



**National Council of  
Women of New Zealand**

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Wahine O Aotearoa

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**Submission to the National Ethics Advisory Committee on the  
System of Ethical Review of Health and Disability Research in New Zealand.**

The National Council of Women of New Zealand (NCWNZ) is an umbrella organisation representing 42 nationally organised societies. It has 33 branches throughout the country attended by representatives of those societies and some 150 other societies. The Council's function is to serve women, the family and the community at local, national and international levels through research, study, discussion and action. NCWNZ has a longstanding history of encouraging the promotion of social and health issues, particularly as they affect women.

NCWNZ is disappointed that there was not a longer time frame within which we could consult the wider membership. Comments are those from members of the Health Standing Committee and interested parties.

NCWNZ has over time made submissions regarding health ethics and associated issues. In 1992 members voted, "That NCWNZ urge the establishment of a national ethics committee to set standards for all biotechnical research and that these standards be open to public scrutiny."

**Specific Comments**

**Section 1**

NCWNZ agree with the overall goals and commend consultation by means of the National Ethics Advisory Committee's (NEAC's) questionnaire survey.

**Section 2**

It has been suggested that there are currently two statutory bodies that could undertake the role as a national primary committee to oversee the "assessment of national and multi-centre studies." These are the National Ethical Advisory Committee (NEAC), and the Health Research Council Ethical Committee (HRCEC).

Respondents believe that neither of these is suitable. NEAC may compromise its statutory role as "an independent (policy) advisor to the Minister of Health on ethical issues of national significance regarding health and disability research and services."

Similarly, the Health Research Council Ethical Committee (HRCEC) currently acts as a provider of second opinions on matters of ethics committee review. This role could become compromised if it is then required to provide 'first opinions' on proposed multi-centre studies.

NCWNZ therefore supports the establishment of an independent national ethics committee to review national and multi-centre study proposals and to monitor ethical research issues. This would simplify the processes for research and give consistency.





It would make sense to include the National Ethics Committee on Assisted Reproduction in this national committee. The national ethics committee would then be responsible for reviewing all human subject research ethics and any other ethical issues related to human and animal well-being. A cross-sectorial approach also makes sense, as the ethical issues remain the same for the public agencies mentioned on page 3, i.e. health, tertiary education, environment, research science and technology and possibly other organisations.

The regional ethics committees need to remain as the primary “approval body” for local studies. The national ethics committee should then consult the regional ethics committees when there are “local or ethically relevant matters”. Many regional ethics committees already consult each other especially in health.

This same committee would have responsibility to resolve differences between regions. Decisions could be expedited with standardisation of meeting dates throughout New Zealand and lead to consistency and timely reviews.

Thus, the option preferred by the majority of respondents is, “**Option 2(a): National Primary Committee approval with full review also by each secondary committee**”.

One respondent favoured a reduction in the number of regional ethic committees. Another respondent noted that whether the regional ethics committees have, or have not, as much work to do is beside the point. The important thing is that the diversity of the community is well represented on any such committee and participants are well qualified for the job.

### Section 3

The second opinion process, similar to that of the Danish Protocol, should remain for checks and balances. A right of appeal would add robustness and fairness to the process and the achievement of goals.

#### **Option 1: Second opinion process only (status quo).**

This option was not favoured. It is interesting that a second opinion would not be binding.

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

This is the process recommended by the Crown Law Office, and the statement from them on page 30, that given the role that regional ethics councils fulfil that, “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”, sums it up very well.

Therefore, with regard to the questions raised on page 31 NCWNZ’s responses are as follows:

1. *Should second opinions address only the processes by which an ethics committee decision is made, or also the ethical merits of that decision?*

If ethical merits were part of the decision-making in the first process, then they should be part of it in the second.

2. *Would the addition of an appeals process enhance the system of ethical review, in terms of the desired outcomes set out in Section 1 (P4)?*

Yes. However, there must be clear reasons and processes for accessing the appeals process, or every time a decision was not favourable to the parties, it would be tied up in appeals. Questions regarding other forms of challenge are raised on Page 52 Question 3. Section 51.1 to 51.4.



3. *If an appeals process were to be established, which body should be the appeal body, and why?*

It was generally agreed that, (a) NEAC should hear appeals from all committees, thereby providing consistency of decision. A separate appeals committee would only lead to delays and be another layer of opinion.

NCWNZ thanks for this opportunity to make comment on this document and looks forward to the final version.

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National President

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Convener, Health Standing Committee