National Ethics Advisory Committee Secretariat
PO Box 5013
Wellington 6145

Re: Submission on cross-sectoral ethics arrangements for health and disability research - consultation

Thank you for the opportunity to provide a written submission on this consultation document.

Regional Public Health serves the greater Wellington region, through its three district health boards (DHBs): Capital and Coast, Hutt Valley and Wairarapa and as a service is part of the Hutt Valley District Health Board.

We work with our community to make it a healthier safer place to live. We promote good health, prevent disease, and improve the quality of life for our population, with a particular focus on children, Māori and working with primary care organisations. Our staff includes a range of occupations such as: medical officers of health, public health advisors, health protection officers, public health nurses, and public health analysts.

Regional Public Health have an interest in this area because we carry out programme and project evaluations in order to improve our service delivery. As evaluation research is classified as audit activity under the current ethics guidelines, questions about this area are the focus of our submission.

We are happy to provide further advice or clarification on any of the points raised in our written submission. The contact point for this submission is:

Christine Roseveare
Senior Public Health Analyst
Email: Christine.Roseveare@huttvalleydhb.org.nz
Phone: 04 570 9002

Kind regards

Dr Jill McKenzie
Medical Officer of Health

Peter Gush
Service Manager

National Ethics Advisory Committee
Kāhui Matatika o te Motu

Submission form

Discussion document on the cross-sectoral ethics arrangements for health and disability research

Introduction

The National Ethics Advisory Committee (NEAC) is seeking your feedback on the current health and disability research ethics arrangements, issues with these arrangements and ideas for enhancing them.

This work covers the responsibility for ethical health and disability research and the standards, processes and structures that support this responsibility.

Your feedback will help to inform advice and recommendations to the Associate Minister of Health on how to address the current issues. Your feedback will also inform NEAC's 2015 review of *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies*.

You can access an electronic version of the discussion document on NEAC's website http://neac.health.govt.nz/consultations

How to have your say

We are seeking feedback by **Friday 27 February 2015**.

To take part, please complete this submission form. You can complete the submission form electronically and send by email to neac@moh.govt.nz or post a printed copy to us to:

National Ethics Advisory Committee Secretariat
PO Box 5013
Wellington 6145

If you have any questions, please contact us by email at neac@moh.govt.nz.

Official Information Act 1982

Your submission may be requested under the Official Information Act 1982. If this happens, it will normally be released to the person who requested it. However, if you are submitting as an individual (rather than representing an organisation), your personal details will be removed from the submission if you check the following boxes:

☐ I do not give permission for my personal details to be released under the Official Information Act 1982.

☐ I do not give permission for my name to be listed in the summary of submissions.

After you've taken part

Your feedback will be analysed and summarised by secretariat staff. The analysis of submissions will be considered by NEAC and assist the committee to provide advice to the Associate Minister of Health.

A summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details under the Official Information Act 1982, the name of the organisation will be given if supplied.

☐ I do want to receive a copy of the summary of submissions.

Submitter's details

Name:	Christine Roseveare
If this submission is made on behalf of an organisation, please name that organisation here:	Regional Public Health
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National Ethics Advisory Committee
Kāhui Matatika o te Motu

Your feedback

The discussion document outlines issues across six areas, discusses current and other possible responses to these issues, and asks questions for feedback. The final section gives you an opportunity to tell us about anything else that has not been covered by the six areas.

1. Complex research ethics landscape
2. Māori and health research
3. Alternative ethical review structures
4. Peer review for scientific validity
5. Audit and audit-related activity
6. Innovative practice
7. Other issues

The questions in the discussion document are replicated below. We have included a space for you to write your response to these questions.

1. Complex research ethics landscape

a. What could be done to achieve more cohesion across the ethical review system?

No specific comments to make on this question

b. How useful is NEAC's statement of *Goals, objectives and desired outcomes of an ethical review system* (GODO)?

No specific comments to make on this question

c. Are the GODO goals adequately covered by the objectives?

No specific comments to make on this question

d. How could the GODO statement be improved?

No specific comments to make on this question

e. Is the plurality of functions that various public agencies (eg, Ministry of Health, NEAC, HRC) have to set standards for researchers and for ethics committees sufficiently clear and coherent overall?

We agree with the comment in the discussion paper that the lack of a clear framework or 'one-stop-shop' for the various guidelines and standards for ethical review is a barrier to navigating the ethics landscape. Currently it is up to researchers to determine the potential level of risk posed by research and it can be quite difficult to decide whether and how to decide if research meets the threshold for review.

f. What would help parties involved in research navigate through the current system?

We support the proposal in the document to establish a one stop shop of guidance to the research community and an on line step by step guide to help make decisions about ethical review. A flowchart to work through based on yes/no options and including guidance on when to seek further clarification would be very useful.

g. What mechanism(s) could be used to direct or facilitate access to ethical review where a researcher is otherwise unable to access it?

   No specific comments to make on this question

h. What would an opt-in review option for HDECs mean for HDEC workloads, and how would it fit with the recent changes? Does this have the potential to create inefficiencies?

   No specific comments to make on this question

i. Who could provide informal advice for borderline cases for HDEC review or minimal risk applications excluded from HDEC review?

   No specific comments to make on this question

j. How might monitoring and accountability mechanisms for researchers (eg, to ensure good design and conduct of research and communication of results) be improved?

   No specific comments to make on this question

k. How might monitoring and accountability mechanisms for ethics committees be improved?

   No specific comments to make on this question

2. Māori and health research

a. What additional support or guidance on Māori research ethics would be helpful?

No specific comments to make on this question

b. How could Māori ethical ideas and frameworks be placed at the centre of research guidelines?

No specific comments to make on this question

c. Would integrating Māori ethical ideas and frameworks into the core principles of New Zealand's general research guidelines be one way of contributing to or supporting placing Māori ethical ideas and frameworks at the centre of research guidelines?

No specific comments to make on this question

d. What are the barriers for researchers in undertaking an appropriate consultation process with Māori?

No specific comments to make on this question

e. What mechanisms could be available for HDECs to obtain further advice, if required, on Māori consultation and research design?

No specific comments to make on this question

f. What more could be done to ensure research outcomes are relevant to Māori interests, aspirations and wellbeing?

No specific comments to make on this question

3. Alternative ethical review structures

a. What mix of HDECs and institutional ethics committees (both public and private sector) should be allowed or encouraged?

No specific comments to make on this question

b. Should the emergence of ethics committees that are established by standalone businesses or trusts be allowed, or even encouraged?

No specific comments to make on this question

c. Should alternative ethical review structures be monitored, and if so, who could do this?

No specific comments to make on this question

d. What would an accreditation process for alternative review structures need to include to be credible?

No specific comments to make on this question

e. Are there any other suggestions (apart from accreditation) for ensuring good governance frameworks and quality of review for ethical review structures?

No specific comments to make on this question

f. What is the indemnity status of alternative ethical review structures?

No specific comments to make on this question

g. Is the indemnity status a barrier to seeking ethical review from alternative structures?

No specific comments to make on this question

4. Peer review for scientific validity

a. What are the barriers to accessing scientific peer review?

No specific comments to make on this question

b. What other options could be provided for researchers seeking scientific peer review?

No specific comments to make on this question

c. What additional guidance on scientific peer review would be helpful?

No specific comments to make on this question

d. What mechanisms could be available for HDECs to obtain advice on the scientific peer review of a proposed study?

No specific comments to make on this question

5. Audit and audit-related activity

a. Does the current classification of studies into observational research and audit or related activity act as a barrier to audit and related activity?

We agree with the comment in the discussion document that the distinction between observational research and audit based on intention/outcome of the work is not helpful. We comment further on this under question 5c.

b. Do you think the definition of audit could be improved, and if so, how?

No specific comments to make on this question

c. How useful is it to classify studies into observational research and audit for the purposes of knowing whether or not ethical review is required?

There are several aspects of this classification that are confusing.

1. When do the guidelines for observational research apply to audit?

Both the *Operational Standard for Ethics Committees* and the *Ethical guidelines for observational studies* clearly distinguish between audit (10 categories) and observational research (6 categories). The *Operational Standards* state clearly that in general, audit activity does not require ethical committee review.

However they go on to say:

"In some cases, ethics committee review is required, however, in expedited form, in accordance with the National Ethics Advisory Committee's Ethical Guidelines for Observational Studies".

The difficulty is, that it is not clear in the *Ethical guidelines for observational studies document* in **which** cases guidance provided for observational studies also applies to audit activities such as programme evaluation.

The observational studies guidelines say very little about audit activities, other than to distinguish them from observational research (section 2.3-2.4) and to comment [in section 2] that "*audits and other activities are included [in the guidelines] because they share ethically relevant characteristics with observational research".*

The main section in the *Ethical guidelines for observational studies* that deals with when ethical review is required is *Section 11: Features of observational studies that pose more than minimal risk*. According to Section 11, more than minimal risk observational research triggers the need for ethics committee review.

Section 11 does not comment on whether the guidance about more than minimal risk for observational research may also apply to audit activities.

As a public health service, we carry out programme or project evaluations, (which are audit activities under the current classifications) . Programme or project evaluations may have some of the more than minimal risk features that are highlighted in section 11 (e.g. 11.6 seeking information from vulnerable populations). Recently we sought advice from NEAC about a project evaluation that we thought involved potentially vulnerable populations and were advised that as we were evaluating a service the work was considered an audit and would not require review. However in the past we have been advised to submit service evaluation projects for ethical review, so it is a confusing area for us.

2. Expedited Review

The reference to review to an expedited form of review in the *Operational Standard for Ethics Committees* is also confusing

> *"In general, audit does not require ethics committee review. In some cases, ethics committee review is required, however, in **expedited form**, in accordance with the National Ethics Advisory Committee's Ethical Guidelines for Observational Studies".*

There is no mention of expedited review in the Ethical Guidelines for Observational Studies other than a brief mention in the foreword to the previous (2006) guidelines that appears at the front of the document. It would be useful to clarify for readers what an expedited review requires.

d. Could a risk assessment approach be applied to observational studies when thinking about whether or not ethical review is required?

We support the suggestion to introduce a risk assessment approach, not just for observational studies but for audit studies as well, to determine whether or not ethical review is required. It would be very helpful to have

- a clearly defined threshold of risk
- criteria for judging whether an activity had reached the threshold
- clarification of when expedited review versus full review is required

6. Innovative practice

a. Should further guidance be developed on innovative practice?

No specific comments to make on this question

b. What guidance on innovative practice would be helpful for health professionals?

No specific comments to make on this question

c. What are your views on current processes for reviewing innovative practice?

No specific comments to make on this question

7. Other issues

a. What other issues are associated with the cross-sectoral ethics arrangements for health and disability research?

No specific comments to make on this question

b. How might these issues be addressed?

No specific comments to make on this question