



**National Council of  
Women of New Zealand**

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Wahine O Aotearoa

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14 December 2004

S04.57

**Submission to the Ministry of Health on Ethical Guidelines for  
Observational Studies: Observational Research, Audit  
and Related Activities**

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 has, over a number of years, been invited to make submissions regarding ethics committees. In 2003 NCWNZ was pleased to be able to make submissions regarding the "System of Ethical Review of Health and Disability Research in New Zealand" and "Ethical Review of Observational Research, Audit and Related Activities" which was a useful experience when considering this document.

NCWNZ's most recent input was earlier in 2004 when a submission was made regarding the 'Terms of Reference for Multi-Centre and Regional Ethics Committees', the forerunner to this present document.

Members of the Health Standing Committee, and other interested parties were asked for their input into this document and the following is a summary of their comments.

**1 How appropriate is the inclusion of audit and related activities within the same Guideline as observational research?**

Members believe that all research should be open to audit and review, especially for Quality Assurance and Resource Utilisation. Therefore inclusion of audit and related activities is appropriate as the aims are the same –to improve quality of healthcare through improving health outcomes. The potential benefits of audits are more general and predictable than those of research. There is also likely to be an overlap of activities between audits and research. It is, therefore, appropriate to use the same guidelines.

**2 The Guidelines offer definitions of the different types of observational research and audit related activities. Please comment on these definitions**

NCWNZ agrees that the definitions are clear and concise and seem to be adequate.

**3 Is the Guidelines' approach to the question "When does observational study require ethics committee review?" (Section 10) satisfactory? In particular:**





**(a) How clear are the Guidelines about when ethics committee review is or is not required for the different kinds of observational studies (i.e. epidemiological observational research, clinical observational research and audit and related activities)?**

The Guidelines seem to outline clearly the procedure to be followed when defining whether ethics committee review is required or not. NCWNZ believes that they appear to cover the vast majority of situations and that the message to consult the committee, if there is any uncertainty of interpretation is very clear.

**(b) How well do the Guidelines attend to the question of when ethics committees review is required for all types of observational studies; and especially for minimal risk observational research, and for audit and related activities?**

The Guidelines also appear to be quite clear with regard to the process to determine when studies fall into the category of “minimal risk observational research” and when it is necessary to seek ethics committee review. Again, there is a clear need to consult with the ethics committee if there is any uncertainty.

The importance of informed consent, privacy and confidentiality cannot be too strongly emphasised. Members believe that participants should be assured of feedback. Some reservations were expressed about the obtaining of group consent and protecting the rights of the individual to withdraw.

**4. After the Guidelines are completed, NEAC will facilitate ongoing comment from Guidelines users. NEAC also intends to review the Guidelines in the future with good process and timing. Please make any suggestions you have on how best to do these things.**

Members are pleased to see that the importance of audit and audit related activities are acknowledged.

However, NCWNZ believes that NEAC should actively encourage the feedback from participants involved in studies by means of interviews and/or questionnaires. The monitoring of professional skills and accuracy of documentation should also be an on-going consideration.

This document does not however address the very real problem of who will fund collection, collation and management of data. Already, a number of national registries have been lost because of the Privacy Act or loss/lack of funding, e.g. the Haemophilia Register. This comment is based on the working experience of one of our members.

The Guidelines are really helpful, but if NEAC wants the whole process to work well and in particular to be able to collect important national data and not just from those who may reply (this, in effect, would compromise equity of access to care) the question of funding must be addressed now. If it is not, the net result may well be a less efficient system.

**5 Please add any comments you have on the proposed Guidelines.**

NCWNZ strongly agrees that before interviewing participants explanatory information should be forwarded together with consent forms.



This document was seen by one respondent as rather academic and without examples of case studies included found it difficult to offer a qualified opinion. The language can, at times, be somewhat convoluted e.g. generalisable.

Another respondent wondered whether inducements are ever justifiable, given her experience with a family member taking part in an international heart study. The inducement was a contribution towards travel costs. However, immediate access to the best possible care was sufficient inducement in itself.

NCWNZ agrees with respect for persons, but acknowledges that there is a real ethical dilemma when considering that as of right a patient, or the person responsible for the patient, can expect their cultural rights or beliefs to be respected. In many instances our society does not give the same respect to all cultural rights or beliefs.

Members are also concerned that there should be adequate representation on all committees/reviews panels of people who are actively doing research,

NCWNZ thanks you for this opportunity to make comment on this document. Members are pleased to see the progression of thought expressed in the discussion documents, particularly over the last two years.

Christine Low  
**National President**

Catherine Gurnsey  
**Convener, Health Standing Committee**