Review of the Current Processes for Ethical Review of Health and Disability Research in New Zealand

Report to the Minister of Health

National Advisory Committee on
Health and Disability Support Services Ethics
Kāhui Matatika o te Motu

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Foreword

Kia Ora Koutou

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, NEAC has given priority since its appointment in late 2001 to its review of the system of ethical review of health and disability research in New Zealand. As NEAC Chair, I am pleased to present this report of NEAC's findings and recommendations.

NEAC has used a wide range of methods to involve stakeholders, lay people and professional, Māori and non-Māori, in the health sector and the disability sector, and to draw upon their experience and expertise. The review's structure and methods are set out below. The Committee believes its recommendations rest upon the strong foundations of a fair and robust review process.

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

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

NEAC's review has focussed on processes for ethics committee review of national and multi-centre studies, options for second opinion and appeal, and observational studies and audit. Stakeholders have also offered insight into many wider issues. NEAC anticipates that it will in future be in a position to address these issues through its work to develop a Māori ethical framework for health research, and through review of the *Operational Standard for Ethics Committees* (2002). NEAC also believes follow-up work is needed on governance issues, concerning 'who is responsible for what' in relation to health and disability research ethics.

Andrew Moore
Chair
National Ethics Advisory Committee

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Executive Summary

The purpose of this paper is to:

- report to the Minister of Health on the results of the review of the current processes for ethical review of health and disability research in New Zealand carried out by the National Advisory Committee on Health and Disability Support Services Ethics (NEAC); and
- provide advice and make recommendations on how to address issues arising from that review.

The Minister of Health has asked NEAC to address as a priority, and to report back to the Minister on, four matters relating to ethical review arising from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (the Gisborne Inquiry), namely, national and multi-centre studies, second opinion and appeal processes, operation of ethics committees, and observational studies and related matters. These four matters combine to form a focused review of the current processes for ethical review of health and disability research in New Zealand.

NEAC has undertaken various and extensive consultation processes with stakeholders to obtain information on the operation of the current ethical review system and to develop and consider options for the future of the ethical review system. The information collected informs this review, and will also be used to inform NEAC's work in other areas.

As part of this review, NEAC sought to identify the overall goals, objectives, and desired outcomes that an ethical review system should achieve and be assessed against. The proposed goals, objectives and desired outcomes were developed with stakeholder input. They were used as a basis for development and consideration of the proposals in this report and will be used to inform NEAC's forthcoming review of the *Operational Standard for Ethics Committees 2002* (*Operational Standard*).

NEAC has identified and addressed the following key issues in this review:

1. Ethics Committee Review of National and Multi-centre Research, including which body should be the primary review body for such research, what secondary role there should be, and which body or bodies should have any such secondary role.
2. Statutory or Non-statutory Basis for Ethics Committees
3. Complaints, Second Opinions and Appeals for challenge to Ethics Committee decisions
4. Ethical Review of Audit and Related Activities
5. Privacy and Secondary Use of Identifiable Health Data for Research.

As part of this review, NEAC also prepared Draft Ethical Guidelines for Observational Studies and requested comments to assist in constructing a final set of guidelines.

Recommendations

In forming its recommendations, NEAC has focused on the strength of the arguments with regard to the options, rather than on the number of stakeholders for or against a particular option.

NEAC recommends that the Minister of Health:

Goals, objectives and desired outcomes

1. **Agree** that the goals, objectives and desired outcomes of an ethical review be used to inform NEAC's forthcoming review of the *Operational Standard for Ethics Committees* (*Operational Standard*).

Ethical review of national and multi-centre research

Which body should lead?

2. **Agree** that a new national ethics committee be established to be the primary review body for all multi-centre and national research studies.

What should the secondary role be?

3. **Agree** that, as part of the review of national and multi-centre studies, there be a 'locality assessment' for each region in which the research is to be conducted, assessing 'locality issues' only (suitability of any local researcher and of any local research environment and facilities; any specific issues relating to the local community). The key locality assessment question is, 'Given that this research would meet established ethical standards, is this particular locality and local researcher satisfactory?'

Which body or bodies should have that secondary role?

4. **Agree** that the secondary role of locality assessment of proposed national and multi-centre research be undertaken by the research host organisation(s) – such as DHB(s), Ministry of Health, iwi service provider(s), disability organisation(s) – as part of its authorisation process for research involving its staff or facilities; or, if there is no research host organisation, by a health and disability ethics committee in each region in which the proposed study is to be conducted.

Additional recommendations

5. **Agree** that further work be undertaken on the appropriate number and location of regional health and disability ethics committees.

6. **Agree** that NEAC addresses the issue of appropriate guidance on locality assessment and locality issues, including for single centre studies, in its review of the *Operational Standard*.

Statutory or non-statutory basis for ethics committees

7. **Agree** that health and disability ethics committees, and their review activities, be established on a direct statutory basis.

Second opinions and appeals

Complaints

8. **Agree** that NEAC addresses the issue of education about the availability of, and how to access, the complaints process in its review of the *Operational Standard*.

Second opinions

9. **Agree** that the current second opinion process, covering both the process and merits of an ethics committee decision, should be retained.

10. **Agree** that NEAC works with the Health Research Council Ethics Committee to address the issue of information about availability of, and how to access, the second opinion process.

Appeals

11. **Agree** that, in addition to the second opinion process, a right of appeal be established (including appeal on the merits) from ethics committee decisions.

Appellate body

12. **Agree** that an appellate body to hear any appeal from an ethics committee decision be established.

13. **Agree** that the appellate body should be a subcommittee of NEAC, with the power to co-opt appropriate expertise.

14. **Note** that any appellate body would need to be a properly constituted ethics committee in accordance with relevant paragraphs of the *Operational Standard*.

Ethical review of audit and related activities

15. **Agree** that ethical issues regarding audit and related activity be reviewed by those conducting the activity rather than by an ethics committee, where the activity meets the following criteria:

    15.1 it is to be conducted either internally or externally by persons who are under a professional obligation to preserve confidentiality;

    15.2 it does not include the collection of new or additional information from patients / consumers; and

    15.3 it does not include anything being done to (or withheld from) patients beyond their normal clinical management.

Expedited review

16. **Agree** that there be a process for expedited review in any cases in which ethics committee review of audit and related activities *is* provided.

Inform ethics committee

17. **Agree** that those who perform audits and related activities need not inform ethics committees, if these activities do not require ethical review.

Additional recommendations

18. **Agree** that NEAC further address in its review of the *Operational Standard* the issue of appropriate guidance on what are 'audit and related activities', and whether and to what extent they require ethics committee review, particularly when new or additional information is to be collected from patients / consumers.

19. **Agree** that service providers and the Ministry of Health continue to inform the public that audit and related activities are necessary for the provision of high quality health care.

Privacy and secondary use of identifiable data for research

20. **Agree** that NEAC address the issue of policy on the secondary use of identifiable data, where the data is initially collected for a purpose such as health care and is then used for research, as part of further work on the *Draft Ethical Guidelines for Observational Studies* (recommendation 22, below); and

21. **Agree** that in the interim NEAC give researchers and ethics committees guidance about when identifiable data can be used without consent, and in particular draw their attention to the section of the Health Research Council's *Guidance Notes on the Health Information Privacy Code*, which states:

The use of health records for research without the authorisation of the individual concerned should only be undertaken subject to certain extra conditions:

(1) the reasons for not seeking consent should be justified to the ethics committees. These reasons may be scientific, practical, or ethical ....

(2) the potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.

[The full *Guidance Note* includes examples of the reasons for not seeking consent and examples of the benefits of such research.]

Draft ethical guidelines for observational studies

22. **Agree** that NEAC undertake further work and consultation on its *Draft Ethical Guidelines for Observational Studies*.

Other issues

23. **Agree** that NEAC scope the task of developing a governance framework for health and disability research ethics. A completed framework (eg, as the UK has) would identify and clearly match accountable parties, such as the investigator, research sponsor, ethics committee, and research host organisation, with the key accountabilities, including ethical review, assessment of legal issues, scientific assessment, consultation with Māori, monitoring of study conduct, and adverse event reporting.

24. **Note** that information gathered from stakeholders relating to Māori responsiveness will be used:

    24.1 to inform NEAC's ongoing work to develop a Māori framework for ethical review; and

    24.2 in NEAC's review of the *Operational Standard*.

25. **Note** that the findings from the questionnaires, interviews, discussion documents and cross-sectoral consultation workshops relating to the operation of ethics committees

    25.1 will be used to inform NEAC's review of the *Operational Standard*; and

    25.2 may highlight areas requiring further work, which will be discussed with the Minister as part of the development of NEAC's future work programme.

Background

NEAC was established by, and is accountable to, the Minister of Health under section 16 of the New Zealand Public Health and Disability Act 2000, and its members were appointed in December 2001.

NEAC's statutory functions are to:

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

NEAC's membership is set out in Appendix 1.

Review work arising from the Gisborne Inquiry

The Minister asked NEAC to address as a priority, and to report back on, four matters arising from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (the Gisborne Inquiry).

These are to:

- 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)
- consider the application of second opinion and appeals processes and recommend their appropriate use for ethics committees
- review the current processes for the ethical review of national and multi-centre research
- 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.

These four matters combine to form a focused review of the current processes for ethical review of health and disability research in New Zealand.

The specific recommendations that the Gisborne Inquiry made in relation to ethics committees are set out in Appendix 2.

Work outside the scope of the review

This report concerns only the review of the current processes for ethical review of health and disability research in New Zealand. The report does not address NEAC's other ongoing or forthcoming work.

Review of the *Operational Standard for Ethics Committees*

The *Operational Standard for Ethics Committees* was last updated by the Ministry of Health in 2002. The Minister of Health has signalled that NEAC will be responsible for future revisions to the *Operational Standard*.[1]

Wider review of the operation of ethics committees

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 issues relating to the operation of the current system for ethical review of health and disability research, such as structure and resourcing. Some of the wider matters raised will be addressed in NEAC's forthcoming review of the *Operational Standard* (See Recommendation 25, below).

Development of a Māori framework for ethical review

NEAC is also responsible for the development of a Māori framework for ethical review.[2] As the first stage in this project, NEAC has completed background interviews with key informants. The committee has agreed that the second stage will be to commission a background 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.

[1] Hon Annette King, Foreword to *Operational Standard for Ethics Committees*. Ministry of Health, 2002.

[2] Hon Annette King, letter to NEAC, 20 November 2002.

Processes of the Review

In accordance with section 16(4) of the New Zealand Public Health and Disability Act 2000, NEAC has undertaken consultation with stakeholders on the operation of the current ethical review system and on options for the future of the ethical review system.

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 informing them of the review and inviting 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 (n=158) and a sample of researchers (n=166) in June 2003. Researchers were selected by choosing every 13th researcher from lists of single-centre and multi-centre applications submitted to regional ethics committees in 2001 and 2002. Additional questionnaires were sent to researchers who approached NEAC for input to the review (n=17), and to Māori researchers currently funded by the Health Research Council (n=85). The main purpose of the questionnaire survey was to elicit the range of key stakeholder views on the issues.
- Two consultation meetings with Chairs of health and disability ethics committees (focused on perceptions of current system of ethical review; and on review process and goals, objectives, and desired outcomes for a system of ethical review, respectively).
- 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, and carried forward where relevant to this report.

In the second stage of the review, NEAC developed, and undertook the following consultation on, the options for the future of the ethical review system:

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

- release of two discussion documents for comment over a six-week consultation period. More than 600 copies of the discussion documents were distributed. The discussion document, *System of Ethical Review of Health and Disability Research in New Zealand*, received 84 submissions. The discussion document, *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
- one consultation meeting with members of regional health and disability ethics committees, focused on options contained in NEAC's discussion documents
- one consultation meeting with staff and the Chair of the Health Research Council.

The lists of interviewees, respondents to the questionnaire survey, attendees of the cross-sectoral consultation workshops, and respondents to the discussion documents, are attached as Appendices 3–6, respectively.

In addition, NEAC benefited throughout its review process from information and advice provided by the Health Research Council and the Health Research Council Ethics Committee.

There was significant diversity of stakeholder opinion on some key issues. NEAC has worked hard to reflect convergences of view where these could be identified, and divergences where these remain. In forming its recommendations, NEAC has focused on the main reasons stakeholders have given for their views and the strength of the arguments, rather than on the number of stakeholders for or against a particular position.

In addition, there were two criticisms of the review process: insufficient engagement with or responsiveness to Māori, and an inadequate consultation timeframe.

Māori responsiveness

Issues of Māori responsiveness have been raised throughout the review, including most recently in responses to the discussion documents and during the cross-sectoral workshops. For example, one Māori researcher, who responded fully to both discussion documents, also commented that, 'This whole review doesn't deal sufficiently with Māori research communities' needs and concerns, the Treaty of Waitangi and its appropriate application in research or ethical review'.

In addition to the general consultation activities outlined above, there were a number of points in the review process where NEAC specifically sought Māori input (eg, the additional sample of Māori researchers surveyed, invitations to participate in the cross-sectoral workshops). However, these opportunities were not taken up to the extent that the Committee feels as confident as it would wish that it has obtained fully representative statements of Māori stakeholder views. For example, of the 85 Māori researchers who were sent the questionnaire survey in the additional sample, only 16 responses were received.

The Minister of Health noted in November 2002 that NEAC's review 'will be the main focus of your work over the next year. However, as NEAC's focus shifts from the priority areas to the wider tasks ... I would appreciate being informed of how you plan to progress the work to develop a framework for Māori ethical review.'[3] NEAC anticipates that the information gathered from stakeholders in this review that relates to Māori responsiveness will inform both its work on the Māori framework, and its review of the *Operational Standard* (See Recommendation 24, below).

Consultation period for discussion document

The Health Research Council Ethics Committee felt that the six-week consultation period provided for the two discussion documents was not adequate.

NEAC notes the various and extensive consultation processes that it has undertaken during this review, as set out above.

[3] Hon Annette King, letter to NEAC, 20 November 2002.

Goals, Objectives and Desired Outcomes of an Ethical Review System

While the principles to be applied to research proposals within ethical review are clearly set out in the *Operational Standard*,[4] NEAC has sought to identify the overall goals, objectives, and desired outcomes that an ethical review system itself should achieve and be assessed against.[5] The proposed goals, objectives and desired outcomes, set out in the table below, were developed with stakeholder input. They were used as a basis for development and consideration of the proposals in this report.

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 • Ensuring consistency with the Treaty of Waitangi	
Objectives	**Desired outcomes**
Accountable	• Public accountability requirements are defined • Ethical reviews meet internationally recognised standards • Ethical reviews take into account relevant legislation
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

[4] Ministry of Health, 2002.

[5] A system of ethical review includes ethical aspects of self-review, peer review, scientific review and grant committee assessment, as well as ethics committee review. The focus of this NEAC review has been on matters concerning ethics committee review.

Objectives	Desired outcomes
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
Responsive to Māori	• A Māori ethical framework is developed and implemented • Processes for consultation with Māori are clear and appropriate • Māori participation in the decision-making component of the system is maintained • Iwi and regional diversity is understood and accommodated • 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

Recommendation

NEAC recommends that:

1. the goals, objectives and desired outcomes of an ethical review be used to inform NEAC's forthcoming review of the *Operational Standard*.

Key Issues and Findings

Set out below is a discussion of each of the core issues covered by this review, including:

- a description of the current situation
- concerns with the current situation
- options
- stakeholder comment on the options
- NEAC's recommendations.

Ethical review of national and multi-centre research

Current situation

Multi-centre research is, 'Research conducted simultaneously by several investigators at different centres, with identical methods and following the same protocol'.[6] The *Operational Standard* does not define 'national research', but it can be characterised as, 'Research conducted by the investigator(s) at one centre, potentially or actually involving participants nationwide; eg, through a nationwide telephone survey, or through access to a database of a national organisation.' On this definition, the national study is *not* a form of multi-centre study.

At present there are 15 regional health and disability ethics committees, almost exactly reflecting the 14 Area Health Board regions that were in place until 1993 (now replaced by 21 District Health Boards).[7] For workload reasons, the 15 committees include two committees each in the Auckland and Canterbury regions. The role of these ethics committees is to provide independent ethical review of innovative practice and health or disability research to be conducted in their region.

In current practice, applications for national research are reviewed by one committee in each of the involved regions.

[6] *Operational Standard*, p 134.

[7] This review focuses only on the publicly funded health and disability ethics committee system, and consequently not on all ethics committees that are approved or accredited by the Health Research Council Ethics Committee.

The current process for the review of multi-centre research[8] is that:

a. the committee for the region in which the lead investigator is based acts as the primary committee, co-ordinating the responses from the other regional committees involved in the study

b. these secondary committees respond to the primary committee on the research application, and communicate to the primary committee their concerns and any recommended alterations to the application

c. The Chair of the primary committee convenes the discussion of concerns with the Chairs of the regional committees that expressed those concerns

d. The primary committee conveys the consensus view of the involved ethics committees to the applicant.[9]

The current system for the review of multi-centre research results in the lead researcher being presented with one decision on the protocol from the lead ethics committee, following the collation, by the lead committee, of comments from the ethics committees of all regions involved in the research. If there is a difference of opinion among committees, the Chair of the lead committee must seek agreement with the Chairs of those committees in order to reach a consensus decision, either to approve, or conditionally approve, defer, or (very rarely) decline the proposal. Once agreement is reached, the lead committee provides the decision on the study on behalf of the other committees.[10] The system thus produces a single expression of the decision reached by the committees involved in the review.

The policy for the operation of multi-centre ethics committee review, as set out in the *Operational Standard*, allows in principle for more than one decision to be made on a protocol, by allowing a regional ethics committee to make a decision for its region, which may differ from the consensus decision presented to the researcher by the lead committee. Paragraph 312 of the *Operational Standard* implies that any participating committee with concerns 'on the basis of local or ethically relevant matters' is authorised, subject to the process requirements of paragraph 314, to make its own decision for its own region. This policy could result, in rare cases, in a region not participating in the study, should the committee for that region not approve the study for conduct in that region.

[8] *Operational Standard*, paragraph 308.

[9] *Operational Standard*, paragraph 308. It should also be noted that there are other important processes whose results, though not strictly part of ethics committee review, are reported through ethics committee review. These include applicant consultation with Māori, and technical review in relevant cases (eg, by the Standing Committee on Therapeutic Trials, or by the Gene Technology Advisory Committee).

[10] Evans D. 2002. *The New Zealand System of Ethical Review of Multi-Centre Research*, p 3.

Whether New Zealand's multi-centre review process demands a single ethics committee opinion, or allows multiple single-centre opinions, is important, because there is an issue about whether New Zealand is in accord with important international legislation on health research, such as the European Union Directive 2001/20/EC on clinical trials. The Directive states:

> *For multi-centre clinical trials limited to the territory of a single Member State, Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State.*
>
> *In the case of multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given for each Member State concerned for the clinical trial.*[11]

Other ethics committees

In addition to review provided by the 15 regional ethics committees, ethics committee review is also conducted in New Zealand by the National Ethics Committee on Assisted Human Reproduction (NECAHR), institutional ethics committees and private sector ethics committees, and in a small range of cases, especially in the provision of second opinions, by the Health Research Council Ethics Committee (HRCEC). Some of the institutional and private sector committees are also approved by the HRCEC. NECAHR is established by the Minister of Health under section 11 of the New Zealand Public Health and Disability Act 2000.

Workload

During the period 2000–02, review of multi-centre research proposals constituted more than half the workload (average: 62%) for nine of the 13 regional ethics committees – here treating the two Auckland committees as one, and prior to the establishment of the second committee in Canterbury. More detail is set out in Table 1 below.

Multi-centre studies form a small percentage of *studies* that receive ethics committee review. In 2002, it was just 15% (121 out of 811 studies). In the current system, however, each involved ethics committee fully reviews each multi-centre study. The consequence is that multi-centre studies form a high percentage of ethics committee *reviews*. In 2002, it was 47% (608 out of 1298 reviews), with each multi-centre study receiving, on average, five full ethics committee reviews.

Table 2, below, sets out the total number of multi-centre studies from 1999 to 2001.

[11] Directive 2001/20/EC of the European Parliament, 2001, Article 7.

Table 1: *Reviews* of multi-centre studies as percentages of overall REC workloads (total reviews)

Committee	2000 %	2001 %	2002 %	Average %
Auckland (X and Y)	30	22	29	27
Bay of Plenty	65	61	88	71
Canterbury	30	37	37	35
Hawkes Bay	64	80	71	72
Manawatu/Whanganui	45	64	66	58
Nelson/Marlborough	100	92	66	86
Otago	30	27	41	33
Southland	69	90	85	81
Tairawhiti	59	78	83	73
Taranaki	57	96	93	82
Waikato	56	59	61	59
Wellington	28	37	44	36
West Coast	83	100	86	90

Source: Regional Ethics Committee Annual Report data 2000–02.

Table 2: Number of national and multi-centre research *studies* reviewed by regional health and disability ethics committees

	1999	2000	2001	Average per annum
National multi-centre studies	6	3	9	6
Non-national multi-centre studies	45	55	80	60
Total number multi-centre studies	51	58	89	66

Source: Regional health and disability ethics committee data: Protocol Numbers of Multi-centre studies from 1999 to 2001 (Donald Evans, personal communication).

Note: 2002 data are not included because 'national study' data is not given in Annual Reports.

Concerns with current situation

The Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region (the Gisborne Inquiry Report) identified several areas that it regarded as problematic for the operation of regional ethics committees in the current system of ethical review. The report suggested that the involvement of multiple ethics committees in the review of multi-centre or national research proposals created difficulties for investigators. It recommended that a national ethics committee be established to review national and multi-centre study proposals (Ref. Section 9.33, and also 9.17, and Recommendation 11.22).

The Minister of Health has asked NEAC to examine further certain matters concerning ethics committee review on which the Gisborne Inquiry made recommendations. In particular, the Minister asked NEAC to review the current processes for the ethical review of proposals for national and multi-centre research and to make recommendations on these. In effect, this is a request for NEAC's independent second opinion on this policy issue.

During NEAC's review, ethics committees and their members generally expressed strong support for the current system of ethical review, and for its retention. A wide range of other stakeholders, including a number of researchers, expressed similar views. Ethics committees and their members also commented that they do listen to concerns expressed about the processes for ethical review and work to modify their processes accordingly. However, ethics committees and members also acknowledged there may be some issues that need to be addressed, particularly in the area of ethical review of multi-centre research studies (eg, clarifying the extent of secondary committee review; reconsidering the ability of secondary committees to opt out of multi-centre or national research; and providing better resourcing to facilitate learning, common understanding and consistency among ethics committees).

On the whole, researchers were significantly less positive about the current system and raised a number of concerns. Further, there are some indications that Māori researchers are less than satisfied with the current system of ethical review, although the response rate to the survey of Māori researchers (16 responses out of 85 surveyed) is too low to form any firm conclusions from that source on its own.

Stakeholders, including researchers, ethics committee members, and others involved in ethical review, expressed concerns about the following aspects of the current system, the first of which relates specifically to review of multi-centre studies:

- Multi-centre applications – delays, duplication, variation of approaches and decisions between regional committees (eg, one multi-centre study where the participants had to be provided with three different ways of declining to participate – phone number to call, stamped self-addressed envelop to respond, oral response); and the need for greater clarity and consistency across ethics committees in terms of standardised forms, processes, and a common understanding of issues like 'audit'.
- Issues concerning Māori research – there was widespread support from both Māori and non-Māori for the importance of Māori-responsive research and ethical review, including support for consultation and for Māori workforce development. There were also concerns, expressed especially by some researchers, including Māori. These stakeholders perceived ethics committees' requirements for approval of studies involving Māori as more onerous than for other studies. Concerns were also expressed about ethics committees' lack of understanding of tikanga Māori, the Treaty and kaupapa Māori research; and that the current processes required for researchers to consult with local iwi are problematic because iwi are not established (do not have personnel, resources and processes) to respond to this consultation.

- Regional ethics committee members' level of expertise or knowledge of research issues and methodologies, including elements that are essential for validity of research, and the need for there to be more 'fluent' connections between ethical review and scientific review.
- Transparency and accountability of ethics committees, including how members are appointed; how decisions are made and on what basis; and accountability if committees do not follow the *Operational Standard*. There were also several comments expressing concern to ensure that research is not unfairly blocked or delayed by particular biases on a committee or certain power dynamics on committees.
- Jurisdiction and boundaries of ethics committees, including a number of comments about the extent of committees' focus on study design and methodological research issues as well as ethical issues and extending into the realm of scientific debate; comments on committees' attempting to 'micromanage' research (eg, minor wording and 'typos' in information sheets and consent forms) rather than focusing on key ethical issues; the need for greater clarity around the functions and roles of the regional ethics committees in relation to other ethics committees; issues around audit versus research, privacy and ethics.

Options

As a result of examining the current system for the review of national and multi-centre research, and exploring stakeholder experiences and suggestions concerning this system, a number of options were generated for consideration.

Which body should lead?

In terms of a primary review body for national and multi-centre research proposals, NEAC considered two main options:

1. A regional primary committee model, such as the one currently in operation, where the primary regional ethics committee would vary based on the region in which the applicant is based; or
2. A national primary committee, as recommended by the Gisborne Inquiry (Recommendation 11.22), which would be one and the same for all national and multi-centre studies.

The key question for the primary review body to address is: 'Would this research, if carried out at a satisfactory locality by a satisfactory researcher, meet established ethical standards?'

The composition and membership of a national ethics committee for lead review would need to meet the relevant requirements of section 6.2 of the *Operational Standard*. Any national ethics committee would also need to be approved by either the Director-General of Health or the Health Research Council Ethics Committee (HRCEC), if participants in research approved by it were to enjoy certain entitlements under the Injury Prevention, Rehabilitation and Compensation Act 2001. The HRCEC would also need to approve the constitution of any such national ethics review committee, if it were to review any study approved for Health Research Council funding. It would also be desirable for any national ethics review committee to secure endorsement under the US Department of Health and Human Services regulation 45 CFR 46.103(d), to facilitate the small number of multi-centre studies conducted in New Zealand under a US Federal Wide Assurance.[12]

The workload of such a national ethics committee would be the total number of national studies plus multi-centre studies per annum (121 in 2002). Assuming 11 meetings per annum, in 2002 this would have averaged at 11 new national or multi-centre studies for review per meeting. To put this in perspective, the average number of new studies reviewed per meeting by a regional ethics committee in 2002 was 8.5 (93 for the year).[13] Were a national committee to be established for review of national and multi-centre studies, policy-makers might also wish to explore whether, with appropriate configuration of membership and/or sub-committee structuring, it could conduct the review activities currently conducted by NECAHR in the area of assisted human reproduction.

Extent of assessment by secondary committee(s)

A second question, related to 'Who leads?', concerns the extent of secondary assessment. NEAC considered the following 'sub-options' under each of the main options (regional lead committee or national lead committee), concerning the extent of secondary assessment:

a. A full review also, by each secondary committee

   Under this sub-option, as currently, in addition to review by the primary or lead body, each relevant secondary ethics committee would also conduct a full review of each multi-centre proposal. Each secondary body would consequently also address the central question of ethics committee review, 'Would this research, if carried out at a satisfactory locality by a satisfactory researcher, meet established ethical standards?'

b. Locality assessment only, by each secondary committee

   Under this option, each relevant secondary ethics committee would assess 'locality issues' only. These are: suitability of any local researcher, and of any local research environment and facilities; and any specific issues relating to the local community. The key question to be addressed through locality assessment is, 'Given that this research would meet established ethical standards, is this

[12] See *Operational Standard*, section 3.3, regarding approval of research receiving US federal funding.

[13] Regional Ethics Committee Annual Report data 2002.

particular locality and local researcher satisfactory?' This option is current policy in the United Kingdom regarding the role of secondary assessment.[14]

c. No review by secondary committee(s)

Under this option no secondary regional ethics committee would conduct any review or assessment. One possibility in such a system would be for the relevant research host organisation(s)[15] (eg, District Health Board(s), Ministry of Health, iwi provider(s), or disability support organisation(s)) to make a 'locality assessment' as part of its authorisation process for research involving its staff or facilities. This policy option is under consideration in European Union countries, including the United Kingdom.

In a system with either a regional or a national lead committee for review of multi-centre studies, any move to sub-option b 'locality assessment only', or to sub-option c 'no assessment or review' for secondary committees, would considerably reduce the workload of some regional committees, given current workload practices. Consideration would need to be given to either increasing regional ethics committee workload in other areas, or to amalgamation of some of these committees into a smaller number of regional ethics committees serving larger regions. If the latter option were taken, consideration would need to be given to appropriate realignment to relevant District Health Board boundaries, and to a membership profile reflective of the larger regions.

Stakeholder comment

Which body should lead?

The majority of responses to the two main options favoured Option 1 – regional lead committee (and its various sub-options), with fewer, although still a significant number, supporting Option 2 – national lead committee and its sub-options.

One of the perceived benefits of a regional committee system identified by respondents is the ability for ethical review to be responsive to the community. This was spelt out in terms of community knowledge, local consultation and input (including Māori consultation and the opportunity for the researcher to attend meetings), ownership, and ability to assess impact of research on local communities. An added argument was that the principle of decentralisation of decision making was consistent with the philosophy underpinning the *New Zealand Health Strategy* and the *New Zealand Disability Strategy*. Another identified benefit of a regional committee system was the expertise that has been developed over time by the regional committees.

Perceived risks identified for a regional system were lack of expertise (particularly about research methodologies), duplication, high workload, resource issues, inefficiencies and inconsistencies.

[14] Central Office for Research Ethics Committees (COREC). *Governance Arrangement for NHS Research Ethics Committees*, London: July 2001, section 8.8.

[15] The 'host organisation' is the organisation in which the research takes place. In multi-centre studies, there will typically be more than one host organisation. In some national or multi-centre studies, however, there may be no host organisation.

It was felt that a major risk about the establishment of a national ethics committee would be that the benefits of the regional committee system (eg, community responsiveness; expertise developed over time) would be lost. There were also concerns about the cost of establishing a national organisation, bureaucratic delays, academic bias and the professionalisation of the ethical review process. Some thought a national committee would have too high a workload; others thought its workload would be too low.

Most, if not all, of the identified risks for a regional system were seen to be resolved by (benefits of) a national committee structure. Cancer Trials New Zealand suggested that a national committee would be operationally easier, and that it would be even better if there could be such a committee for Australasia. The benefits of a national ethics committee were also seen to include the ability to attract and maintain a high level of expertise and experience, and to centralise and thereby strengthened reporting and monitoring of serious adverse events in clinical trials.

Some stakeholders proposed a third option, reducing the current number of regional committees, to address the issues identified with the current regional system.

The emphasis of many of the concerns expressed by stakeholders appears to be, not so much whether there should be a national or regional lead reviewer, but more to do with the role of secondary review or assessment, including lack of clarity about its purpose and extent, the duplication of work it is perceived to involve at present, associated delays, and perceived inconsistent approaches of individual regional committees.

Extent of assessment by secondary committee

In terms of the sub-options, support was fairly evenly divided between options a (full secondary review) and b (locality assessment only), with only relatively a small number of respondents expressing support for option c (no secondary review by ethics committees).

Broken down under the main options, the majority of those favouring Option 1 (retaining the regional committees as lead review bodies), supported sub-option a (full secondary review). Of those favouring Option 2 (a national committee for lead review), greatest support was for sub-option b (locality assessment only, by regional committees).

One concern expressed about sub-option c (locality assessment carried out by the host organisation) was that it was perceived to be reminiscent of the situation prior to the Cartwright Inquiry, where host organisations were responsible for the ethical review of research involving their staff or facilities. On the other hand, two respondents noted that host organisations:

> *... already have statutory responsibilities in provision of care that meets the Health Commissioner Act and various accreditations. Health Research Protection Administrators (HRPAs) [in place in 10 DHBs] already have accountability for protection of research participants ... so suggest we build on that system.*

It is clear that, whichever option is chosen for lead review, there is a lot of support for some form of continued local input into the ethical review process, including concern to take into account the cultural perspectives of the affected regions.

Recommendations

Which body should lead?

There was significant endorsement from within NEAC's membership of a regional committee lead, on grounds of its 'community responsiveness', its continuation with experience and expertise already well developed, and its ease of communication between researchers and committees. From this viewpoint, many of the issues identified with the current system for ethical review of national and multi-centre studies (lack of expertise, duplication, high workload, resource issues, inefficiencies and inconsistencies) were also thought to be related more to process than structure, and to be addressed to at least some extent by NEAC's other recommendations (clarifying the secondary role in ethics committee review, having a direct statutory basis for ethics committees, providing an appeals process, etc.), discussed below. The significant costs associated with establishing and sustaining a new national body were also noted.

On the other hand, there was also significant endorsement from within NEAC's membership of a national committee lead. This was on grounds of increased consistency and efficiency in ethics committee review process and decision, considerable potential for concentration of expertise and experience in the review of national and multi-centre studies, reduced compliance costs, and a perceived serious need for a new national organisation to lead further development of high quality and publicly accountable ethics committee review practice.

While an appreciable minority of NEAC supported Option 1, the majority of the Committee supported Option 2. Consequently, NEAC recommends that:

2. a new national ethics committee be established to be the primary review body for all multi-centre and national research studies.

What should the secondary role be?

NEAC was also persuaded that there is need for only *one* ethics committee review of each multi-centre study. Many single-centre studies are ethically just as complex as multi-centre studies, and policy and practice has long accepted that single-centre studies need only one ethics committee review. Furthermore, some studies that are currently reviewed through the single-centre process are in fact multi-national, multi-centre studies, with a single New Zealand centre. Again, policy and practice has long accepted that these multi-centre studies need only one full ethics committee review. NEAC's view is consequently that any secondary role in ethics committee review should *not* be full ethics committee review. It should instead be locality assessment only, concerning: adequacy of any local researcher, facilities, and resources; and any special features of populations in the locality in which the research is to be conducted.

A defining feature of multi-centre research, under current policy, is that it is conducted in more than one region. In these cases, NEAC was persuaded of the need for some form

of continued local input, and for review that takes serious account of cultural perspectives from each of those regions. National studies, however, are conducted by researchers at only one centre, potentially or actually involving participants nationwide (eg, by telephone interview, or by access to a national database). National studies will need only one locality assessment.

NEAC recommends that:

3. as part of the review of national and multi-centre studies, there be a 'locality assessment' for each region in which the research is to be conducted, assessing 'locality issues' only (suitability of any local researcher and of any local research environment and facilities; any specific issues relating to the local community). The key locality assessment question is, 'Given that this research would meet established ethical standards, is this particular locality and local researcher satisfactory?'

Which body or bodies should have that secondary role?

NEAC supports the need for local input from each region in which health and disability research is to be conducted. The Committee notes that research host organisations already have responsibilities, arising from a variety of statutory and contractual sources, to ensure that their facilities and resources are adequate for the service and research activities that use these, and to ensure that any researchers who use these are competent to do so. Host organisations typically also have clear obligations to be responsive to Māori and to their other communities. In short, host organisations – the DHB, Ministry, iwi, disability, and other organisations in which health and disability research is conducted – already have obligations to conduct 'locality assessment'. Where there is a research host organisation, then, the issue is whether its locality assessment would be *sufficient* input into an ethics committee review process that would in every case be conducted *independently* of the host organisation. The fact that there would always be independent ethics committee review under this option distinguishes it sharply from the pre-Cartwright situation of institutional review.

NEAC notes the possibility that host organisations might sometimes face conflicts of interest here (eg, where they would receive payment for hosting the research). On the other hand, it also notes that host organisations are often uniquely well placed to assess whether proposed research would conflict with important interests, such as with patient access to the organisation's facilities, or with the non-research obligations that its researcher-employee might have within its organisation. On balance, NEAC's view is that locality assessment for national and multi-centre studies is best conducted by host organisations.

NEAC also notes the possibility that for some national or multi-centre research, there might be no research host organisation. In such cases, there will be no locality issues concerning host organisation facilities or resources, but important issues might remain concerning the local researcher, or concerning the populations with whom the study is to be conducted. In light of these considerations, NEAC recommends that:

4. the secondary role of locality assessment of proposed national and multi-centre research be undertaken by the research host organisation(s) – such as DHB(s),

Ministry of Health, iwi service provider(s), disability organisation(s) – as part of its authorisation process for research involving its staff or facilities; or, if there is no research host organisation, by a health and disability ethics committee in each region in which the proposed study is to be conducted.

In addition, in light of Recommendations 2–4, above, NEAC recommends that:

5. further work be undertaken on the appropriate number and location of regional health and disability ethics committees
6. NEAC address the issue of appropriate guidance on locality assessment and locality issues, including for single-centre studies, in its review of the *Operational Standard*.

Statutory or non-statutory basis for ethics committees

Current situation

The actions of regional ethics committees do not have any direct statutory basis, but their public authority arises indirectly via such statutory provisions as:

- section 32 of the Injury Prevention, Rehabilitation, and Compensation Act 2001, concerning the role of ethics committees in relation to personal injury caused by medical misadventure
- section 25(1)(c) of the Health Research Council Act 1990, concerning the approval of ethics committees
- the Health Information Privacy Code 1994, where approval by an ethics committee is referred to (see Rules 2, 10 and 11 of the Code).

Concerns with current situation

The issue of a lack of direct statutory basis for ethics committees was one of the issues raised by members of the Health Select Committee with the NEAC Chair during in-person discussion in August 2003 of NEAC's submission on the Human Assisted Reproduction Supplementary Order Paper. These Select Committee concerns were also reported to NEAC through the Ministry of Health on other occasions. A direct statutory basis would provide a clear and explicit source of public authority and framework of public accountability for the important work of ethics committee review. NEAC also understands that there is policy-maker concern that there may be a need to introduce a statutory requirement on researchers to submit proposals for ethical review, and a feeling that the ethics committees considering such proposals would themselves need a direct and accountable statutory basis on which to perform this public function.

Options

Under a system with either a regional or a national lead committee, consideration will need to be given to whether the system of ethical review of health and disability research in New Zealand should have:

- no direct statutory basis. This is the current situation for regional ethics committees. It would be an option also for any national committee established for review of multi-centre studies. Non-statutory options include establishment by Cabinet decision (eg, Toi Te Taiao: The Bioethics Council) or establishment by the Ministry of Health (regional ethics committees are established in this way)
- a direct statutory basis. This could involve having the committees that carry out ethical review of health and disability research established under statute (eg, under section 11 of the New Zealand Public Health and Disability Act 2000, by the Minister of Health, by written notice to Parliament).

Stakeholder comment

The discussion document did not contain a specific question on this matter, although the issue was set out in the body of the document and the feedback form contained space for 'other comments'. The issue was also addressed in the Auckland cross-sectoral consultation workshop and in the Auckland meeting with members of regional ethics committees.

Of the submissions that highlighted this topic, responses were almost evenly divided amongst those opposing, those for, and those with no views on whether or not the ethical review system ought to have a direct statutory basis. According to the Health Research Council Ethics Committee, ethics committees already have sufficient authority, responsibilities and accountabilities without encumbering their operation, and establishing them under statute would have a detrimental effect on the principles of ethical review.

Stakeholders in the cross-sectoral consultation workshop, particularly some ethics committee members, felt that a non-statutory basis provided committees with more independence and was less prescriptive. In terms of independence, respondents expressed concern about:

- political influence if members are appointed by the Minister
- the potential for academic/professional bias.

However, some queried the perception that a non-statutory basis would provide independence for ethics committees, stating that it is more a perceived than a real difference and that much depends on the nature of the appointment process (eg, transparency, openness, local community involvement).

Other stakeholders in the workshop noted that a lack of statutory basis means ethical review is not mandatory, and one stakeholder thought that it would also mean there is no indemnity for ethics committee members.

In general, stakeholder comment indicates there is perceived to be insufficient information about the need for, or the implications of, a statutory basis for ethical review and ethics committees.

Recommendation

The Committee believes that a direct statutory basis would provide a clear and secure source of public authority for the important function of health and disability ethics committee review, together with a clear framework of public accountability for the exercise of that public function. It would also provide a foundation on which to base any future consideration of whether to introduce a statutory obligation for researchers to seek ethics committee review of health and disability research.

NEAC recommends that:

7. health and disability ethics committees, and their review activities, be established on a direct statutory basis.

Complaints, second opinions and appeals

Current situation

Complaints

The *Operational Standard* provides that complaints may be made about:

- the performance or conduct of committee members or the administrative procedures of a committee, either directly to the committee or to the National Co-ordinator (section 7.13)
- the decisions of ethics committees to the committee itself, NEAC or the Health Research Council Ethics Committee (section 7.14).

Second opinions

The *Operational Standard* (section 7.12) allows for ethics committees to seek second opinions during the consideration of research applications, and also for applicants who disagree with a decision made by an ethics committee to do so. It states:

- a second opinion is not regarded as a higher judgment but as a review of the proposal by an independent committee. The second opinion is not binding and neither the National Ethics Committee nor the HRC Ethics Committee is an appeal body in the strict legal sense[16]
- the final decision on an application rests with the original ethics committee, which must take into account the second opinion. The original committee must provide reasons for the final decision to both the applicant and the committee from which the second opinion was sought
- ethics committees may be requested to review decisions made if relevant new information is received

[16] By arrangement between NEAC and the Health Research Council Ethics Committee (HRCEC), the HRCEC is the current presumptive provider of second opinions, at least until NEAC completes its current review.

- in the case of multi-centre research proposals the concerns of any committee should be clearly identified before a second opinion is requested. Such a request would usually be sought after the primary committee has made a decision. The primary committee and the relevant secondary committee(s) must take into account the second opinion when making the final decision, and must provide reasons for the decision to both the applicant and the committee from which the second opinion was sought.

In the period 2000–03, the Health Research Council Ethics Committee provided five second opinions to researchers and regional ethics committees, and four pieces of advice or independent comment to regional ethics committees. Over the same period six complaints were received, from researchers, participants and in one case, a third party.[17]

Appeals

Under the current system, there is no process to allow regional ethics committee decisions to be appealed to an independent body.

As indicated above, in the current system, a second opinion is not a binding determination, but is instead only advisory to the ethics committee that made the initial determination. The committee that provided the original opinion might be vulnerable to judicial review, if it does not adequately consider the significance of the second opinion for its final decision. Even so, it remains the case that the providers of second opinions are not appeal bodies, as they cannot overturn or affirm an original decision in a binding manner.

Concerns with current situation

Advice obtained by NEAC from the Crown Law Office is that, while ethics committees are not statutory bodies, the Legislation Advisory Committee's publication, *Guidelines on Process and Content of Legislation*, indicates that 'In general there should be a right of appeal against the findings of officials, tribunals and other bodies making decisions that affect important rights, interests and legitimate expectations of individuals.' Crown Law advised:

> *there is little doubt that HDECs [regional ethics committees] make decisions that impact on researchers (and subjects') rights, interest and legitimate expectations. Thus, it seems appropriate for the Operational Standard to provide for a right of appeal.*

Crown Law's advice also indicates the possibility of a claim for breach of natural justice under section 27 of the New Zealand Bill of Rights Act 1990. A copy of the opinion from the Crown Law Office is attached as Appendix 7.

During NEAC's review, some stakeholders stated that Denmark is the only country in which provision is made for appeal from ethics committee determinations. However,

[17] Health Research Council, e-mail correspondence, September 2003.

NEAC's review has confirmed that policy in Canada, the United Kingdom, and the United States also provide for some form of appeal.[18]

Options

Second opinions and appeals

NEAC considered two options regarding whether provision should be made for ethics committee decisions to be appealed to an independent body:

1. Second opinion processes only (status quo)

   This option is based on challenge options available in the current system for ethical review. It allows for a second opinion to be sought from an independent committee by either an ethics committee considering a proposal or by an applicant to the committee. Second opinions are not binding. The final decision on the application rests with the ethics committee that provided the first opinion.

2. Second opinion processes remain, and a new process for appeal is added to the review system.

   A right of appeal or of 'binding third opinion' in the ethics committee context would be, or would include, a right to an independent and binding determination on the ethical merits of the issue addressed by the original decision.

Both options could operate within either the current fully regional system, or within a system that also included a national committee for the review of national and multi-centre studies.

Appellate body

NEAC also proposed three sub-options for any appellate body:

a. NEAC or subcommittee of NEAC. NEAC, or an appeals sub-committee of NEAC, would be the body to consider all applications for appeal. If a new national committee were established for review of national and multi-centre studies, NEAC or its appeals sub-committee would also consider any appeals resulting from decisions of that national committee. This is the option suggested in the Crown Law opinion.

b. New national committee (for review of national and multi-centre studies), plus NEAC or sub-committee of NEAC. A national committee, established for the review of multi-centre studies, would also be the appeal committee for all proposals, except for national or multi-centre proposals, where it would have provided the first opinion. In cases of national or multi-centre proposals, NEAC, or an appeals sub-committee of NEAC, would be the appeal body.

c. New committee established for the purpose of hearing appeals. A separate ethics committee would be established, and convened when needed, specifically for the purpose of hearing appeals.

[18] National Ethics Advisory Committee (NEAC) Kāhui Matatika O Te Motu. *System of Ethical Review of Health and Disability Research in New Zealand*. Discussion Document, 2003, pp 24–5.

Stakeholder comment

Complaints

The NEAC questionnaire survey indicated that a large proportion of regional ethics committee members, and almost all researchers surveyed, either had not used the complaints process or did not know how the process operated.

Little comment was received in submissions on the discussion document about the issue of the current complaints process or the need for change. The discussion document did not contain a specific question on this, although the issue was set out in the body of the document and the feedback form contained space for 'other comments'.

Second opinions

The NEAC questionnaire survey indicated that a large proportion of regional ethics committee members and researchers surveyed either had not used the second opinion process or did not know how the process operated.

In addition to the findings from the questionnaire survey, information provided by the Health Research Council indicates that the second opinion process is used infrequently. There were varying explanations given for this at the Auckland cross-sectoral consultation workshop, from the view that New Zealand has a very high standard of research, so second opinions are not generally required or tend to be used by people who have not done research before; to the view that researchers are often operating under time constraints and make changes they do not necessarily feel are valid rather than taking additional time to obtain a second opinion. The NEAC questionnaire indicated that it may also be due in part to lack of knowledge about the process. Finally, some stakeholder comments indicate that a researcher may simply choose not to go ahead with a study if he or she felt that the effort to get approval was going to become too great.

Despite the infrequent use of and lack of knowledge about the process, both the questionnaire survey and the workshop indicated support for the second opinion process and respect for the Health Research Council as the provider of second opinions. The overwhelming majority of respondents to the discussion document who commented on this section agreed that second opinions should address both the processes by which an ethics committee decision is made and the ethical merits of that decision.

Appeals

Approximately one-third of respondents to the discussion document supported the option that an appeals process be added to a second opinion process. Comments on the potential place of an appeals process in the system of ethical review were wide-ranging and drew, to a greater or lesser extent, upon the goals, objectives, and desired outcomes outlined in the discussion document, including:

- fairness/natural justice issues (in particular independence and the researcher right of reply)
- robustness
- accountability
- consistency of decision making
- responsiveness to Māori, although this was seen to be conditional upon the establishment of a Māori appeals committee and/or the need for appeal committee members to be appropriately experienced in kawa and tikanga Māori.

A number of respondents also indicated that one benefit of a new appeals committee would be that it could draw on and/or develop ethical review expertise.

Several other submissions stated clearly that there would be no enhancement of the ethical review with an appeals process. Approximately one-fifth of submissions urged that the current system of a second opinion process only be retained. Half of these submissions were from ethics committees or ethics committee members, while only two were from researchers. The Health Research Council Ethics Committee (HRCEC) felt a legalistic appeals process to be inappropriate for ethical review and that the opportunity already exists for reconsideration of any proposal by another body which can look into the merits of the proposal. In relation to the question of a 'binding' decision, the HRCEC went on to state:

> *having (judicial or quasi-judicial) powers to enforce any or all parties to adhere to its decision – this the regional ethics committees and the HRC Ethics Committee have not wanted and would not want to have; it would also not be appropriate to have or want to have that because it would be at odds with the way in which ethical issues are reflected on and opinions formed and conveyed to another moral equal by entering into dialogue and by persuasion on rational grounds.*

Other reasons given for opposing an appeals process included the potential for delays and issues to do with local knowledge and input.

Appellate body

Of the three options for an appellate body proposed in the discussion paper, the preferred option was for NEAC or a sub-committee of NEAC as the appellate body. There was less support for a new committee and only small support for a National Committee plus NEAC or a sub-committee of NEAC. A large number of submissions, as well as workshop participants, provided a variety of alternative suggestions, including:

- the Health Research Council Ethics Committee
- the District Court
- the Human Rights Tribunal or
- having either the Health Research Council or NEAC being able to convene a panel of appropriate members as required to hear the particular appeal.

Concern was voiced about adding layers of bureaucracy and the costs of establishing a new committee.

Recommendations

Complaints

The Committee was concerned about the large proportion of stakeholders who were not aware of the complaints process or did not know how it operated.

NEAC recommends that:

8. NEAC address the issue of education about the availability of, and how to access, the complaints process in its review of the *Operational Standard*.

Second opinions

Similarly, the Committee was concerned about the large proportion of stakeholders who were not aware of the second opinion process or did not know how it operated. However, despite the infrequent use of and lack of knowledge about the process, NEAC noted the positive experiences of those who had used the process.

NEAC recommends that:

9. the current second opinion process, covering both the process and merits of an ethics committee decision, be retained
10. NEAC work with the Health Research Council Ethics Committee to address the issue of information about availability of, and how to access, the second opinion process.

Appeals

NEAC is persuaded by the central argument made by the Crown Law Office. From the standpoint of natural justice also, there is a need to provide a right of appeal from an ethics committee decision. The Committee also believes that over time an appeals process will lead to greater consistency and quality in ethics committees' decisions, through providing a body of decisions on important issues to inform those decisions.

NEAC recommends that:

11. in addition to the second opinion process, a right of appeal be established (including appeal on the merits) from ethics committee decisions.

Appellate body

NEAC does not believe establishing yet another new committee as an appeals body is appropriate. For two reasons, NEAC also does not believe a new national ethics committee for review of national and multi-centre studies would be the best option for the appellate body. First, provision would still need to be made for appeal from determinations of *this* body regarding national and multi-centre studies. There would be a consequent need for a second body to be empowered to consider appeals in those cases, which in turn creates potential for conflicting appeal decisions from the two appellate bodies. Second, a new national ethics review committee for national and

multi-centre studies would have a standing equal to, not higher than, that of the regional ethics committees reviewing single-centre studies, and this would make it inappropriate to be their appellate body.

NEAC recommends that:

12. an appellate body to hear any appeal from an ethics committee decision be established
13. the appellate body be a sub-committee of NEAC, with the power to co-opt appropriate expertise
14. it be noted that any appellate body would need to be a properly constituted ethics committee in accordance with relevant paragraphs of the *Operational Standard*.

Ethical review of audit and related activities

Current situation

The current New Zealand *Operational Standard* (Section 4.1) defines 'audit' as an activity that measures practice against a standard. Current guidance is that ethics committee review is not required for audit or monitoring of quality of care, if:

- the audit or monitoring is carried out by those with professional obligations to maintain privacy
- no new information is to be gathered from patients.

Concerns with current situation

Audit and related activities

Following the Gisborne Inquiry it was evident that parameters needed to be defined for the ethical review of audit and related activities.

The Inquiry Committee was concerned that an ethics committee decision had prevented an independent audit of the cervical screening programme in New Zealand. The Committee believed that it is unethical to have a screening programme that is not evaluated, without informing women of the limitations of the programme arising from this lack of evaluation. The Inquiry Report (p 235) states:

> *Today quality assurance and audit and evaluation are so much part of health delivery that it could be said that it is no more than one of the components of the original treatment, which happens to be carried out later on. On this view treatment which does not include a subsequent audit could be seen as incomplete treatment.*

The Inquiry also raised the concern that statements relating to audit in the *National Guidelines for Ethics Committees in New Zealand* ('*National Standard*') were contradictory in respect of whether an independent team could audit the cervical screening programme. The Inquiry Report stated that clarification was necessary to determine the jurisdiction of ethics committees in relation to audit and related activities,

as evidence was given that there is international consensus that ethical approval is not necessary for audit/quality assurance. The Inquiry recommended (paragraph 11.18):

> *[a] change to guidelines ... to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.*

In light of this recommendation the Ministry of Health included some further guidance on this matter in the *Operational Standard*.

However, NEAC's review indicates there is still some confusion and disagreement surrounding when ethical review of audit and related activities is required. For example, the *Operational Standard's* definition of audit, as an activity that measures practice against a standard, excludes audit that does not measure against a standard (eg, outcome analysis).[19] As another example, the *Operational Standard* indicates that if new information is to be gathered the activity will require ethics committee approval but is ambiguous as to whether ethical review is required for the whole activity or just the gathering of the extra information.

The role of ethics committees in the review of research is complicated by difficulties in defining which activities are research and which are not. Non-research activities, such as audit, can employ methods similar to those used in research, but they are considered to be distinct activities. These activities have the potential to raise the ethical issues that are also raised in research.

In a recently published document, the Australian Health Ethics Committee (AHEC) notes that 'no authority or agency has been able to create definitions that clearly separate 'quality assurance' from 'clinical research'.'[20] The document focuses on the characteristic features that need to be considered when deciding whether quality assurance activities require independent ethical review.

The ambiguity surrounding the distinction between research and audit has led to one study being declined for publication, as the authors believed they were undertaking audit and had not sought ethics committee approval, whereas journal editors considered it to be research that lacked ethics committee approval.[21]

Options

NEAC considered three options for the ethical review of audit and related activities:

[19] Outcome analysis involves retrospective examination of medical notes to determine the outcome of medical treatment, or the course of a particular illness. An example of this is a 1983 New Zealand study, which analysed the survival of children with cancer, comparing survival rates across regional centres in New Zealand. Such studies are used to determine whether health service initiatives are maximising outcomes such as survival rates. For definitions of other audit-related activities, see National Ethics Advisory Committee. 2003. *Ethical Review of Observational Research, Audit and Related Activities Discussion Document*. Wellington: Ministry of Health, pp 8–9.

[20] National Health and Medical Research Council (NHMRC). 2003. *When Does Quality Assurance in Health Care Require Independent Ethical Review?* Canberra: National Health and Medical Research Council, p 1.

[21] Goodyear-Smith F, Arroll B. 2001. Audit or research? *New Zealand Medical Journal* 114(1143): 500–2.

1. No ethics committee review. Ethical matters are to be reviewed by those conducting the activity.
2. Ethics committee review is to be conducted when the activity reaches a threshold of risk. Criteria are used to determine whether an activity requires ethics committee review. This option is similar to that provided by the current *Operational Standard*. Under this option, two questions would need to be asked to determine the necessity of ethical review:
   i. Is there a serious risk of harm if the activity is delayed?
   ii. What are the risks to participants in the activity?

   If delays in the conduct of the activity will generate serious risk to public health or health service quality, and if ethics committee review is likely to cause such delays, then there should be no ethics committee review.
3. Ethics committees review all audit and related activities.

Expedited review and informing ethics committees

In addition to the three options, NEAC asked stakeholders:

- if there is to be review of some or all audit and related activities, should there be expedited review, using delegated authority?
- should investigators be required to keep ethics committees informed of audit and related activities not considered to require ethical review?

Stakeholder comment

Of the respondents to the discussion document who clearly stated a preference for one option, the majority favoured Option 2, largely with the qualification that the threshold of risk would need to be clearly defined, with criteria for judging whether an activity reaches the threshold. Several respondents favoured Option 1 for cases in which no new information was to be gathered, and Option 2 for cases in which extra treatment would be given or extra information would be gathered. Similarly, several respondents favoured Option 1 for internal audit and Option 2 for external audit.

The Christchurch cross-sectoral workshop also indicated some support for Option 2 and that, if there was to be some ethics committee review of audit and related activities, then the triggers for such review should be new or additional information being sought, the detail and level of consent previously given by a patient; who will have access to what level and kind of information (eg, identifiable versus encrypted or anonymised data); and the level of risk involved.

The workshop's discussion of this issue demonstrated a difficulty in identifying the risks to participants in an audit or related activity. The chief concerns appeared to be:

- researchers would designate their activities as 'audit' so as to avoid ethics committee review
- individuals' rights to privacy in relation to their health information and concern about release of this information to third parties, including the risk of individuals not

providing their clinician with essential details if they think the information might be more widely shared.

On the other hand, researchers expressed concern that an individual's right to privacy should not outweigh the New Zealand public's right to quality health care. Researchers and health practitioners were also concerned that, as audit becomes more and more accepted as a fundamental quality assurance procedure for health providers, requiring ethics committee review of such activities would overload the ethics committee review system.

The workshop also highlighted the need to build public understanding about what 'confidentiality' does and does not mean in relation to their health information, and that audit is implicit in the provision of public health care.

The majority of respondents to the discussion document, as well as participants in the cross-sector workshop, expressed support for the view that:

- expedited review is appropriate for any cases in which ethical review of audit and related activities is required
- ethics committees do not need to be informed of audits that do not require ethical review, or they need to be informed only if the audit is external or includes an element that is not an integral part of health care provision.

Recommendations

NEAC is aware of the need to find the appropriate balance between an individual's right to privacy and the New Zealand public's right to quality health care. The Committee is of the view that there is no need for ethics committee review of audit and related activities, provided that there is greater clarity about when such activities come within the scope of 'audit' rather than 'research'.

NEAC recommends that:

15. ethical issues regarding audit and related activity be reviewed by those conducting the activity rather than by an ethics committee, where the activity meets the following criteria:[22]
    - 15.1 it is to be conducted either internally or externally by persons who are under a professional obligation to preserve confidentiality
    - 15.2 it does not include the collection of new or additional information from patients / consumers
    - 15.3 it does not include anything being done to (or withheld from) patients beyond their normal clinical management.

[22] This is drawn from Ministry of Health. 2002. *Toward Clinical Excellence: An introduction to clinical audit, peer review and other clinical practice improvement activities*. Wellington: Ministry of Health.

Expedited review

NEAC recommends that:

16. there be a process for expedited review in any cases in which ethics committee review of audit and related activities *is* provided.

Inform ethics committee

NEAC recommends that:

17. those who perform audits and related activities need not inform ethics committees, if these activities do not require ethics committee review.

Additional recommendations

NEAC also recommends that:

18. it further address in its review of the *Operational Standard* the issue of appropriate guidance on what are 'audit and related activities', and whether and to what extent they require ethics committee review, particularly when new or additional information is to be collected from patients / consumers
19. service providers and the Ministry of Health continue to inform the public that audit and related activities are necessary for the provision of high quality health care.

Privacy and secondary use of identifiable data for research

Current situation

An important and controversial issue in observational studies is the secondary use of identifiable data, where such data, initially collected for a purpose such as health care, is then used for research.[23] The current *Operational Standard* has no discussion on when such use might be justified.

[23] Lowrance W. 2002. *Learning from Experience: Privacy and the secondary use of data in health research*. London: The Nuffield Trust (http://www.nuffieldtrust.org.uk/bookstore). This form of research has made some important contributions to health. The following are three New Zealand examples: (1) The paper that led to the Cartwright inquiry (McIndoe WA, McLean MR, et al. 1984. The invasive potential of carcinoma in situ of the cervix. *Obstetrics and Gynaecology* 64(4): 451–8) would not have proceeded without the examination of hospital data that had been gathered for another purpose. (2) A study of health records determined there was a link between fenoterol, a drug used for asthma, and deaths in young New Zealanders (Crane J, Pearce N, et al. 1989. Prescribed fenoterol and death from asthma in New Zealand, 1981–83: case-control study [comment]. *Lancet* 1(8644): 917–22). (3) The secondary use of health records was also used in a New Zealand study that linked fatal pulmonary embolism and oral contraceptive use (Parkin L, Skegg D, et al. 2000. Oral contraceptives and fatal pulmonary embolism. *The Lancet* 355: 2133–4).

Concerns about current situation

Until the 1980s, guidelines in New Zealand allowed secondary use of data as an extension of medical practice, without explicit consent in certain situations, subject to safeguards against breaches of confidentiality.[24]

The culture around the privacy of health records became more restrictive in the 1990s. In part this was due to the Health Information Privacy Code, although the Code allows the use and disclosure of health information in certain circumstances without the authorisation of the individual concerned. This change in culture has led to ethics committees becoming increasingly cautious about the secondary use of data for research without explicit consent.

In other countries concerns have been raised that research in the public interest – such as disease surveillance, evaluation of health care services and drug safety analyses – is impeded by an unbalanced emphasis on privacy.[25]

Both in New Zealand and internationally, there is a concern to resolve this controversy by finding a new and publicly acceptable balance between societal and individual interests.[26]

In finding a balance between societal and individual interests, several features are required of any public policy or regulatory framework.

Required features:[27]

- careful handling of identifiability (including anonymisation where possible, otherwise methods of coding, including 'key-coding')
- training of personnel
- controlling access and disclosure
- maintaining security
- arranging independent ethical oversight.

In other areas a choice between different approaches needs to be made.

Options

NEAC considered five options for policy on the secondary use of identifiable data, where the data is initially collected for a purpose such as health care and is then used for research. NEAC sought comment from stakeholders on which of the options would

[24] Medical Research Council of New Zealand (MRCNZ). 1986. *Project and Programme Grants*. Auckland: Medical Research Council of New Zealand.

[25] Lowrance W. 2002. *Learning from Experience: Privacy and the secondary use of data in health research*. London: The Nuffield Trust.

[26] Ibid.

[27] Ibid.

best protect participants from harm while enabling high quality research to benefit the community.

The options were:

1. move to statutory sanctioning of all research use of secondary data without explicit consent
2. build on the regulatory endorsement of research use for the common good, without consent if necessary, by developing detailed guidance for ethics committees on when identifiable data can be used without consent
3. consult with the public about whether the presumption of implied consent for research use of data held by health care providers in New Zealand is justified
4. seek broad authorisation from all users of health services for the secondary use of data for research. This would require an opt-out option
5. move to requiring informed consent for all research uses of identifiable data.

Stakeholder comment

Both the respondents to the discussion document and participants in the Christchurch cross-sectoral consultation workshop expressed a range of views on the proposed options.

The workshop did not indicate any obvious consensus or majority view on the options. The majority of respondents to the discussion document favoured Option 2, many with the qualification that guidelines must be explicit, and developed in consultation with the public.

Several respondents noted that the options are not mutually exclusive, and expressed a preference for some combination of the options. However, similarly to the workshop, there was no obvious consensus on any particular combination.

Several respondents felt that Option 5 should be maintained as an ideal, or ultimate goal, or that Option 5 is appropriate where identifiable data is to be used, with a provision for people to waive informed consent requirements. Options 2, 3 and 4 were favoured for cases in which it is not practical to obtain informed consent.

Several respondents commented that public consultation (Option 3) should take place regardless of which option was recommended.

Recommendations

Given the wide range of stakeholder views about the secondary use of identifiable data, where the data is initially collected for a purpose such as health care and is then used for research, NEAC believes that this area needs further work and consideration.

NEAC recommends that:

20. it address the issue of policy on the secondary use of identifiable data, where the data is initially collected for a purpose such as health care and is then used for research, as part of further work on the *Draft Ethical Guidelines for Observational Studies* (recommendation 22, below)

21. in the interim it give researchers and ethics committees guidance about when identifiable data can be used without consent, and in particular draw their attention to the section of the Health Research Council's *Guidance Notes on the Health Information Privacy Code*, which states:

> *The use of health records for research without the authorisation of the individual concerned should only be undertaken subject to certain extra conditions:*
>
> *(1) the reasons for not seeking consent should be justified to the ethics committees. These reasons may be scientific, practical, or ethical ...*
>
> *(2) the potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.*

[The full *Guidance Note* includes examples of the reasons for not seeking consent and examples of the benefits of such research.]

Draft ethical guidelines for observational studies

The Gisborne Inquiry recommendation 11.21, that

> *ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies*

highlights the Inquiry's concern that there is a lack of consensus in New Zealand about the ethical considerations involved in observational studies, and that ethics committees require guidance to assess instances in research in which personal privacy may be overridden by the need to gain information to advance public health.

As part of its work programme, NEAC has agreed with the Minister of Health that it will 'develop guidelines on conducting observational studies in an ethical manner and establish the parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research)'.

NEAC prepared Draft Ethical Guidelines for Observational Studies and requested comments to assist in constructing a final set of guidelines. NEAC asked particularly for responses to the following questions:

- Is the structure of the draft guidelines useful, ie, guidelines structured around the process of designing and undertaking an observational study, followed by major statements from existing documents?
- Are the draft guidelines complete? Have any major ethical considerations regarding observational studies been left out?
- Are there any issues in the draft guidelines that you disagree with, or wish to comment on?

- The draft guidelines include the expectation that observational studies will accord with the ethical principle of justice, but they do not endorse any particular view of justice. On one view, justice requires efforts to reduce inequalities. Should reference to this particular understanding of the requirements of justice be added to the guidelines? This might be achieved by a statement that decision-making about the research question should consider the potential to reduce health inequalities.

Stakeholder comment

The comments received on the discussion document and the discussion in the Christchurch cross-sectoral consultation workshop highlight the need for further work and consultation on the *Draft Ethical Guidelines for Observational Studies*. Many stakeholders were unclear about:

- the specific purpose of the Guidelines (eg, to provide guidance on ethical *conduct* or ethical *review* of observational studies) or
- for whom the Guidelines were primarily intended (ethics committees or researchers).

There was some concern about the overseas information used in the Guidelines, which was felt to be either duplicative of issues already covered in the *Operational Standard* or not appropriate for the New Zealand context.

There was also comment on the need for:

- general principles to be clearly identified;
- clear guidance or indicators to determine whether research is observational; and
- practical examples in the Guidelines to illustrate some its points, including not only examples of good practice, but also problematic examples to highlight things that should be prevented and the difficult questions and explain what to do when they are encountered.

Finally, a number of people expressed a desire for an opportunity to comment on the next version of the Guidelines.

Recommendations

As noted above, the comments received on the discussion document and the discussion in the Christchurch cross-sectoral consultation workshop highlight the need for further work and consultation on the *Draft Ethical Guidelines for Observational Studies*.

NEAC recommends that:

22. NEAC undertake further work and consultation on its *Draft Ethical Guidelines for Observational Studies*.

Other Issues Raised by Stakeholders

The following issues noted during the analysis of responses to the discussion document or in other parts of its review were felt to be of particular significance.

The Gisborne Inquiry's recommendations as a basis for the review

A number of stakeholders, primarily ethics committee members or former members, have expressed concern about NEAC's review being based on the findings and recommendations of the Gisborne Inquiry. The Health Research Council Ethics Committee's (HRCEC) written response to the discussion documents highlights this point when it comments, 'the findings of the Gisborne Inquiry have not been universally accepted'. The HRCEC response includes a critique of the Gisborne Inquiry's recommendations.

As the NEAC Chair noted during the workshops when this was raised, NEAC has been directed to implement some of the Gisborne Inquiry Report's recommendations (11.19, to review the operation of ethics committees; 11.21, to develop guidance concerning observational studies; and 11.23, to consider processes for appeal of ethics committee decisions to an independent body). It has also agreed to develop options for addressing one other Gisborne Inquiry Report recommendation (11.22, through its review of the current processes for ethical review of national and multi-centre research). In addition, the Minister has accepted the recommendations of the Gisborne Inquiry Report and the state of implementation of those recommendations is a matter of ongoing monitoring and report to the Minister of Health and to Parliament. In this public policy context, strong reasons would need to be presented if any of the recommendations were not to be implemented. NEAC's review has been an important opportunity for stakeholders to present any such reasons.

Governance issues

Several stakeholders noted that some research host organisations are developing their own systems of ethical appraisal, with potential for overlap with ethics committee roles. Others stated that it is not always clear who is responsible for assessing key issues, such as the science of certain research protocols, or the potential of some proposed protocol changes to affect that scientific assessment. These stakeholders were in effect raising governance issues: Who are the accountable parties here? What matters are they each accountable for? To whom are they accountable? Such issues have been systematically addressed in some other jurisdictions, including the United Kingdom. As its title makes plain, New Zealand's *Operational Standard for Ethics Committees* (2002) addresses only one sub-set of such issues, and future review of this document would greatly benefit from being seen in the larger context of an overall framework for governance and accountability.

Recommendation

The Committee believes there is important follow-up work to be done on these broad governance framework issues in health and disability research ethics.

NEAC recommends that:

23. NEAC scope the task of developing a governance framework for health and disability research ethics. A completed framework (eg, as the UK has) would identify and clearly match accountable parties, such as the investigator, research sponsor, ethics committee, and research host organisation, with the key accountabilities, including ethical review, assessment of legal issues, scientific assessment, consultation with Māori, monitoring of study conduct, and adverse event reporting.

A cross-sectoral approach to research involving human participants?

Stakeholders suggested in the course of NEAC's review that in future a cross-sectoral approach be taken to the ethics, and ethical review, of research involving human participants. Any such approach would require collaboration from leading public sector organisations in multiple sectors; for example, in health, tertiary education, and research science and technology. It would potentially also involve organisations beyond the public sector. One model for an overarching policy framework for such an approach is provided by the Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998). However, the idea of such an approach raises issues well beyond NEAC's current work programme.

Other issues arising during the review

As discussed in the beginning of this report, while NEAC's current review has focused on certain areas, the review processes have canvassed a range of information and have highlighted wider matters relating to Māori responsiveness and to the operation of the current system for ethical review of health and disability research (eg, structure and resourcing). As a consequence, NEAC recommends that:

24. information gathered from stakeholders relating to Māori responsiveness will be used
    - 24.1 to inform NEAC's ongoing work to develop a Māori framework for ethical review
    - 24.2 in NEAC's review of the *Operational Standard*.

25. the findings from the questionnaires, interviews, discussion documents and cross-sectoral consultation workshops relating to the operation of ethics committees
    - 25.1 will be used to inform NEAC's review of the *Operational Standard*; and
    - 25.2 may highlight areas requiring further work, which will be discussed with the Minister as part of the development of NEAC's future work programme.

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This bibliography is a list of all published work that has informed NEAC's review. Every attempt has been made to ensure that it is complete.

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Appendix 1: Membership of NEAC

Professor Michael Ardagh
Dr Dale Bramley
Dr Anne Bray
Dr Fiona Cram
Philippa Cunningham
Professor Donald Evans
Dr Allison Kirkman (Deputy Chairperson)
Dr Andrew Moore (Chairperson)
Associate Professor Charlotte Paul
Professor Neil Pearce
Dr Martin Sullivan
Mele Tuilotolava

Appendix 2: Relevant Gisborne Inquiry Recommendations

The Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (the Gisborne Inquiry) made the following recommendations that are relevant to this review:

11.18 There needs to be change to guidelines under which ethics committees operate to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.

11.19 There should also be a review of 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.

11.20 Ethics Committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. Ethics Committees need to be informed that the interpretation of legislation relating to personal privacy is for the agency holding a patient's data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.

11.21 Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.

11.22 A national ethics committee should be established for the assessment of multi-centre or national studies.

11.23 The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.

Appendix 3: Interviewees and Group Consultation Meetings

The following individuals were interviewed or participated in a group consultation meeting.

Name	Organisation/position
Carol Algie	National Co-ordinator, Regional Ethics Committees, Ministry of Health
Linda Young	Administrator, Otago Ethics Committee
Pat Chaney	Administrator, Auckland Ethics Committees
Jean Gibbons	Manager (Administration) Health Research Council
Richman Wee	Policy Advisor, Health Research Council
Sylvia Rumball	Chair, National Ethics Committee on Assisted Human Reproduction
Jo Fitzpatrick	Women's Health Action Trust
Judi Strid	Women's Health Information Service
Lynda Williams	Auckland Women's Health Council
Teenah Handiside	Women's Health Council
	Foundation for Research, Science and Technology
Sharron Cole	Former Chair of Wellington Ethics Committee
Barbara Beckford	Secretary to Chairs of Ethics Committees
Katrina Sharples	Data Safety Monitoring Board
Gary Williams	Disabled Persons Assembly
Margaret Southwick	Whitireia Community Polytechnic Pacific Research Group
Lesley Harwood	Ministry of Consumer Affairs
Missy Morton	CCS
Michele Grigg	Quit Group
Wendi Wicks	Disabled Persons Assembly
Gary Williams	Disabled Persons Assembly
Peter Dady	Cancer Society
Geoff Shaw	Intensive Care, Canterbury DHB
Andrew Jull	Clinical Trials Unit, University of Auckland
Brian Cox	Dunedin School of Medicine
Peter Herbison	Dunedin School of Medicine
David Skegg	University of Otago
Andrea Elliott	Te Runanga o Kirikiriroa Trust
Maurice Austin	Chair, West Coast Ethics Committee
John Curry	Chair, Wellington Ethics Committee
Brian Smythe	Chair, Nelson/Marlborough Ethics Committee
Denise Wilson	Chair, Auckland Ethics Committee Y
Dena Hale	Chair, Hawkes Bay Ethics Committee
Catherine Quinn	Chair, Taranaki Ethics Committee
Peter Allan	Chair, Waikato Ethics Committee

Group consultation meeting – Christchurch School of Medicine (29 October 2003)

Name	Organisation/position
Professor Peter Davis	Professor of Public Health
Professor Les Toop	Professor of General Practice
Dr Dee Richards	Senior lecturer in General Practice
Andrew Ball	Environmental Science and Research Ltd.
Dr Rob Weir	Senior Research Fellow
Gillian Abel	Researcher
Suzanne Pitama	Rakaipaaka – Ngati Kahungunu, Psychologist
Dr Ann Richardson	Senior Lecturer in Public Health
Dr Elisabeth Wells	Biostatistician
Dr Cheryl Brunton	Senior Lecturer in Public Health

Group consultation meeting – Cancer Trials New Zealand (4 September 2003)

Name	Organisation/position
Mike Findlay	Director
Jonathan Koea	Steering Group Member
Katrina Sharples	Steering Group Member
Greta Riley	Project Manager

Group consultation meeting – Regional Ethics Committee members (7 November 2003)

Participants in this meeting did not consent to have their names released for this report.

Appendix 4: Respondents to Questionnaire

Respondents to the questionnaire were not required to give their name. Consequently not all respondents are named in this list.

1. Researcher applicants to regional ethics committees

Name	Organisation
Rosemary McKellar	
Alison Howitt	Merck Sharp and Dohme (NZ) Ltd
Grant Gillett	Bioethics Centre, University of Otago
Greta Riley	Cancer Trials NZ (University of Auckland)
John Broughton	Dunedin School of Medicine
John Waldon	School of Māori Studies, Massey University
Marie Nixon	
Denise Rudolph	
Dr Marewa Glover	
Greg Lewis	
Rachel Rapira	
Andrew Sporle	Statistics Department, University of Auckland
Veronica Kururangi	
Carla Houkamau	
Nicholas M Birchall	Auckland Dermatology
Shane McCardle	
John Phillips	Department of Optometry and Vision Science, University of Auckland
David Porter	Medical Oncologist, Auckland Hospital
Murray Edgar	
Dr DH Friedlander	Cardiology Department, Waikato Hospital
Rosemary Escott	
Josee Lavoie	Centre for Aboriginal Health Research (Canada)
Anne Duncan	Public Health Intelligence, Public Health Directorate, Ministry of Health
Dr RL Spearing	Department of Haematology, Christchurch Hospital
Sally Merry	Department of Psychiatry, University of Auckland
Debbie McLeod	GP Department, Wellington School of Medicine
Tim Williams	
Dr Shane Reti	
Shaun Holt	Director, P3 Research
Steve LaGrow	School of Health Sciences, Massey University
Rachel March	Canterbury Geriatric Medical Research Trust
Ian Campbell	Breast and General Surgeon, Waikato Hospital
Professor Ian Town	
Maralyn Fovreur	Women's Health Service, CCDHB
Robin Taylor	Dunedin School of Medicine
Dr PI Thompson	Oncology Department, Auckland Hospital

Name	Organisation
Andrea Elliott	Research and Development Unit, Te Runanga O Kirikiriroa Trust Inc
Naina Watene	Research and Development Unit, Te Runanga O Kirikiriroa Trust Inc
Kieren Faull	Queen Elizabeth Hospital
Diana Richardson	Psychiatric Liaison Department, Middlemore Hospital
Alison Vogel	South Auckland Health
Jacqueline Ryan	Urology Department, Auckland Hospital
Dr Alan Barber	Auckland Hospital
Andrew Hill	Middlemore Hospital
Abigail Wroe	Department of Psychology, Institute of Psychiatry (London)
Professor JE Harding	University of Auckland
Bridget Robinson	Oncology Service, Christchurch Hospital
Ross Kennedy	Department of Anaesthesia, Christchurch Hospital
Andrew Jull	Clinical Trials Research Unit, University of Auckland
Dr Louise Rummel	Manakau Institute of Technology
Brett Shand	Lipid and Diabetes Research Group, Christchurch Hospital
Brian Cox	Department of Preventive and Social Medicine, University of Otago
Andrew Simpson	Consultant Medical Oncologist, Wellington Cancer Centre

2. Regional ethics committee members

Name	Region
Alma Rae	Christchurch
Judi Strid	Waitakere City
LM Gallagher	
Kiri Munro	Auckland
Dr Patricia O'Brien	Auckland
MK Farrant	Nelson
Tom James	Gisborne
Dorothy Bulling	Southland
Peter T Ropiha	Dannevirke
Hamish Kynaston	Wellington
Paul Flanagan	Hamilton
Patricia Finlayson	Auckland
Archdeacon Harvey Ruru	Nelson
John Kleinsman	Wellington
Alison Masters	Wellington
Nicole Presland	Drury
Nicola Peart	Dunedin
Marina Hughes	Christchurch
Brian Irvine	New Plymouth
Carolyn Mason	Christchurch
Dr Donald Budge	Motueka
Catherine Quin	New Plymouth
John Currie	Masterton

Name	Region
Catherine Graham	Te Anau
David Haigh	Auckland
Christine Forster	Auckland
Denis Mellsop	Nelson
V Thorpe	Gisborne
Peter Herbison	Dunedin
Wendy V Parr	Golden Bay
Tom Scott	Gisborne
Hugh Miller	Invercargill
Brian Smythe	Nelson
Dr Alan Doube	Hamilton
John R Inder	Marlborough
John Solomon	Dunedin
Dr Alex Luft	Napier
R Laverty	Dunedin
Denise Wilson	Auckland
Roger Ngahooro	Dunedin
John France	Auckland
GD Gordon	Auckland
Roy Carroll	Tauranga
Bernadette Coutts	Westland
Peter Anderson	Greymouth
John Duryer	Napier
Quentin Grady	Greenmeadows East
Peter Allan	Hamilton
Dena Hale	Hastings
Aroha Houston	
Roy Simons	Levin
F Dumble	Hamilton
Dr John Fitzpatrick	Hamilton
Mark P Smith	Christchurch
Shane Ruwhia	North Shore City
Maui Hudson	Manukau City
Fay McDonald	Otago
Mathew M Bennett	Hastings
FN Glass	
Ken Becker	
Chris Hannah	Gisborne
Paul Green	Palmerston North
Naheed Omar	Marton
Gerard Aynsley	Dunedin
Phil Sunderland	Palmerston North
Robin Fraser	Christchurch

Appendix 5: Cross-Sectoral Consultation Workshop Attendees

1. Workshop on the NEAC discussion document 'Ethical Review of Observational Research, Audit and Related Activities', Christchurch, 3 November 2003

Name	Organisation/position
Derelie Richards	Christchurch School of Medicine
Lionel Hume	Consumer Advocacy Service, Health and Disability Commissioner
Diane Harker	Canterbury Ethics Committee
Peter Davis	Christchurch School of Medicine
Richard Robson	Health Research Council Ethics Committee, and SCOTT
Barbara Nicholas	Bioethics Council Secretariat, Ministry for the Environment
Richman Wee	Health Research Council Policy Advisor
Ashley Bloomfield	National Screening Unit, Ministry of Health
Patricia Priest	Department of Medical and Health Sciences, University of Auckland
Fay McDonald	Otago Ethics Committee
Joan Dodd	Research Coordinator, Auckland DHB
Judi Strid	Women's Health Action
Barbara Beckford	West Coast Ethics Committee Administrator
Virginia Irvine	Research Manager, Christchurch School of Medicine
Elizabeth Cunningham	Research Manager Māori, Christchurch School of Medicine

2. Workshop on the NEAC discussion document 'System of Ethical Review of Health and Disability Research in New Zealand', Auckland, 5 November 2003

Name	Organisation/position
Robyn Hunt	Human Rights Commissioner
Joan Dodd	Research Coordinator, Auckland DHB
Clive Aspin	Ngā Pae o te Māramatanga, University of Auckland
Linda Grennell	Consumer Advocacy Service, Health and Disability Commissioner
Wendy Brandon	Lawyer, former ethics committee member
David Hay	Auckland Ethics Committee member
Stephen Baxter	Chair of KIDS Foundation, Anglican vicar
Kevin Dew	Department of Public Health, Wellington School of Medicine
Bruce Scoggins	Chief Executive, Health Research Council
Karlo Mila	Pacific Health Manager, Health Research Council
Elizabeth Barry	National Council of Women
John Hobbs	Sector Policy Directorate, Ministry of Health
Denise Wilson	Auckland Ethics Committee Y member
Peter Allan	Waikato Ethics Committee Chair, and Chair of Chairs of Ethics Committees
Sally Cook	Canterbury Ethics Committee administrator
Marge Scott	Chair, Health Research Council Ethics Committee
Jo Fitzpatrick	Women's Health Action, and regional ethics committee member
Ian Reid	Department of Medicine, University of Auckland
Mike Gourley	Disability activist, broadcaster
Philippa Ellwood	Department of Paediatrics, University of Auckland

Appendix 6: Respondents to Discussion Documents

1. Respondents to discussion document *System of Ethical Review of Health and Disability Research in New Zealand*

Name	Organisation
Richard Robson	Christchurch Clinical Services Trust
Andrea Elliott and Naina Watene	Te Runanga O Kirikiriroa Trust Inc
Margaret Blackburn	Auckland University of Technology Ethics Committee (Committee response)
Dr Ruth Spearing/Jo Sanders	Christchurch Hospital
Dr Louise Rummel	Manukau Institute of Technology
Trevor James	Taranaki Ethics Committee
Dorothy Bulling	Southland Ethics Committee
Dr Marewa Glover	University of Auckland
Phil Sunderland	Manawatu/Whanganui Ethics Committee
Lynda Sutherland	National Council of Women
Ron Paterson	Health and Disability Commissioner
Greta Riley	Cancer Trials New Zealand
Andrew Hill	University of Auckland
J Elizabeth Wells	Christchurch School of Medicine
Denise Diedrichs	West Coast DHB
Joan Dodd/Candy Pettus	Auckland DHB
Carol Semple and Alison Howitt	Merck Sharp and Dohme (NZ) Ltd
Dr Jenny Neale	Human Ethics Committee, Victoria University (committee response)
Jean Simpson/Dorothy Begg	Injury Prevention Research Unit, University of Otago
Dr Brian Cox	Dunedin School of Medicine
Rosemary McKellar	Quintiles Pty Limited
Peter Davis	Christchurch School of Medicine
Dr Michael McCabe	New Zealand Catholic Bioethics Centre
Dr Jocelyn Peach	Nurse Executives of New Zealand
Denise Wilson	
Jan Campbell	Roche Products
West Coast Ethics Committee	
Dr Nigel Gilchrist/Rachel March	CGM Research Trust
Martin Bradley	Genesis Research and Development
Ann Richardson	Christchurch School of Medicine
April Bennett	ACC
Dr Hilary Lapsley	Mental Health Commission
Sylvia Rumball	National Ethics Committee on Assisted Human Reproduction (Committee response)
Mike Thompson	Researched Medicines Industry

Name	Organisation
Professor Ian Town	Christchurch School of Medicine
John France	
Susan Dovey	Australian Primary Health Care Research Institute
R Laverty	Otago Ethics Committee
Professor Jane Harding	University of Auckland
Roy Carroll	Bay of Plenty Ethics Committee
Owen Hughes	Office for Disability Issues
Robert Logan	Director of Medicine, Hutt Valley DHB
Nicola Peart	
Jennifer Ngahooro	Dunedin Bioethics Centre
Cathy Webber	Royal New Zealand College of General Practitioners
Sonja Rathgen	Office of Ethnic Affairs
Joy Bickley Asher	Graduate School of Nursing and Midwifery, Victoria University
Steward Mann	Cardiac Society of Australia and New Zealand
Barbara Robson	Federation of Women's Health Councils
James Wilding	Canterbury Ethics Committee R (Committee response)
Judith Hoban	Canterbury Ethics Committee B (Committee response)
Nicole Presland	Auckland Ethics Committee X (Committee response)
Barbara Beckford	
Ann Martin	Hospice New Zealand
Brian Smythe	Nelson-Marlborough Ethics Committee (Committee response)
Janet Peters	Mental Health Research and Development Strategy, Health Research Council
Marge Scott	Health Research Council Ethics Committee (Committee response)
PE Holst	Royal Australasian College of Physicians
Dr Michael Sullivan	Children's Cancer Research Group
Dr Marten Hutt	Ministry of Research, Science and Technology
Raewyn Dowman	MidCentral Health
Paul Gibson	CCS
Marion Clark	Nursing Council of New Zealand
Deirdre Milne	UNITEC Ethics Committee (Committee response)

There were an additional 11 respondents who did not wish their personal details to be released.

2. Respondents to discussion document *Ethical Review of Observational Research, Audit and Related Activities*

Name	Organisation
Drs CS Benjamin and Vernon Harvey	Auckland Breast Cancer Study Group
PE Holst	Royal Australasian College of Physicians
Dr Michael J Sullivan	Children's Cancer Research Group
Dr Marten Hutt	Ministry of Research, Science and Technology
Katie Graham	
Cathy Webber	Royal NZ College of General Practitioners
John Simpson	Royal Australasian College of Surgeons
Sonja Rathgen	Office of Ethnic Affairs
Carol Algie	Regional Ethics Committee Administration Team
Catherine Williams	Ministry of Women's Affairs
Jennifer Ngahooro	Dunedin Bioethics Centre
Warwick Gilchrist and Lesley Mack	National Screening Unit, Ministry of Health
Marge Scott	Health Research Council Ethics Committee (Committee response)
Prue Fraser	Southland Ethics Committee
Raewyn Dowman	MidCentral Health
Lynda Sutherland	National Council of Women
Professor Jane Harding	University of Auckland
Dr Brian Cox	Dunedin School of Medicine
Robert Logan	Director of Medicine, Hutt Valley DHB
Brian Smythe	Nelson-Marlborough Ethics Committee (Committee response)
Ann Martin	Hospice New Zealand
Barbara Beckford	
Nicole Presland	Auckland Ethics Committee X (Committee response)
James Wilding	Canterbury Ethics Committee R (Committee response)
Barbara Robson	Federation of Women's Health Councils
Stewart Mann	Cardiac Society of Australia and New Zealand
Alistair Humphrey	Community and Public Health, Canterbury DHB
R Laverty	Otago Ethics Committee
John France	
Professor Ian Town	Christchurch School of Medicine
Felicity Goodyear-Smith	University of Auckland
Dr Hilary Lapsley	Mental Health Commission
April Bennett	ACC
West Coast Ethics Committee	
Ann Richardson	Christchurch School of Medicine
Denise Wilson	
Dr Bridie Kent	Auckland DHB/University of Auckland
Richard Seigne	Christchurch Hospital
Peter Davis	Christchurch School of Medicine
Joan Dodd/Candy Pettus	Auckland DHB
Denise Diedrichs	West Coast DHB

Name	Organisation
J Elizabeth Wells	Christchurch School of Medicine
Andrew Hill	University of Auckland
Ron Paterson	Health and Disability Commissioner
Phil Sunderland	Manawatu/Whanganui Ethics Committee
Dr Marewa Glover	University of Auckland
Dorothy Bulling	Southland Ethics Committee
Trevor James	Taranaki Ethics Committee
Dr Louise Rummel	Manukau Institute of Technology
Dr Ruth Spearing/Jo Sanders	Christchurch Hospital
Margaret Blackburn	Auckland University of Technology Ethics Committee (Committee response)
Roy Simons	
Andrew Elliott and Naina Watene	Te Runanga O Kirikiriroa Trust Inc
Richard Robson	Christchurch Clinical Studies Trust
	Canterbury Ethics Committee B (Committee response)
Jinny Willis	Lipid and Diabetes Research
Susan Dovey	Australian Primary Health Care Research Institute
Marion Clark	Nursing Council of New Zealand

There were an additional 16 respondents who did not wish their personal details to be released.

Appendix 7: Crown Law Office Opinion

6 August 2003

National Ethics Advisory Committee
Ministry of Health
PO Box 5013
WELLINGTON
Attention: Elizabeth Fenton, NEAC Secretariat

Fax No: 496 2340

Dear Ms Fenton

Second opinion and appeal processes for ethical review
Our Ref: HEA007/533

Introduction

1. I refer to your letter of 24 April 2003, and the associated papers. I apologise for the delay in providing this advice.

2. In that letter, you posed the following questions, which I have slightly rephrased:

   2.1 Do the forms of challenge to the decisions of regional ethics committees that are currently available within the ethics committee domain, and which are contained in the Operational Standard, meet good governance criteria, such as accessibility and natural justice?

   2.2 What are the forms of challenge to regional ethics committee actions that are currently available (eg, challenge by way of judicial review)?

   2.3 Given the kinds of actions that regional ethics committees may and do perform, and the forms of challenge to those actions that are currently available, what other forms of challenge might the National Ethics Advisory Committee ('NEAC') consider? In particular, would introduction of any form of challenge by appeal be possible? If so, what sort of appeal?

   2.4 What sorts of legal considerations are relevant as NEAC develops its advice regarding which body should consider challenges to the actions of ethics committees (eg, rights of applicants to ethics committees)?

3. My advice follows. It may be that after the next NEAC meeting on 11 August you have subsequent questions, and I am happy to provide further advice at that stage.

Background

4. The 2000 Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region ('CSI Report') made recommendations on ethics committees as a result of the difficulties experienced by health researchers in attempting to gain access to information from the Cancer Register needed to conduct audits of the Cervical Screening Programme. It was reported that Cancer Registry staff would not release the information to the evaluation team without them having Ethics Committee approval for the evaluation (para 6.88 and para 6.91 of the CSI Report).

5. The CSI Report made a number of recommendations for improving ethics committee guidelines including the recommendation that (11.23):

> *'The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.'*

6. Consequently, the Minister of Health asked the NEAC to address certain matters arising from the CSI Report, including the operation of regional ethics committees operating under the Operational Standard for Ethics Committees ('Operational Standard'), current processes for the ethical review of national and multi-centre research, guidelines on conducting observational studies, and second opinion and appeal processes.

The legal environment in which ethics committees operate

7. Before addressing the specific questions you have raised, it is important to clarify the legal environment in which the various ethics committees operate.

8. The ethical review system in the health and disability sector comprises a number of ethics committees established under different pieces of legislation.

The National Advisory Committee on Health and Disability Support Services Ethics

9. Section 16(1) of the New Zealand Public Health and Disability Act 2000 requires the Minister of Health to appoint a national advisory committee on the ethics governing health and disability support services for the purpose of obtaining advice on ethical issues of national significance in respect of any health and disability matters (including research and health services). This occurred in December 2001.

10. NEAC is required by section 16(2) to determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services.

11. In addition, under section 16(3), the Minister of Health may appoint either the ethics committee of the Health Research Council, or a special committee under section 11 of the New Zealand Public Health and Disability Act 2000, to obtain advice on specific ethical issues of national, regional or public significance in respect of any health or disability matters. The National Ethics Committee on Assisted Human Reproduction ('NECAHR') is such a Ministerial committee established under this subsection. I am not aware of any others.

12. There is no statutory right of appeal from these committees. This is not surprising in the case of the NEAC given it exists primarily to advise the Minister, and promulgate national ethical standards. However, it may be somewhat more problematic in the case of the NECAHR given that in addition to advising the Minister, it has the function of reviewing assisted human reproductive proposals (ie, making decisions with impact on third parties).

The Health Research Council Ethics Committee

13. The Health Research Council Ethics Committee ('HRC Ethics Committee') is established under section 24 of the Health Research Council Act 1990. Its functions are set out in section 25 of that Act, and those which could theoretically require review and appeal rights include:

    - Considering and making recommendations to the Research Council on ethical issues in relation to health research (section 25(1)(a)).
    - Ensuring that, where an application is made to the Research Council for a grant for health research, an independent ethical assessment of the proposed health research is made either by the HRC Ethics Committee itself or a health and disability ethics committee ('HDEC') approved by the HRC Ethics Committee (sections 25(1)(c) and (d)).

14. Again, there is no statutory right of appeal from recommendations or assessments by the above committees. However, where the HRC Ethics Committee has itself approved an HDEC pursuant to section 25(1)(c), it is empowered to review, at the request of any person who has made an application for a grant for the purposes of health research, the independent ethical assessment made by the HDEC (section 25(1)(e)). The HRC Ethics Committee can also provide independent comment on ethical problems that may arise in any aspect of health research (section 25(1)(g)).

Health and Disability Ethics Committees

15. I am not clear as to the basis by which HDECs are established. The Operational Standard asserts that the Ministry of Health funds and indemnifies them and that the Director-General may from time to time alter the number of HDECs and their corresponding regions of authority (see para 163). However, there is nothing in any legislation allowing for their establishment so that they are not statutory bodies.

16. I understand that there are currently 14 HDECs in New Zealand, approved by the HRC Ethics Committee for the independent ethical review of innovative practice and health research. The regions covered by these HDECs are broadly in line with those of the former Area Health Boards.

17. Apart from the Health Research Council Act 1990, HDECs are referred to in two other pieces of legislation:

    17.1 Section 32 of the Injury Prevention, Rehabilitation and Compensation Act 2001 refers to persons seeking cover for personal injury caused by medical misadventure. The combined effect of sections 32(3), (4) and (5) is that personal injury caused by medical misadventure includes personal injury a person suffers as a result of medical error or medical mishap in anything done or omitted as part of a clinical trial either:

        17.1.1 where the claimant did not agree in writing to participate in the trial, or

        17.1.2 where an HDEC approved the trial and certified that it was satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.

    17.2 The Health Information Privacy Code 1994, where approval by the NEAC, the HRC Committee or an HDEC, is required before health information can legally be used or disclosed (see Rules 2, 10 and 11 of Code).

18. I understand that it is in respect of the HDECs that the current task is primarily concerned.

Other committees

19. I note that in addition to these regional HDECs, there also exist institutional ethics committees and private sector ethics committees, some of which are also approved by the HRC Ethics Committee.

Question One: The current forms of challenge

20. The Operational Standard contains six different terms for related concepts, but in some instances seems to use those terms more or less synonymously. It is important to clarify the differences between them. The terms are:

    20.1 Complaint

    20.2 Second opinion

    20.3 Challenge

    20.4 Review

    20.5 Appeal

    20.6 Judicial review.

21. I suggest what is really meant is a continuum of formality of challenge. At the one end, informal complaint, leading to perhaps a request for a second opinion or an independent review of the decision, with formal appeal or judicial review being at the other end of the spectrum.

Informal complaints and second opinions

22. The Operational Standard contains the following mechanisms at the informal end:

    22.1 Para 7.10: Ethics Committees must review any new information that relates to any previous decision to grant or decline ethical approval of a proposal (including the investigation of reports that a proposal is not being implemented in a safe and ethical manner).

    22.2 Para 7.12: Second opinions from the NEAC or the HRC Ethics Committee may be sought by an ethics committee in the process of considering a proposal, or by the investigator submitting the proposal who disagrees with a decision made by an ethics committee. It is stated (at 289–90) that:

> *'A second opinion is not regarded as a higher judgement [sic] but rather as a review of the proposal by an independent committee. The second opinion is not binding and neither the National Ethics Committee nor the HRC Ethics Committee is an appeal body in the strict legal sense.*
>
> *The final decision rests with the original ethics committee, which must take into account the second opinion.'*

    22.3 Para 7.13: Complaints may be made regarding the performance or conduct of committee members or the administrative procedures of a committee, either directly to the committee or to the National Co-ordinator.

    22.4 Para 7.14: Complaints may be made regarding the decisions of ethics committees to the committee itself, the NEAC or the HRC Ethics Committee. This is not a formal appeal process, and the Operational Standard also notes that it does not preclude an action for judicial review.

Do these current forms of challenge meet standard common law criteria such as accessibility and natural justice?

23. A helpful starting point in considering appropriate mechanisms for the operation of decision-making bodies, and appeal procedures from their decisions is the Legislation Advisory Committee's publication 'Guidelines on Process and Content of Legislation' ('LAC Guidelines'). Although the HDECs are not statutory bodies, and the processes NEAC is now considering will not form the basis of legislation, the LAC Guidelines are nonetheless instructive on principles of good and fair decision-making, and sound processes for review and appeal.

24. As a matter of principle, the LAC Guidelines say:

> *'Where legislation authorises decisions that impact on a person's rights, interests, or legitimate expectations, consideration should be given to providing a right of appeal from individual decisions, by which a new decision can be made on the merits by the appellate body. The choice of an appellate body, and the procedure to be followed in making and deciding an appeal, should follow principles based on past experience.*
>
> *...*
>
> *In general there should be a right of appeal against the findings of officials, tribunals and other bodies making decisions that affect important rights, interests and legitimate expectations of individuals. The greater the effect on an individual person's rights, interests or legitimate expectations, the stronger the case for providing a right of appeal.'*

25. The functions of the HDECs are set out in paragraphs 169 and 170 of the Operational Standard. Their principal role is:

> *'[to] provide independent ethical review of innovative practice and health research that will be conducted in their designated region of authority.'*

26. Given these functions, there is little doubt that HDECs make decisions that impact on researchers' (and subjects') rights, interests, and legitimate expectations. Thus, it seems appropriate for the Operational Standard to provide for a right of appeal.

27. The current forms of review in the Operational Standard lack an appeal process. A possible process is suggested below in answer to Question Four.

28. However, in relation to the informal challenges as they presently exist in the Operational Standard, I note the following.

29. First, it is not clear what you mean by 'accessibility' in the framing of your question. It is assumed that you refer here to the ease with which applicants for ethical approval can avail themselves of the various avenues of informal challenge. I have of course only reviewed these processes as they are set out in the Operational Standard, but on their face they appear relatively easy to invoke. I cannot comment on whether this is reflected in actual practice.

30. Second, as to whether the forms of challenge meet 'natural justice' criteria, I consider that if an HDEC disposed of an application in accordance with the guidelines as to process set out in the Operational Standard, it would very likely be insulated from the risk of a successful judicial review action for breach of natural justice.

Question Two: Legal challenges: judicial review, breach of the Bill of Rights Act, complaint to the Ombudsmen

Judicial review

The difference between appeal and review

31. Appeal and judicial review are formal mechanisms. It is important to note the crucial difference between judicial review and appeal. A court in judicial review proceedings does not have the power to substitute its decision on the merits for that of the body being reviewed. Rather, judicial review concerns itself with the process leading to a decision. The merits of the decision are the domain of the appeal right.

32. Another ground for review is legality, or the extent to which the decision-maker has turned its mind to the statutory framework in which it operates. Because the HDECs operate in a non-statutory context, this is not a ground for review with which you need be concerned.

33. Whilst the distinction between review and appeal is not always maintained in practice (judicially reviewing a decision on the basis of unreasonableness comes very close to review on the merits), it is important to keep the distinction intact for the purposes of the current exercise.

The nature of judicial review

34. In brief, judicial review is the review by a judge of the High Court of a decision, proposed decision, or refusal to exercise the power of decision, to determine whether that decision is unauthorised or invalid. Judicial review may be brought under statute (the Judicature Amendment Act 1972 ('JAA') or Part VII of the High Court Rules) or common law.

35. Where any of the various ethics committees exercise a statutory power, including a statutory power of decision, that decision will be amenable to judicial review under section 4(1) of the JAA. This will be so notwithstanding any right of appeal available.

36. However, non-statutory powers are also reviewable if they are sufficiently public in nature. What is reviewable are exercises of power that:

> *'... in substance have important public consequences however their origins and the persons or bodies exercising them might be characterised'. Royal Australasian College of Surgeons v Phipps [1999] 3 NZLR 1, 15*

37. It is now well established that the nature of the decision making body is less relevant than the nature of the decision. In *R v Panel on Takeovers and Mergers, ex p Datafin plc* [1987] 1 QB 815, judicial review was sought of a determination of the Panel on Takeovers and Mergers, an unincorporated association, without any legal authority. Although the Panel lacked 'any authority de jure', it exercised 'immense power de facto'.

38. The English Court of Appeal held that the Panel was the proper subject of judicial review as, *inter alia*:

    38.1 a periphery of statutory powers and decisions were dependent on the Panel's decisions

    38.2 the Panel operated wholly in the public domain

    38.3 control by established forms of private law would not be effective.

39. Lloyd LJ emphasised (at 848) that 'it is not just the source of the power that matters, but also the nature of the duty'.

40. The New Zealand Court of Appeal adopted the *Datafin* approach in *Electoral Commission v Cameron* [1997] 2 NZLR where the Court had to determine whether a ruling of the Advertising Standards Complaints Board was subject to judicial review. The Court of Appeal held that section 4(1) of the JAA was triggered and therefore it did not need to rely on its common law jurisdiction. However Gault J did emphasise that (at 424):

> *'whether by contract or by industry practice, the Board exercises a regulatory function by which it determines what advertising is or is not communicated to the public by substantially the whole of the media throughout the country.'*

41. His Honour went on to state (at 433):

> *'The Board in carrying out its public regulatory role, though in accordance with powers conferred ... by a private organisation, must be regarded as exercising public power. That will be reviewable on public law principles.'*

42. Thus, the HDECs, whilst not statutory bodies, may be subjected to judicial review, depending on the nature of the decision at issue.

43. The grounds on which an action may be brought in judicial review against an ethics committee include:

    43.1 that the action of the committee was unlawful or unreasonable

    43.2 that committee members acted with bias or predetermination

    43.3 that the committee failed to take into account relevant matters in making its determination

    43.4 that the committee took into account irrelevant matters

43.5 that the committee failed to observe the principles of natural justice, for example by failing to give an applicant an adequate opportunity to comment on any adverse findings.

44. The Court in judicial review proceedings may issue a declaration in respect of the decision, quash the decision and/or send the decision back to the relevant ethics committee for reconsideration (with directions as to that reconsideration, ie, without the presence of the element of flawed process identified by the Court).

45. However, one of the significant deficiencies of judicial review as a means of challenging a decision is that the proceedings will often not result in a different decision being made. As stated above, the Court will not substitute its own view on the merits of a decision for that of the body under review. This is particularly so in a specialist area such as ethical approval of research proposals. If the decision is found by a Court to be unreasonable it may be quashed, but unreasonableness requires a very high threshold.

Breach of the New Zealand Bill of Rights Act 1990

46. The New Zealand Bill of Rights Act 1990 ('BORA') applies (section 3) to acts done –

46.1 By the legislative, executive, or judicial branches of the government of New Zealand; or

46.2 By any person or body in the performance of any public function, power or duty conferred or imposed on that person by or pursuant to law.

47. The HDECs may fall within the second limb of the section 3 definition (for the same arguments as discussed above in relation to the nature of the powers they exercise). Therefore, they may also be the subject of a claim for breach of BORA, the most likely action being for breach of section 27 and the right to the observance of the principles of natural justice.

48. In terms of remedy for breach of BORA, although the Act itself contains no express remedies clause, in *Simpson v Attorney-General [Baigent's case]* [1994] 3 NZLR 667 (CA) the Court of Appeal held that in order to provide effective protection for the rights and freedoms guaranteed it was appropriate to interpret the Bill of Rights as creating a direct Crown liability regime for rights violations. In particular, the Court of Appeal found that there is a jurisdiction to award monetary compensation for breaches of the Bill of Rights. Since that case there have been a number of reported and unreported judgments in which monetary compensation has been awarded for breaches of the Bill of Rights.

Complaint to the Ombudsmen

49. It would appear that no complaint to the Ombudsmen is available with respect to any of the various ethics committees.

50. The Ombudsmen have no jurisdiction to investigate any complaint made in respect of the HRC Ethics Committee or the HDECs because neither the NEAC nor the HRC, nor the HDECs are listed in Schedule 1 to the Ombudsmen Act 1975.

Question Three – Other forms of challenge for NEAC to consider

51. As discussed above, it is desirable some kind of appeal process from decisions of the HDEC's be put in place. In formulating this, NEAC will need to consider a number of questions:

    51.1 What will be the grounds for an appeal?

    51.2 Is the right to be a general right of review of the decision? Or will it be a limited type of appeal?

    51.3 Which body should hear the appeal? Should it be NEAC or the HRC Ethics Committee? Or will an ad hoc committee of appropriate experts be convened for the purpose?

    51.4 Who should have a right to appeal? Will it be just the applicant researcher, or should it also be available to the patient in respect of whom the novel/experimental process is being suggested? Should special interest groups have any standing at an appeal, or a right to appeal? Who should have a right to be heard in any appeal?

52. You may wish to discuss these questions at your next meeting. I am happy to assist with any further inquiries as well as the formulation of the appeal provisions themselves.

Question Four – Relevant legal considerations for NEAC

53. For the purposes of facilitating NEAC's discussion on this issue, the following possible scheme is suggested, which adds to the current scheme as to second opinions already set out in the Operational Standard:

    - An HDEC receives an application. It must then either:
        - make a decision on the application (approved, approved with conditions, or declined), or
        - seek a second opinion (from the HRC Ethics Committee) and then make a decision, taking account of the second opinion. The HDEC ought to advise the applicant of its intention to seek a second opinion, the particular matter upon which the second opinion ought to be sought, and the proposed source of the second opinion.
    - If the HDEC makes a decision that the applicant does not accept (ie, an approval with conditions or a declination), the applicant can ask for a second opinion (also from the HRC Ethics Committee), but only where a second opinion has not already been sought by the HDEC.

    The second opinion should then be received by the HDEC, which should review its original decision, taking into account the second opinion.

This process is consistent with the 'review of decisions' procedure recorded at para 7.10 of the Operational Standard.

If the HDEC had already obtained a second opinion in the course of making its decision, the applicant could proceed straight to the appeal process.

- In providing second opinions the HRC Ethics Committee is responsible to ensure that the second opinion is informed by such specialist advice as is required to fully address the issues upon which the HDEC is seeking guidance, and that all advisers and members of the HRC Ethics Committee that are to deliberate on the matter are independent and free from any conflicts of interest.
- If that process has still not been completed, and the applicant is still not satisfied with the outcome, the applicant may lodge with NEAC (or appropriate body) an appeal (or what is in fact a request for a **third and binding** opinion) on specified grounds.
- NEAC will then be required to determine whether the HDEC decision should stand or should be modified in some way.

  This will require a modification to the terms of reference for NEAC (if it is decided that NEAC will be the appellate body). Two possible grounds for appeal sit well with the existing terms of reference:

  - Grounds that the matter is of national significance to an extent overlooked or not given proper weight by the HDEC (c.f. Terms of Reference, clause 3(a): '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').
  - That the decision is inconsistent with decisions made in other HDECs (c.f. Terms of Reference, clause 3(b): 'to determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services').
  - In this regard, I note that a central repository for HDEC decisions that can be accessed by all HDECs and by NEAC, would be useful.
  - To these two specific grounds could be added a third general ground 'or where for any other specified reason or reasons the applicant believes the decision of the HDEC should be modified'.

54. I hope that the above discussion assists you in your next meeting. Please do not hesitate to contact me (DDI 470 4479), or John Beaglehole (DDI 470 4463), if you have any other queries either before or after that meeting.

Yours faithfully

Rachael Schmidt
Associate Crown Counsel

Crown Counsel responsible: John Beaglehole