activities in an open and ethical manner. The National Ethics Advisory Committee has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference.

## **General**

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

2. There is an expectation that members will make every effort to attend all the National Ethics Advisory Committee meetings and devote sufficient time to become familiar with the affairs of the committee and the wider environment within which it operates.
3. Members have a duty to act responsibly with regard to the effective and efficient administration of the National Ethics Advisory Committee and the use of committee funds.
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](mailto:appeals_neac@moh.govt.nz)