System of Ethical Review of Health and Disability Research in New Zealand

Discussion Document

September 2003
How to Respond

NEAC is asking stakeholders for their comments on this discussion document in order to assist the Committee to develop advice to the Minister of Health. There are questions in a tear-out section at the back of this document. You might like to use the questions as a way of organising and presenting your feedback. Please feel free to make additional comments if you wish. Your assistance is much appreciated.

There are three ways in which you can respond to this document:

1. Write your comments in the tear-out section at the back of this document and send them back to NEAC in the enclosed envelope.

2. Complete the questions as a Word document and either email it to NEAC or send it by post. The Word document is on the NEAC website at http://www.newhealth.govt.nz/neac.htm.

3. Write your comments as an email, or as a letter that you can send to NEAC in the enclosed envelope.

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# System of Ethical Review of Health and Disability Research in New Zealand

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Section One

1.1 Introduction

The purpose of this paper is to present, for consideration by stakeholders, options concerning the ethical review of national and multi-centre research; and second opinion and appeals processes within the system of ethical review for health and disability research in New Zealand.

These options are presented for consideration as part of a review being undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Advisory Committee or NEAC).

Section One of this document outlines the review context and focus, and proposes a framework for considering the goals, objectives and desired outcomes of a well functioning system of ethical review.

Section Two examines the current system of ethical review for national and multi-centre research; considers stakeholder comment on the current system and suggestions for improvements; and explores options for the future review of national and multi-centre research.

Section Three presents options for the appropriate application of second opinion and appeal processes to the system of ethical review.

NEAC invites comment from stakeholders on the options and other content presented in this paper. The responses to this document will contribute to the development of recommendations to be presented by NEAC to the Minister of Health in November 2003.

1.2 Review focus

The National Ethics Advisory Committee was established 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 of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
- determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

The Minister of Health has asked NEAC to address as a priority 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 review of the current processes for ethical review of health and disability research in New Zealand.

**Recommendations from the Gisborne Inquiry relevant to this review**

- 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 (11.18) [This recommendation is considered in a separate NEAC discussion document ‘Ethical Review of Observational Research, Audit and Related Activities’].
- 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 medical research generally in New Zealand (11.19) [This recommendation is also considered in the discussion document ‘Ethical Review of Observational Research, Audit and Related Activities’].
- Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies (11.21) [This recommendation is considered in the discussion document, ‘Ethical Review of Observational Research, Audit and Related Activities’].
- A national ethics committee should be established for the assessment of multi-centre or national studies (11.22).
- 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 (11.23).

These recommendations have significantly influenced the focus of options presented in this paper.
It has been suggested that a possible future cross-sectoral approach be considered for the ethical review of research involving human participants. This would require collaboration across multiple public agencies (for example, in health; tertiary education; environment; and research science and technology), and potentially also other organisations, in a cross-sectoral approach. One model for this is provided by the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (1998). However, investigation of any such model in the New Zealand setting goes beyond NEAC’s current brief.

1.3 Goals, objectives and desired outcomes of an ethical review system

While the principles of ethical review are clearly set out in the Operational Standard (Ministry of Health, 2002), NEAC here seeks to identify the overall goals, objectives, and desired outcomes for an ethical review system. A system of ethical review includes self-review, peer review, scientific review and grant committee assessment, as well as ethics committee review.

The proposed goals, objectives and desired outcomes for an ethical review system are presented in the table below. They will be used to assess options and guide NEAC’s development of recommendations to the Minister of Health. The goals, objectives, and desired outcomes will also be used to stimulate responses on the options presented in Sections Two and Three.
## 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

<table>
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<tr>
<th>Objectives</th>
<th>Desired outcomes</th>
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| **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 |
| **Informed** | • Researchers consider ethical implications from the outset, e.g. 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  
• Reviews are timely  
• 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 |
1.4 Processes of the review to date

The review processes undertaken by NEAC in 2003 have included:

- The development of goals, objectives, and desired outcomes for ethical review processes, with input from stakeholders.
- 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-site and multi-centre applications submitted to RECs 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).
- Interviews with stakeholders. Individuals and groups interviewed are listed on the NEAC website.
- Preparation of two discussion documents.
- A legal opinion from the Crown Law Office on actual and possible second opinion and appeal processes.
- A literature survey of recent material published in New Zealand and internationally on issues covered in the review.

1.5 Next steps for NEAC’s review

1. Disaggregated data from the questionnaire survey and interviews will be placed on the NEAC website.

2. There will be a six-week consultation period on NEAC’s two discussion documents:
   - *System of Ethical Review of Health and Disability Research in New Zealand* (this document), and

3. Cross-sectoral workshops will be held to discuss review issues and options with key stakeholders.

4. Further interviews with key stakeholders will be undertaken.

5. Comment from stakeholders on options for ethical review of national and multi-centre research will be analysed and recommendations will be made to the Minister of Health in November 2003.

6. Comment from stakeholders on options for second opinions and appeal processes will be analysed and recommendations will be made to the Minister of Health in November 2003.

7. Comment from stakeholders on the ethical review of observational research, audit and related activities, and proposed guidelines for observational studies, will be
analysed and recommendations will be made to the Minister of Health in November 2003.

1.6 Future NEAC work on the system of ethical review of health and disability research

The questionnaire and interviews with regional ethics committee members, researchers, and other key stakeholders canvassed a range of issues relating to the system for ethical review of health and disability research.

In this discussion document the findings from the questionnaire and interviews relating to the processes for national and multi-centre research are outlined in Section Two and the findings relating to second opinion and appeals processes are outlined in Section Three. In both these sections the findings have informed NEAC’s work including the development of the options that are presented.

Additional findings relating to the operation of ethics committees are included as Appendix 1. These preliminary findings from questionnaires and interviews have not been further developed at this stage given that the primary focus of this review is to explore the areas of national and multi-centre research; second opinion and appeals processes; and observational studies.

When the Minister of Health has considered the recommendations made by NEAC in the above three areas, NEAC may be required to carry out further work in relation to the review of the operation of ethics committees.

The findings from the questionnaires and interviews relating to the operation of ethics committees will also be used to inform NEAC’s forthcoming review of the Operational Standard for Ethics Committees.

Information gathered from stakeholders relating to Māori responsiveness will be used to inform NEAC’s ongoing work to develop a Māori framework for ethical review. It will also be used in the review of the Operational Standard for Ethics Committees.

1.7 Structure of Sections Two and Three

Sections Two and Three are set out as follows:

- Current system: policy and practice
- Stakeholder comment on the current system and suggestions for improvements
- Options for consideration
- Questions concerning the proposed options, with reference to the goals, objectives and desired outcomes of ethical review.
Section Two: Processes for the Review of National and Multi-centre Research

2.1 Purpose

The purpose of this section is to:

1. Examine the current system of ethical review for national and multi-centre research.
2. Consider stakeholder comment on the current system and suggestions for improvements.
3. Explore options for the future review of national and multi-centre research.

2.2 Background and rationale

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 accepted the Gisborne Inquiry Report and has asked the Ministry of Health to implement its recommendations. The Minister 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 (Hon Annette King, letter of 4 April 2002).
2.3 Definitions: what are multi-centre studies?

Multi-centre studies can be categorised in the following ways:

1. Type of research: for example, observational, interventional, or social.

2. Level of regional involvement:
   a. centralised studies, with investigators based in one region only, with no investigators regionally based
   b. partly centralised studies, with no lead investigators regionally based, but with regional collaborators (e.g. GPs, midwives), aiding in the collection of data
   c. fully regionalised studies, carried out by a different lead investigator in each region (though with an overall principal investigator).

There are three aspects to the definition of multi-centre studies in health and disability research:

- What is regarded as a multi-centre study in current New Zealand practice?
- What is regarded as a multi-centre study in current New Zealand policy?
- What is regarded as a multi-centre study in ethical review internationally and in other New Zealand research contexts?

In current practice, New Zealand regional ethics committees regard as multi-centre research any study that involves more than one study region. This includes studies that gather or access information from more than one region, but are conducted by investigators based in one region only. Such studies proceed through the multi-centre review process, in the same way as studies that involve investigators from multiple regions.

The current Operational Standard (Ministry of Health, 2002, p.134) defines multi-centre research as:

*Research conducted simultaneously by several investigators at different centres, with identical methods and following the same protocol. The aim of such research is to collect data as rapidly as possible for unified analysis leading to a single report.*

This definition states a narrower understanding of multi-centre studies than that operating in current practice, as it does not include studies where researchers in one region gather information from more than one region.

The Health Research Council’s Guidelines for Completion of Application Form EA 05/02 (Health Research Council, 2002, pp.21–22) contain the following guidance on this matter:

*The principal researcher will be responsible for simultaneously sending the appropriate number of copies of the proposal to each and every ethics committee in all areas/localities involved in the study ... The application form must indicate all other centres at which the study will be conducted, and, if appropriate, contain statements from local researchers and their institutions indicating their willingness to participate.*
The Guidelines are ambiguous with regard to whether the areas/localities involved in the study are only those in which researchers are based or also those from which information will be gathered (Evans, 2002, p.21).

There is some debate internationally about whether studies in which researchers in just one region gather information from more than one region should be considered multi-centre research. The policy on this point has implications for the way in which such studies are to be reviewed.¹

Many New Zealand university-based studies conducted in more than one region are currently treated as single-centre studies, in that they are assessed only by the ethics committee of the university in question. The focus of the discussion below, however, is on ethics committee review within the health sector, rather than on these university-based studies.

2.4 Current system of ethical review for national and multi-centre research

Structure, processes, operation

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).² 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 (Operational Standard, Section 6.0).

The actions of regional ethics committees (RECs) 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).

¹ Multi-centre research in the NHS – the process of ethical review when there is no local researcher (Supplementary Operational Guidelines for NHS Research Ethics Committees, November 2002, v.2, COREC, in Eckstein (2003)).

² 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.
Summary of current process
The current process for the review of multi-centre research is that:

(a) The committee for the region in which the lead investigator is based acts as the primary committee, coordinating 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.3

(Operational Standard, paragraph 308.)

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, the proposal. Once agreement is reached the lead committee approves the study on behalf of the other committees (Evans, 2002, p.3). 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.

3 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 (e.g. by the Standing Committee on Therapeutic Trials, or by the Gene Technology Advisory Committee).
It is a matter of interest whether New Zealand’s multi-centre review process demands a single ethics committee opinion, or allows multiple single-centre opinions, because of the level of accordance of the system 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.* (Directive 2001/20/EC of the European Parliament, 2001, Article 7.)

**Other ethics committees**

In addition to review provided by the 15 regional ethics committees, ethical 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 under section 11 of the New Zealand Public Health and Disability Act 2000.

**Workload**

During the period 2000–2001, nine out of 13 regional ethics committees (considering the two Auckland committees as one, and prior to the establishment of the second committee in Canterbury) had a substantial proportion (more than 50%) of their annual workload generated by the review of multi-centre research protocols. The average proportion of multi-centre studies in the workload for each ethics committee over this period is 62 percent. More detail is set out in Table 1.

The nationwide total number of multi-centre applications reviewed by ethics committees is a small proportion of the total number of applications reviewed. In the current system, however, each multi-centre study application is fully reviewed by an ethics committee in each involved region, and consequently by at least two committees. Applications for national studies are reviewed by one committee in each of the 13 regions. This means that applications for multi-centre studies have a significant overall presence in the review system. Some committees have most, if not all, of their work consisting of the review of multi-centre studies. Table 2, below, sets out the total number of multi-centre applications from 1999 to 2001.
Table 1: Reviews of multi-centre studies as percentages of overall REC workloads (total reviews)

<table>
<thead>
<tr>
<th>Committee</th>
<th>2000</th>
<th>2001</th>
<th>Average %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auckland (X and Y)</td>
<td>30</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td>Bay of Plenty</td>
<td>65</td>
<td>61</td>
<td>63</td>
</tr>
<tr>
<td>Canterbury</td>
<td>30</td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td>Hawkes Bay</td>
<td>64</td>
<td>80</td>
<td>72</td>
</tr>
<tr>
<td>Manawatu/Whanganui</td>
<td>45</td>
<td>64</td>
<td>54</td>
</tr>
<tr>
<td>Nelson/Marlborough</td>
<td>100</td>
<td>92</td>
<td>96</td>
</tr>
<tr>
<td>Otago</td>
<td>30</td>
<td>27</td>
<td>49</td>
</tr>
<tr>
<td>Southland</td>
<td>69</td>
<td>90</td>
<td>80</td>
</tr>
<tr>
<td>Tairawhiti</td>
<td>59</td>
<td>78</td>
<td>69</td>
</tr>
<tr>
<td>Taranaki</td>
<td>57</td>
<td>96</td>
<td>76</td>
</tr>
<tr>
<td>Waikato</td>
<td>56</td>
<td>59</td>
<td>58</td>
</tr>
<tr>
<td>Wellington</td>
<td>28</td>
<td>37</td>
<td>33</td>
</tr>
<tr>
<td>West Coast</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>


Table 2: Number of national and multi-centre research applications to health and disability ethics committees

<table>
<thead>
<tr>
<th></th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>Average per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>National multi-centre studies</td>
<td>6</td>
<td>3</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Non-national multi-centre studies</td>
<td>45</td>
<td>55</td>
<td>80</td>
<td>60</td>
</tr>
<tr>
<td>Total number multi-centre studies</td>
<td>51</td>
<td>58</td>
<td>89</td>
<td>66</td>
</tr>
</tbody>
</table>

Source: Regional health and disability ethics committee data: Protocol Numbers of Multi-centre studies from 1999 to 2001 (Donald Evans).
2.5 Stakeholder comment on the current system and suggestions for improvements

NEAC administered a questionnaire survey to all regional ethics committee members and a sample of one in every 13 researchers who submitted single-centre and multi-centre research proposals to regional ethics committees in 2001 and 2002. A range of other stakeholders were interviewed. A list of interviewees can be found on the NEAC website.

Responses by REC members and researchers regarding their experiences of the current process

REC members
Regional ethics committee members with involvement in the review of multi-centre research, were asked to comment on their experience of this process.

Approximately two-thirds of the REC responses were in favour of retaining the current multi-centre review processes. Over a quarter of responses favoured retaining local input and input from different RECs. It was not always clear from the responses whether this referred to local input through the REC structure, or the retention of local input per se. Some respondents stated that recent changes have improved, or have the potential to improve, the process.

Researchers
A sample of researchers who had submitted applications for ethics committee review were asked to comment on their experiences of the process.

Twenty-eight responses described negative or frustrating experiences, with comments ranging from mildly negative to very negative.

A small number of comments suggested that one committee approve multi-centre studies.

Nine respondents had a positive experience of the process.

Comment
The issue of multi-centre research was also raised spontaneously in a general question about what needs to change and what needs to be retained in the current system. Some researchers had concerns about what they saw as inconsistencies in decision-making outcomes between RECs regarding multi-centre studies. There was significant divergence between the responses of REC members and those of researchers. Comments from REC members were predominantly positive. In general, researchers tended either to be somewhat critical in their comments, or they did not have experience of the multi-centre system.

At the time of writing, 81 responses from REC members and 60 responses from researchers had been received and analysed.
Suggestions for improvements

Both REC members and researchers provided suggestions and recommendations for improving the current system. Comments from interviews with other stakeholders are also included here. Disaggregated data from the questionnaire and interviews can be found on the NEAC website.

Recommendations and suggestions include:

- **Ideas for streamlining and assuring efficient use of resources**
  - Reduce the amount of paper used, and paper work involved.
  - Reduce clumsy and burdensome aspects – practical considerations, eg, number of copies of applications to different committees.
  - Avoid duplication.
  - Ensure good co-operation and co-ordination between the primary committee and the secondary committees.

- **Ideas for consultation, positive relationships and focus**
  - Keep people at the centre of multi-centre studies.
  - Ensure consultation with tangata whenua in each region.
  - Ensure that the tone of response to student researchers is not belittling.
  - Show clearly the value of local knowledge/expertise in multi-centre research advice from RECs – it may be there, but is not evident/recorded/connected with committee decisions (researchers do not get feedback).

- **Ideas to assure consistency**
  - Have consistent procedures across different ethics committees and resolve inconsistencies about what committees want.
  - Resolve issues where one committee approves a study and another does not.
  - Resolve issues around international studies.

- **Ideas to ensure robust decisions**
  - Assist less experienced committee members to gain a better understanding of research methodology, including qualitative research.
  - Provide information to answer questions and ensure the primary committee notifies the secondary committees of the eventual outcome.
  - Have a standard meeting date throughout New Zealand and a standard cut-off date to speed up the process.

- **A range of structural solutions were proposed including:**
  - Shifting responsibility within the current structure:
    - Have the primary committee confirm that the research design is acceptable, then obtain views from secondary committees about locality-specific issues such as consultation.
    - Require secondary committees to focus on major ethical concerns while the primary committee provides a full review of the protocol.
- Maintain and refine the current system with greater leadership taken by the lead committee and ability to analyse and overturn decisions of individual RECs.
- Have lead ethics committee as the only ethics committee for those national and multi-centre studies with one investigator. Those studies with more than one investigator to go to all relevant committees where investigators are located.
- Maintain the benefits of the current process.

  - Suggestions for a new structure involving a national committee:
    - Have a single national committee to review multi-centre studies.
    - Consider the establishment of one national committee: a central committee for multi-centre studies and local committees dealing with local applications, or a national committee that has ways of gaining local information. If local RECs are retained, then the smaller ethics committees could become part of institutional committees, especially for ethical issues relating to services.
    - Develop a national ethics committee for national studies for consistency and efficiency. This would be independent of RECs and would not comprise the chairs of RECs (concerned about the unclear and non-mandated role of the Chairs’ group). RECs would continue operating for local applications/studies. RECs would be responsible to the national ethics committee.

2.6 Exploration of options for the future review of national and multi-centre research

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 have been generated for consideration.

Who leads?

One significant question is whether a national primary committee, as proposed by the Gisborne Inquiry, is a better mechanism for the consideration of multi-centre research proposals than a regional primary committee model, such as the one currently in operation. NEAC is mandated by the Minister of Health to consider a national primary committee structure. This option has also been suggested by a number of stakeholders consulted in the review to date.

What secondary assessment arrangements?

A second question concerns the extent of assessment by secondary committees.
Statutory or non-statutory?

A third question is whether the review system should have a direct statutory basis.

These options are presented and explored in more detail below. Prior to setting out the options, information is provided below on what would be required, were there to be a national ethics committee structure.

2.7 Consideration of a national primary committee structure

Recommendation 11.22 of the Gisborne Inquiry Report states that “A national ethics committee should be established for the assessment of national and multi-centre studies”.

The following discussion sets out possible structures for a national primary committee, were it to be established.

Process for approving a national committee

Any national ethics committee would 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 any such national ethics committee, if it were to conduct ethics committee review of any study approved for Health Research Council funding.

Can an existing national committee undertake this work?

Two existing national committees emerge as possible candidates for undertaking this role. Discussion on the appropriateness of either committee for this work is presented below.

National Ethics Advisory Committee (NEAC)

This statutory committee is an independent advisor to the Minister of Health on ethical issues of national significance regarding health and disability research and services. It is established under the New Zealand Public Health and Disability Act 2000, its members are appointed by the Minister of Health, and it is serviced through the Ministry of Health. Review of multi-centre studies could be added to NEAC’s Terms of Reference, perhaps without the need for any statutory change. By statute and by membership, however, NEAC is configured primarily as a policy advisory committee on ethics, rather than as an operational ethics committee. Even if NEAC were to be reconfigured, potential for conflict would remain between its statutory role as a policy advisor on matters of ethics committee review, and any new role as a public body that itself conducts such review for multi-centre studies.
Health Research Council Ethics Committee (HRCEC)

This statutory committee of the Health Research Council is established by the Health Research Council Act. Its membership is appointed by and serviced through the Health Research Council. Review of multi-centre studies could be added to the HRCEC’s tasks, though it currently has statutory authority to review only certain HRC-funded studies. There would also be potential for conflict between the HRCEC’s statutory role to ‘approve’ operational ethics committees, and any new role of itself being such a committee. The HRCEC is also well established as the provider of second opinions on matters of ethics committee review. Some role conflict would potentially arise with this second opinion role, if the HRCEC were also to be given a new role as the provider of ‘first opinions’ on proposed multi-centre studies.

Establishing a new national committee to review national and multi-centre studies

A national ethics review committee could be established under section 11 of the New Zealand Public Health and Disability Act 2000. The Minister of Health may “establish any committee that the Minister considers necessary or desirable for any purpose relating to this Act or its administration or to any services” (New Zealand Public Health and Disability Act 2000, Section 11). It would be accountable to Parliament through the Minister of Health, to whom it would be an independent advisor. Its membership would be appointed by the Minister of Health, and would need to be configured to the appropriate operational standards for bodies that conduct ethics committee review. The National Ethics Committee on Assisted Human Reproduction (NECAHR) is at present established in this way.

2.8 Proposed options

The options that follow present alternatives regarding lead or primary ethics review: by regional committee or by national committee. Within those two main options, there are then various ‘sub-options’ for the level of involvement by secondary ethics committees.

Option 1: Regional Primary Committee

This option has a regional ethics committee as the primary ‘approval body’. The primary REC varies according to the region in which the applicant is based. This is the current arrangement for the primary committee. It is described more fully above under Current review system for multi-centre studies.

Set out below are the ‘sub-options’ for the regional structure option.
Option 1(a): Regional Primary Committee approval with full review also by each secondary committee

This option is current policy in New Zealand. Each relevant secondary ethics committee also conducts a full review of each multi-centre proposal, and has the power of decision regarding study conduct in its region, “but only on the basis of local or ethically relevant matters” (Operational Standard, paragraph 312). As discussed above, this power of separate decision is rarely exercised in practice.

Option 1(b): Regional Primary Committee approval with only locality assessment by each secondary committee

This option is current policy in the United Kingdom. Under this option each relevant secondary ethics committee would assess ‘locality issues’ only. These include: suitability of any local researcher, and of any local research environment and facilities; and specific issues relating to the local community. This option could involve a reduction in the number of RECs, because of the reduced workload.

Option 1(c): Regional Primary Committee approval with no review by secondary committees

Under this option no secondary REC would conduct any review or assessment. One possibility in such a system would be for the relevant health or disability sector host organisation (e.g., DHBs, Ministry of Health) to regard ‘locality assessment’ as part of its authorisation process for research involving staff or facilities. This option would be likely to result in a reduction of the number of RECs, because of the considerably reduced workload.

Option 2: National Primary Committee

This option would have a national ethics committee as the primary ‘approval body’, one and the same for all multi-centre applications. It is described more fully above under Consideration of a national primary committee structure.

Presented below are the same ‘sub-options’ for a national committee structure, as those just outlined for the regional structure option.

Option 2(a): National Primary Committee approval with full review also by each secondary committee

In this option a national committee would be the approval body for all multi-centre and national studies. Each relevant secondary ethics committee also conducts a full review of each multi-centre proposal, and has the power of decision regarding study conduct in its region, “but only on the basis of local or ethically relevant matters” (Operational Standard, paragraph 312).
Option 2(b): National Primary Committee approval with only locality assessment by each secondary committee

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 specific issues relating to the local community. This option could involve a reduction in the number of RECs, because of the reduced workload.

Option 2(c): National Primary Committee approval, with no review by secondary committees

In this option no secondary REC would conduct any review or assessment. As with Option 1(c), one possibility would be for the relevant health or disability sector host organisation (eg, DHBs, Ministry of Health) to regard ‘locality assessment’ as part of its authorisation process for research involving staff or facilities. This option would be likely to result in a reduction of the number of RECs, because of the considerably reduced workload.

2.9 Issues relating to the options

Lead committee workload

If the recommendation of the Gisborne Inquiry Report were implemented, the proposed national committee would be responsible for the ethics committee review of all multi-centre studies, including national studies. This would include various types of multi-centre research, for example, observational, interventional or social research. It would also include multi-centre studies with various levels of regional involvement on the part of researchers and facilities.

Under Option 1, above, in which a regional committee is the primary approval body for a multi-centre study, there would be a number of different regional committees acting as lead committees for different studies. In 2001, for example, seven of the (then) 14 committees acted as lead committee, their workload ranging between one lead review for the least busy committee, and 27 lead reviews for the busiest committee. Under a multi-centre system led by a national committee (Option 2), the workload for that committee would be the total number of multi-centre studies per annum (89 in 2001). Assuming 11 meetings per annum, in a year comparable to 2001 this would average at eight new multi-centre protocols per meeting for the national committee. To put this workload in perspective, in 2002 the five busiest regional committees reviewed an average of 16–17 new protocols per meeting. The review workload for a single national committee would thus be comparatively light, and insufficient to justify establishment of more than one committee. Were such a national committee to be established, policy-makers might wish to consider (with appropriate configuration of

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5 In 2002 the five busiest regional committees (Auckland X and Y, Wellington, Canterbury and Otago) reviewed, as lead committee, 104 multi-centre protocols. Complete data is not yet available from the regional ethics committee annual reports for 2002, but the data for these five committees shows the increase in the number of multi-centre applications from 2001 to 2002.
membership) whether it could also conduct the review activities currently conducted by NECAHR in the area of assisted human reproduction.

**Possible impact on the current system**

In a system with either a regional lead committee or a national lead committee for review of multi-centre studies, it is important to note that any move to ‘locality assessment only’, or to ‘no assessment or review’ for secondary committees, would considerably reduce the workload of some regional committees, if current workload practices were to remain the same. 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 DHB boundaries, and to a membership profile reflective of the larger regions.

**Monitoring of research**

The *Operational Standard* requires that investigators conducting research that has been approved by a regional ethics committee submit to that committee reports on the progress of research, reports of serious or unanticipated adverse events, and reports on the findings of the research or the outcomes of the treatment (7.6). Ethics committees must outline the reporting requirements to applicants, but the Standard does not outline formal processes, other than reporting requirements, by which committees are actively to monitor research.

It is often noted, however, that in current practice ethics committees do conduct informal monitoring of approved research carried out in their regions. It might also be thought that a system with major involvement by secondary committees is especially well placed to carry out this monitoring. Regional committees “get to know of breaches of protocol on their patch through numbers of informal channels” (Evans, 2002, p.4) that are available to them as secondary committees in the review process.

Monitoring of research is a well recognised area of difficulty, and NEAC knows of no robust system for this anywhere in the world. A survey of recent literature in this area suggests that there is support for a uniform system of reporting and evaluating adverse events, and for increased involvement of data monitoring committees in overseeing research (National Bioethics Committee, 2001; Califf, et al, 2003). One approach, taken by the United Kingdom, is that “the REC has no responsibility for proactive monitoring of research, the accountability for which lies with the NHS host organisation” (Central Office for Research Ethics Committees, 2001).
2.10 Statutory or non-statutory?

Under a system with either a regional or a national lead committee, consideration will need to be given to whether the review system would have:

- **No 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 Minute (e.g., Toi Te Taiao: The Bioethics Council), and establishment by the Ministry of Health (regional ethics committees are established in this way).

- **Statutory basis:** established under statute (e.g., under s.11, New Zealand Public Health and Disability Act 2000, by the Minister of Health, by written notice to Parliament).

2.11 Considering the options

NEAC is interested in your responses to the above options, and welcomes your comments, opinions, questions and recommendations.

NEAC invites you to comment on the risks and benefits of the options described above. As you do this, please consider how the different options address the goals, objectives and desired outcomes of an ethical review system listed in Section One (p.4).

These options are set out with questions for you to consider and respond to in the tear-out section at the back of this document.
Section Three: Second Opinion and Appeals Processes

3.1 Purpose

The purpose of this section is to present options for the appropriate application of second opinion and appeal processes in the system of ethical review.

Following analysis of responses to the draft options, recommendations on these processes will be made to the Minister of Health.

3.2 Background and rationale

The Minister of Health has asked NEAC to address the issue of appeal processes. This responds to the following recommendation from the Gisborne Inquiry Report:

\textit{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. (11.23)}

NEAC has sought a legal opinion from the Crown Law Office to inform the development of options relating to second opinion and appeal processes, in addition to surveying the views of stakeholders on the operation of the current processes. The Crown Law Office opinion is attached to this document in Appendix 2.

3.3 Policy issue

Many researchers are required by their own professional codes or standards, or by their employment or contractual relationships with others, to secure ethics committee approval for their proposed research or innovative practice activities. They consequently have significant interests at stake in these ethics committee determinations.

In cases where ethics committees decline ethical approval to research applications, it is consequently important that the applicants have options to challenge these determinations.

The key issues here are: What is the range, nature and appropriateness of the challenge options that are, and could be, available to ethics committee applicants? What are the existing and possible new options that require policy consideration?\(^6\)

\(^6\) This discussion focuses on second opinion and appeal processes regarding regional health and disability ethics committees. These processes are also of interest to other operational ethics committees, such as NECAHR, but NEAC’s brief in this review is to consider only regional ethics committee determinations, and the challenge options concerning these.
3.4 Current systems and forms of challenge

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

Summary

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 second opinion as a relevant consideration to its final decision. Even so, it remains the case that the providers of second opinions are not appeal bodies in the sense that they can overturn or affirm an original decision in a binding manner.

Second opinion data

From 2000–03 the HRCEC 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 (Health Research Council, 2003).

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7 By arrangement between NEAC and the HRC Ethics Committee (HRCEC), the HRCEC is the current presumptive provider of second opinions, at least until NEAC completes its current review.
3.5 International context

NEAC’s literature survey has examined policies relating to second opinions and appeal processes in Australia, Canada, the United Kingdom, the United States and Denmark. In making comparisons with New Zealand policy, however, it is important to note that the systems of ethical review in these jurisdictions differ in some significant respects from each other and from the New Zealand system. Both Australia and the United States, for example, have review systems that are largely institutionally based, whereas systems in Denmark and the United Kingdom consist of committees that are regionally based, and governed by central bodies. The following extracts describe policy regarding second opinion and appeal processes outlined in the ethical guidelines for these countries.

Australia: National Statement on Ethical Conduct in Research Involving Humans

The statement contains no reference to provisions for second opinion or appeal processes.

Canada: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

This policy states that in cases when researchers and Research Ethics Boards (REB) cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB decision by an appeal board, provided that the board’s membership and procedures meet the requirements of this Policy. No ad hoc appeal boards are permitted (D6, Appeals, Article 1.11).

United Kingdom: Governance Arrangements for NHS Research Ethics Committees

7.35. Exceptionally, a further review of a protocol may be undertaken by a second REC.

There is a second review process for applications which have been rejected, but where the rejecting multi-centre research ethics committee (MREC) has expressed its willingness to look at it again if amendments are made.

The United Kingdom has a limited appeal provision for applications where the rejecting MREC has expressed its unwillingness to look at the application and/or that it does not object to the application being reviewed by another MREC (COREC website: Standard Procedures for MREC Second Reviews and Appeals – Update 20 March 2003).

Research covered by this policy that has been approved by an Institutional Review Board (IRB) may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB (46.112 Review by institution).

Denmark: Søren Holm, *The Danish Research Ethics Committee System – Overview and Critical Assessment*

A Central Research Ethics Committee (CREC) serves as an appeal body for the decisions of regional ethics committees, and makes decisions in multi-centre trials where there are irresolvable disagreements among the regional committees. The decisions of the CREC are final.

### 3.6 Stakeholder experiences of current processes

The NEAC questionnaire survey administered to REC members and a sample of researchers asked the following questions:

- *Do you think that processes available for second opinions operate*: well, not well, not used, don’t know.
- *Do you think that processes available for making complaints operate*: well, not well, not used, don’t know.

**Responses by REC members and researchers regarding their experiences of second opinion processes**

**REC members**

Approximately three-quarters of respondents to this question stated that they either had not used the process, or did not know how the process operated. Over a quarter said that the system worked well, and a small number said that it did not work well.

**Researchers**

A large proportion of researcher respondents to this question stated that either they had not used the process, or did not know how it operated. A small number stated that the process worked well, and an equally small number stated that it did not work well.

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8 At the time of writing, 81 responses from REC members and 60 responses from researchers had been received and analysed.
Responses by REC members and researchers regarding their experiences of complaints processes

**REC members**

A large proportion of REC respondents to this question stated that either they had not used the complaints process, or did not know how the process operated. A smaller proportion stated that the process worked well, and a small number stated that it did not work well.

**Researchers**

Almost all respondents to this question stated that either they had not used the process, or did not know how it operated. A small number of respondents stated that the process worked well, and an equally small number stated that it did not work well.

Comments from stakeholders on the risks and benefits of an appeal process

Views on second opinion and appeals were in two categories:

- **Support for second opinions and appeals**
  - An appeals process should be developed, because there needs to be an opportunity for non-researchers and applicants to raise concerns.
  - An appeals process would ensure greater clarity and rigour from ethics committees regarding their decisions. This is especially desirable for local studies.
  - There needs to be a forum in which concerns/complaints can be heard in cases where RECs do not follow due process. This is especially important when significant science and research is being stopped without full discussion/debate.
  - An appeals process would address the perception or reality that ethics committees are adding extra hurdles. One issue raised by several stakeholders involved a requirement from RECs that general practitioners make contact with patients, rather than researchers gaining access to patients from a registry with GP approval. This creates problems for both researchers and GPs.

- **No support for second opinions and appeals**
  - Neither a second opinion nor an appeals process should be part of the review system, because there cannot be a ‘high court’ on ethical considerations.
3.7 Legal advice on second opinion and appeal processes

In addition to gathering views on current processes from key stakeholders, NEAC sought a legal opinion from the Crown Law Office to inform the development of options on second opinion and appeal processes. The key points from this opinion are discussed in the following subsection.

The brief from NEAC to the Crown Law Office asked the following questions:

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

2. What are the forms of challenge to regional ethics committees that are currently available, for example, challenge by way of judicial review?

3. Given the kinds of actions that regional ethics committees may and do perform, and the forms of challenges 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 appeal be possible? If so, what sort of appeal?

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, for example, rights of applicants to ethics committees?

The Crown Law Office opinion

The Crown Law Office notes that the Operational Standard contains six different terms for forms of challenges to ethics committee determinations. The terms are:

1. complaint
2. second opinion
3. challenge
4. review
5. appeal
6. judicial review.

The opinion notes that it is important to clarify the differences between these terms. At one end of the continuum is the process of informal complaint, which may lead to a request for a second opinion or an independent evaluation of the decision. The mechanisms provided for in the Operational Standard are at this informal end of the range. Formal challenge options include processes of judicial review and appeal. An important difference between these latter two processes is that, where judicial review concerns itself with the process leading to a decision, appeal is concerned with the merits of the decision. Consistency with this distinction would require that a right of appeal or “binding third opinion” in the ethics committee context would be or would include a right to a binding determination on the merits of the issue addressed by the original decision.
The Crown Law opinion proposes the following possible scheme for the provision of an appeals process in the ethical review system. This proposal forms the basis of Option 2 below.

A possible appeals process

1. A regional ethics committee (REC)\(^9\) 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 Health Research Council Ethics Committee) and then make a decision, taking account of the second opinion. The REC ought to advise the applicant of its intention to seek a second opinion, the particular matter upon which the second opinion is sought, and the proposed source of the second opinion.

2. If the REC makes a decision that the applicant does not accept (i.e. 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 REC.

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

This process is consistent with the “review of decisions” procedure (section 7.10) in the Operational Standard.

If the REC has already obtained a second opinion in the course of making its decision, the applicant could proceed straight to an appeal process (see 4 below).

3. In providing second opinions the HRC Ethics Committee is responsible to ensure that the second opinion is fully informed by such specialist advice as is required to fully address the issues on which the REC is seeking guidance. It should also ensure that all advisers and members of the HRC Ethics Committee who are to deliberate on the matter are independent and free of any conflicts of interest.

4. 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.

5. NEAC will then be required to determine whether the REC decision should stand or 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:

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\(^9\) The Crown Law Office opinion refers to a regional ethics committee by its full title: Health and Disability Ethics Committee (HDEC).
Grounds that the matter is of national significance to an extent overlooked or not given proper weight by the REC. See 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 RECs. See 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, a central repository for REC decisions that can be accessed by all RECs 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 REC should be modified”.

3.8 Options for second opinion and appeals processes

In response to the Gisborne Inquiry recommendation that 

consideration should be given to processes to allow ethics committees’ decisions to be appealed to an independent body, NEAC has developed two options that draw on stakeholder comments and on the legal opinion provided by the Crown Law Office. The proposed options are described below:

• **Option 1**: Second opinion processes only (status quo).

• **Option 2**: Second opinion processes remain, and processes for appeal are added to the review system.

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 multi-centre studies (see Section Two).

**Option 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.
Were a national committee to be established for the review of multi-centre studies, then Option 1 would operate according to the current Operational Standard guidance. That national committee, and applicants to it, would be able to seek second opinions from a designated body.\textsuperscript{10}

Option 1 does not include any process to allow regional ethics committee decisions, or decisions of any national ethics review committee for multi-centre studies, to be appealed to an independent body.

**Option 2: Second opinion process with the addition of an appeals process**

A right of appeal or of ‘binding third opinion’ in the ethics committee context would be, or would include, a right to a binding determination on the ethical merits of the issue addressed by the original decision.\textsuperscript{11}

The Crown Law opinion quotes the Legislation Advisory Committee’s publication Guidelines on Process and Content of Legislation:

> “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.”

The Operational Standard states that the principal role of regional ethics committees is:

> “to provide independent ethical review of innovative practice and health research that will be conducted in their designated region of authority”.

The Crown Law opinion concludes that given this role, “there is little doubt that HDECs [RECs] 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”.

\textsuperscript{10} One issue about second opinion processes is whether they should address only the process leading to the opinion of the first ethics committee, or also the ethical merits of the issue addressed in that first ethics committee opinion.

\textsuperscript{11} One issue about any appeal or ‘binding third opinion’ process is whether it should address only the ethical merits of the issue addressed in the first ethics committee opinion, or also the process leading to the opinion of the first ethics committee. If an appeals option for applicants were to be introduced, then at some point further questions would also need to be considered. For example, should any parties other than applicants have any appeal rights, potentially including appeal rights against ethics committee approvals? Would any circumstances be urgent and serious enough to justify direct access to appeal from an ethics committee ‘first opinion’, without any second opinion process?
There are three sub-options for Option 2, concerning the possible appellate body.

(a) NEAC, or an appeals sub-committee of NEAC, would be the body to consider all applications for appeal, including any appeals resulting from the determinations of a national committee for review of multi-centre studies, if such a committee were to be established. This is the suggestion made in the Crown Law opinion.

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

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

3.9 Considering the options

The following options for second opinion and appeal processes have been described above.

- **Option 1:** second opinion processes only (status quo)
- **Option 2:** second opinion processes with the addition of an appeals process, and three sub-options for the appellate body:
  (a) NEAC or subcommittee of NEAC
  (b) national committee, plus NEAC or sub-committee of NEAC
  (c) new committee established for the purpose of hearing appeals.

As you consider these options, please respond to the following questions:
1. Should second opinions address only the processes by which an ethics committee decision is made, or also the ethical merits of that decision?
2. Would the addition of an appeals process enhance the system of ethical review, in terms of the desired outcomes set out in Section One (p.4)?
3. If an appeals process were to be established, which body should be the appeal body, and why?

Please feel free to provide additional comment on this topic. You may write your comments in the tear-out section at the back of this document.
The references listed below are those cited in the discussion document. A fuller annotated bibliography of works consulted for this review will be made available via the NEAC website.


1. **Background**

This appendix presents information gathered from stakeholders on the current operation of health and disability ethics committees, beyond the issues of multi-centre studies (Section Two), and second opinion and appeals processes (Section Three).

2. **Key issues and suggested improvements from the perspective of various stakeholders**

As noted in Section One of this discussion paper, NEAC administered a questionnaire survey to all REC members and a sample of one in every 13 researchers who have submitted single-centre and multi-centre research proposals to RECs in 2001 and 2002. A range of other stakeholders were interviewed. A list of interviewees can be found on the NEAC website. The following summary of findings will be finalised once late questionnaire responses have been analysed, and the last of the interviews completed.

2.1 **Information from NEAC questionnaire survey**

The NEAC survey asked questions on the following topics:
1. national application form
2. constitution of regional health and disability ethics committees
3. interaction
4. principles of natural justice
5. conflicts of interest
6. proposal review
7. ethical issues
8. multi-centre studies
9. reporting and monitoring
10. second opinions and complaints
11. Māori responsiveness
12. general comments, including what needs to alter and what needs to be retained
13. other issues that NEAC needs to consider.
### Themes/Issues and Suggestions for Improvements

The amalgamated views of REC members and researchers have been summarised as follows.

<table>
<thead>
<tr>
<th>Theme/Issue</th>
<th>Suggestions for improvements</th>
<th>Question number</th>
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<tbody>
<tr>
<td><strong>System of ethical review</strong></td>
<td></td>
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<tr>
<td>National application form</td>
<td>• Shorten and streamline&lt;br&gt;• Simplify for non-medical and small scale research, eg, student proposals, studies not involving blood samples or drug trials&lt;br&gt;• Have separate guidelines for audit and observational studies&lt;br&gt;• Have specific questions for qualitative research (current form designed for quantitative research)&lt;br&gt;• Provide a lay summary indicating what the research involves, how people/patients are involved, and highlight ethical issues&lt;br&gt;• Provide “Select” instructions, eg, “If this is not a clinical trial, omit pages…”&lt;br&gt;• Clarify and standardise requirements for Māori input – improve section 14&lt;br&gt;• Update as circumstances change, eg, current concern about payments to researchers and conflict of interest</td>
<td>Q.1</td>
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<td>Multi-centre studies</td>
<td>See Section Two of this document</td>
<td>Q.8 Q.12 Final question</td>
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<td>Reporting and monitoring</td>
<td>Reporting:&lt;br&gt;• Researchers to provide more comprehensive annual reports on progress of research&lt;br&gt;Reporting of serious adverse events (SAEs):&lt;br&gt;• Clarify whether SAEs refer only to drug trials&lt;br&gt;• Have an independent “operational group” with appropriate expertise to deal with SAEs and evaluate reports&lt;br&gt;• Ensure better collation of paperwork reporting SAEs from multi-centre studies&lt;br&gt;• Attach a list of SAEs to final reports&lt;br&gt;Monitoring:&lt;br&gt;• Increase monitoring to ensure compliance with ethics protocols – random audit/monitoring (with clear guidelines) may be cost effective&lt;br&gt;• Increase resources and personnel for monitoring as it is too big a task for RECs&lt;br&gt;• Carry out monitoring for certain aspects such as protocol changes, SAEs, when studies stop, difficulties are encountered, and the production of results/reports</td>
<td>Q.9 Q.12</td>
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<td>Second opinions and complaints</td>
<td>See Section Three of this document</td>
<td>Q.10</td>
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| Māori responsiveness | • Provide clearer definition of “responsiveness” so there is less variation depending on the location of the committee  
• Provide more clarity around application of the Treaty and more transparency about REC decisions  
• Provide more guidance on how Māori perspectives contribute to ethical thinking rather than on simply consulting  
• Define Māori ethics  
• Improve and clarify consultation processes, eg, are there occasions when consultation with Māori professional groups is sometimes more appropriate than community consultation?  
• Communicate the process better to researchers (educative function) so that they are not completing section 14 to a set formula  
• Clarify processes – do Māori members seek outside support and advice in support of their role on the committee?  
• Define some words/concepts more clearly, eg, tikanga, whānaungatanga, need to be more clearly defined  
• Hold workshops to make the processes around responsiveness transparent  
• Continue consultation with local Māori health authorities, but recognise the huge demand on a small number of Māori bodies and overburdened Māori researchers  
• Define mana whenua and tangata whenua boundaries for members representing iwi  
• Increase training for Māori members, particularly around Māori ethical principles  
• Resolve issues around international studies  
• Amend section 14 of the application form, eg, make section 14.2 less ambiguous | Q.11  
Q.12  
Final question |
| Mechanisms for input into system of ethical review | • Provide opportunities for ethics committee members to have input in addition to REC chairs’ meetings  
• Provide opportunities for researchers to have input into the ethical review system, and disseminate information about how this can be done | Q.12  
Final question |
| Information issues | • Improve documentation and information  
• Provide more guidelines and definitions | Q.12  
Final question |
| Jurisdiction issues | • Clarify the functions and roles of the RECs in relation to other ethics committees  
• Clarify issues around audit and research  
• Clarify issues around privacy and ethics | Q.12  
Final question |
| Input from research institutions | • Have more input from institutions  
• Make more use of institutional ethics committees  
• Increase researcher training in ethics | Q.12  
Final question |
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<td><strong>Operation of regional ethics committees</strong></td>
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| Composition and expertise of review committees                                                                 | • Monitor the mix of expertise and membership structure  
• Have more qualitative expertise  
• Include a member (lay or professional) from the disability sector  
• Involve outside expertise where necessary  
• Ensure the composition of the committee is transparent, and highlight the experience of members, to mitigate researcher concerns about expertise | Q.2 Q.12       |
| Interaction between researchers and committees                                                                 | • [In some cases] improve the interactions between committee members and researchers  
• Provide guidelines to aid committees and researchers to distinguish between research and audit  
• Improve turnaround time in some cases  
• Encourage new researchers to seek early guidance from committees/the administrator to facilitate the review process  
• Ensure further discussion by all stakeholders on the significance of the Treaty and Māori consultation for ethical review  
• Provide guidelines on the Treaty and Māori consultation to reduce the onus on Māori to provide individual advice | Q.3 Q.12       |
| Principles of natural justice, e.g. fairness, transparency                                                                 | • [Continue to] ensure full membership participation, lay and professional, so that all members feel equally confident to voice opinions  
• [Continue to] ensure researcher attendance and participation to promote transparency and good communication  
• Ensure that research is not unfairly blocked or delayed by particular biases on a committee  
• Consider the implications of ethical review underpinned by European philosophy for some Māori research proposals | Q.4            |
| Understanding of different types of research                                                                 | • Increase knowledge of basic types of research methodologies in ethics training  
• Improve understanding of qualitative research approaches, and complementarity between quantitative and qualitative approaches  
• Call on outside expertise when necessary, eg, for qualitative research, Māori methodologies  
• [Continue to] encourage researcher attendance at meetings | Q.4 Final question |
| Conflicts of interest                                                                                                                                                                                                                                     | • [Continue to] ensure disclosure of interest and withdrawal from the room during discussion  
• [Continue to] ensure that power relations within a committee, or professional rivalry, do not impede the application process  
• Explore Māori perspectives on conflict of interest criteria and protocols | Q.5            |
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<th>Suggestions for improvements</th>
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| Proposal review                    | • Review form templates, and reduce length and complexity if possible  
• Consider whether form templates need adaptation for different types of research  
• Consider perception that there is variation between different committees' expectations regarding forms  
• [Continue to] encourage researchers to attend meetings to facilitate the process and clarify issues  
• Address small queries prior to meetings                                                                                                                                                                                                                     | Q.6             |
| Focus on ethical issues            | • Clarify the ethical review process for both members and researchers, particularly as it relates to study design and methodology. “It is unethical to expect clients to participate in research if the methodology is unsound.” (Respondent)  
• Emphasise the role of the Chair in ensuring members are not sidetracked on minutiae  
• Ensure lay contributions are carefully considered  
• Develop guidelines for Treaty considerations                                                                                                                                                                                                                | Q.7             |
| Application and decision-making processes | • Maintain a regional approach as it encourages research in outlying areas and is more responsive to local issues  
• Address cases of slow turnaround time  
• Committee members to be familiar with relevant documents  
• NEAC could advise on bigger issues, eg, foetal cell research  
• Small committees could meet more often  
• Researchers to read guidelines for completing forms  
• Focus on ethical issues rather than trivial details  
• Deal with administrative details prior to meetings  
• Address cases of inconsistency in decision-making outcomes between RECs regarding multi-centre studies  
• Change the processes for social science studies and small student research projects  
• Ensure decisions are transparent                                                                                                                                                                                                                     | Q.12 Final question |
| Resourcing                         | • Increase resources for administration  
• Increase payments to members                                                                                                                                                                                                                                       | Q.12 Final question |
| Training of committee members      | • Increase training opportunities  
• Include practical as well as theoretical advice, interaction, debate and problem-solving  
• Include discussion on the Treaty and ethics from a Māori perspective                                                                                                                                                                                          | Q.2 Q.12 Final question |
2.2 Suggestions from interviews with key stakeholders

To date, 24 individual interviews and three group-based discussions/interviews have been undertaken. The views of stakeholders and their suggestions for improvements to the ethical review system are summarised below.

(a) System of ethical review

Improve the ethical review system by looking at:

- **Ideas for an integrated overall ethical review system**
  - Greater integration and interaction between the various component parts of ethical review – human subject and animal subject, and bio-ethics; perhaps joint initiative between Ministries of Health, Education, Research, Science and Technology and HRC and Royal Society.
  - Revive the early 1990s concept of an overarching national ethics committee for all human subject research.

- **Ideas for structural change to the current system**
  - Have the Health and Disabilities Commissioner as the reporting body/parent body for RECs – because of consumer protection focus. This was presented as an option in a previous review of RECs in the 1990s.

- **Ideas for improving health ethical review skills within the current system**
  - Enhance Ministry of Health expertise in ethics.
  - Increase and internalise researcher knowledge of ethical issues and upfront consideration of ethical issues in research, for example through researcher education.
  - Increase REC knowledge of research issues and methodologies including elements that are essential for validity of research.

- **Ideas for ensuring a more cohesive, integrated health ethical review system**
  - Create a sense of cohesion and direction for ethical review systems.
  - Ensure stronger, more focused, constructive interaction between RECs and institutional human subject ethics committees (IECs), and RECs and DSMB (Data Safety Monitoring Board). There was some concern expressed about the interaction between IECs and RECs. It was seen as important to identify and build on good practice. For example, Massey University and the local REC have members on each other’s committee – this assists communication and may be a model.
  - Build conversations, dialogue, debate between RECs and researchers. Currently there is a shortage of forums/opportunities to bring people together and strengthen shared understanding and coherent directions.
• **Ideas for a system that has a more explicit and inclusive values base and ethical framework**
  – Develop an ethical framework based on social justice and responsibility.
  – Ensure understanding of the specific issues to do with Pacific research – research by and with Pacific peoples, cultural considerations of reciprocation and community standing. Very important for the ethical review system to acknowledge and reflect Pacific ethical review definitions.
  – Acknowledge that New Zealand is multi-ethnic and multi-cultural, as well as bi-cultural – this should be reflected in the/a system for ethical review.
  – Acknowledge expertise in and relevant approaches to research for, by and with people with disabilities. Currently the system is seen as rendering disability issues “invisible” with a sense of disability discrimination. Important for ethical review systems to work with the national disability strategy.
  – Ensuring that the ethical framework reflects the principles of the Treaty of Waitangi.

• **Ideas for a system that addresses individual autonomy and public health benefit**
  – Foster a system that balances benefits and risks.
  – Have a system of ethical review that can take into account issues of personal autonomy and participant protection, as well as the wider population and public benefit.

• **Ideas for improving information about, and guidance on, the current systems**
  – Introduce clear guidance for the whole system of ethical review. Those not using the system are unsure when they should apply, and to whom, for ethical review. Those using RECs are often only sure of the part they know and work with most frequently and are unsure of the operation and approach of other parts.
  – Reduce the sense of confusion surrounding the current system. Many are not familiar with guidelines. For those who are not sure if they should apply for ethical review and approval there is little information around to clarify this.

• **Ideas for improvement to the operation of the current system**
  – Increase monitoring nationally – need a monitoring system that will follow up on what researchers are publishing, compared what they have been approved to do.
  – Work through definitional issues around ‘health’.
  – Diminish the dominance of the medical model in ethics committees.
  – Develop a code of conduct for researchers with ethics committees overseeing this code. This would be one platform for building capability among researchers across all disciplines.
  – Professionalise the system of ethical review.
  – Develop operational standards with more open, accessible language – the current *Operational Standard* is considered to have been developed without sufficient consultation.
– Improve the system for amendments to the *Operational Standard* – currently the perception is that suggestions go from RECs to Chairs’ meeting.
– Restructure the *Operational Standard*.
– Define ‘lay member’, with the suggestion that this can be looked at in work on operational standards.
– Build on effective models of operation between RECs and DHB ethical review systems. For example, Auckland and Waitemata DHBs and RECs in Auckland. Both DHBs have ethical review systems for DHB research. Approval by DHB facilitates the decision-making of RECs. The professional working relationship between the RECs in Auckland and relevant DHB staff was commented on as being of high quality.
– Develop a system of institutional tick-off/vetting of scientific and ethical soundness before going to the REC.
– Improve the opportunity for REC members to contribute to debate and agenda setting of ethical considerations, systems etc.
– Ensure that government departments who contract research, or contract for services which may involve evaluation and research, are clear about whether researchers or service providers will need to seek ethical approval. If such approval is required, then provide guidelines. Currently there appear to be mixed messages about whether or not ethical approval is required, e.g. for customer surveys.

- **Key aspects of value to maintain in the current system**
  – Regional voices and not dominated by the medical profession.
  – New Zealand’s ‘bottom-up’ approach compared with Australia’s ‘top-down’ approach.

(b) **Operation of RECs**

Improve the operation RECs by looking at:

- **Ideas for strengthening and refinement**
  – Strengthen the current structure to address complex applications.
  – Maintain the value of regional/local knowledge, but explore the variety of ways of getting regional feedback, eg, from West Coast and Tairawhiti – not necessarily through maintaining current committee structure.
  – Reduce the number of RECs depending on workload – include representation from those areas without committees. Savings could go into paying committee members better and increasing administrative professionalism so that effective, consistent guidance and advice can be given.
  – Reduce the burden on Māori members.
  – Appoint people with disabilities who represent the voices of the disability sector. Application form to include a question about disabled people.
  – Increase the number/proportion of researchers or those with research expertise/understanding on committees.
• **Ideas for improving clarity and transparency of communication and decision-making**
  - Maintain the positive experiences with committees.
  - RECs to clarify the nature of local issues and how they are taken into account with ethical consideration.
  - Greater clarification and explanation of ethical considerations in REC decision-making/advice given to researchers.
  - Focus and connect advice to the *Operational Standard* which should form the basis of REC decisions – that is, what is the ethical issue being addressed?
  - Find ways of encouraging applicants to show that ethical considerations are part of the original methodology.
  - Researchers writing in a manner that is easily understood by REC members – perhaps introduce a system for assessing reading levels of applications.
  - RECs develop their own web-site with clear, easily accessible information about guidelines, systems for applications, as well as easier links between HRC web-site and REC web-site.
  - RECs put their meeting minutes on the web-site for transparency of decision-making.

• **Ideas for consistency**
  - Create greater consistency between committees and reduce the variation that seems to occur with turnover of individual membership.
  - RECs to adopt an open-door policy to researchers – currently considered that there is a mixed approach which fosters uncertainty for researchers and heightens researchers' sense of not being sure of the ‘rules of engagement’ or the key people to contact.

• **Ideas for structural issues**
  - Clarify jurisdictional issues.
  - Clarify whether there should be a statutory basis for RECs.

• **Ideas to ensure more robust decisions**

  **Skill enhancement**
  - Improve the training for REC members – there seemed to have been a greater opportunity for shared/consolidated and specifically tailored training in the regional health authority (RHA) era.
  - Place greater emphasis on training for REC members with a focus on: professionalism, change culture of RECs to see research as a positive contributor to people’s health in New Zealand, bring in case law about ethical decisions, (a useful number of precedents have been established over the years) and upskill in how to recognise good research. This would be seen to foster standardised/transparent/compulsory national training. Important to have sufficient resources to allow this to happen.
  - Provide training for committees to resist the temptation of becoming focused on methodological research issues and to ensure focus on ethical issues.
– Develop specific training for Chairs of committees especially for steering through discussions on issues to do with research methodologies and ethical considerations.

– Improve the system for introducing new REC members to the committee by looking at other systems for induction of new committee members.

**Researcher and REC communication**

– Place greater emphasis on improving the communication between researchers and RECs – including greater emphasis on mutual understanding of roles and identification of common ground.

**Tailored processes**

– Tailor applications to suit the type of research and remove the sense that a ‘one size fits all’ approach is appropriate. Currently the application form and guidelines are seen as being oriented towards clinical research, not audit, observational or qualitative research/studies.

– Have simpler forms that are tailored to different types of research – clinical trials, observational, qualitative.

– Have a simpler, more straightforward process for low risk research.

– Develop guidelines that separate and define audit and research.

• **Ideas for improved resourcing of RECs**

– Increase resourcing of RECs. The current culture of saving money means that REC members cannot attend conferences and be part of the debate and professional development around ethical issues and systems of ethical review.

– Increase fee levels for REC members.

(c) **Māori responsiveness**

Improve Māori responsiveness through looking at:

• **Ideas for ensuring a clear basis for consideration of Māori issues – Treaty related or Māori responsiveness**

  – Address a strong concern that honouring the Treaty of Waitangi has become achieving Māori responsiveness which has, in turn, become a series of stock phrases and answers rather than genuine commitment.

• **Ideas for clear processes of engagement for and with Māori to assist in achieving robust and relevant outcomes**

  – Explore ways of achieving Māori input that works for Māori, researchers and ethics committees.

  – Engage Māori with disabilities in the development of the Māori framework

  – Demystify Treaty of Waitangi issues which can be quite frightening.

  – Remove the perceived tick box mentality that can be seen as a hurdle rather than an engagement or learning exercise.
– Have more effective consultation with Māori. There are some high quality experiences but it depends on the type of research and the makeup of the group doing the research – works when there are kaumatua/Māori advisory people who have networks and skills as part of the group working with researchers, and the group has the resources to consult.

– Clarify if written evidence of consultation required. Currently some RECs demand written evidence of consultation. This can be extremely difficult and sometimes impossible.

– Ensure consultation/collaboration about analytical frameworks/ways of thinking. For example, a group of biomedical researchers may not think its research is relevant to Māori, but the researchers probably have not been exposed to or had any ‘connection’ with Māori.

– Update the HRC handbook, mindful that a variety of approaches on consultation are being taken, for example, the Ministry of Social Development is producing a guidebook for researchers engaging in Māori research, and other organisations are using other approaches.

– Increase understanding by researchers of the care required regarding what they promise and what they deliver to Māori communities when they undertake research, and relationships of reciprocation (same issue raised in relation to Pacific peoples).

– Foster iwi/hapū-based ethics committees/advice. Build on positive examples: Whanganui has its own iwi ethics group.
Appendix 2: Crown Law Office Opinion

6 August 2003

National Ethics Advisory Committee
Ministry of Health
P O 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 (e.g. 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 (e.g. 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 s 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 s 16(3), the Minister of Health may appoint either the ethics committee of the Health Research Council, or a special committee under s 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 (i.e. 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 s 24 of the Health Research Council Act 1990. Its functions are set out in s 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 (s 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 (ss 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 s 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 (s 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 ss 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 289–290) 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 s 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 s 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, i.e. 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 (s 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 s 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 s 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 (i.e. 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.

- 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
Appendix 3: Members of the National Ethics Advisory Committee

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