



australian
nursing federation

Review of the National Statement on Ethical
Conduct in Research Involving Humans

March 2005

1. The Australian Nursing Federation

- 1.1 The Australian Nursing Federation (ANF) is the national union for nurses in Australia with branches in each state and territory. The ANF is also the largest professional nursing organisation in Australia. The ANF's core business is the industrial and professional representation of nurses and nursing in Australia.
- 1.2 The ANF's 145,000 members are employed in a wide range of enterprises in urban, rural and remote locations in the public, private and aged care sectors, including hospitals, health services, schools, universities, the armed forces, statutory authorities, local government, offshore territories and industries.
- 1.3 The ANF participates in the development of policy in nursing, nursing regulation, health, community services, veterans' affairs, education and training, occupational health and safety, industrial relations, immigration and law reform.

2. General comments on the first consultation draft

- 2.1 The *National Statement on Ethical Conduct in Research Involving Humans* published in 1999 is a comprehensive and detailed document that has served the research community well. Along with the *Human Research Ethics Handbook* it has provided guidance in ethical considerations for researchers and human research ethics committees (HRECs). Any health professional involved in research involving humans should by now be very familiar with the 1999 National Statement.
- 2.2 However, the research domain is broadening all the time, with qualitative research methods being increasingly recognised as providing important insights into the human condition. This area was barely acknowledged in the 1999 National Statement.

As nurses and midwives are increasingly engaging in research involving health consumers, their families, carers and other people important to their care, the ANF considers that this review is both pertinent and timely. Nursing research predominantly uses qualitative methods.

- 2.3 The first consultation draft developed as part of the Review of the *National Statement on Ethical Conduct in Research Involving Humans* is a considerable improvement on the original Statement. It identifies the responsibilities of organisations hosting research, researchers and Human Research Ethics Committees (HRECs) and is aimed at providing guidance for these critical groups in the ethical review and conduct of research. Importantly, the Statement also outlines the rights of human participants in research, although it seems that they are still relegated to a less significant position in the document at Section 3.
- 2.4 The ANF notes the important collaboration of the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee in jointly authoring the revised Statement. This is an important development as it gives the Statement even stronger endorsement as the standard for ethical review and conduct of all research involving humans which takes place under the aegis of any of these leaders of research in Australia.
- 2.5 The early introduction of the concept of research governance in the Preamble to the Statement is very important, pointing out the responsibilities of institutions for the quality, safety and ethical acceptability of the research they host, sponsor or permit to be carried out under their auspices. The researchers and the HRECs, while very important, are part of a broader structure of governance that is required to ensure that the research is ethical, lawful, closely monitored, well managed and as safe as possible.

- 2.6 The structure of the Statement and the contents have evolved considerably from the earlier very process focussed 1999 Statement. Of particular note for the ANF, given the generally qualitative focus of most nursing research, is the addition of the new sub-section on the ethics of research involving qualitative methods. Another significant improvement is that the document as a whole has been revised to largely 'de-medicalise' the language and content. Like the Working Party, the ANF is of the view that the document should be relevant to all involved in research involving humans – participants, researchers, HRECs, etc.
- 2.7 The restructuring of the Statement around the four key ethical principles of: respect for human beings; beneficence – balancing benefits and risks in research; justice in research; and research merit and integrity, is a profoundly significant change as it emphasises the critical importance of the principles that must underpin the conduct of the organisation(s) hosting the research as well as that of the individual researchers that make up the research project team.
- 2.8 The 1999 Statement's focus on processes rather than principles had the effect in many cases of creating rigid and inflexible processes and requirements for host organisations and researchers to comply with. In turn, at times this created situations that were unhelpful to the furtherance of human knowledge. Some of the barriers preventing the smooth conduct of research include: poor relationships between the researchers and the human research ethics committee (HREC) reviewing the proposal creating frustration and delays on both sides; and the lack of opportunity for researchers to discuss and negotiate around their proposal and the requirements of the HREC and indeed, develop a relationship with the HREC for the duration of the research study. Many researchers describe their contacts with HRECs using terms of conflict and adversarial language.

- 2.9 The ANF is of the view that the more liberal approach that is made possible by the use of first principles as the foundation for the conduct of all research involving humans should provide HRECs, researchers and host organisations with more appropriate tools. The risk will be if the past 'rules' are overlaid upon the newly articulated principles to prevent the exercise of the discretion that the principles allow. The ANF notes that the *Human Research Ethics Handbook* is to be reviewed by 2006 and recommends that this occurs without delay to ensure that there is complete compatibility between the National Statement and the Handbook in both philosophical approach and content.

RECOMMENDATION: 1:

The *Human Research Ethics Handbook* is reviewed without delay to reflect the developments that have occurred in the National Statement.

3. Comments relating to particular parts of the draft statement

3.1 **Section 1: Principles for Ethical Conduct**

Section 1.1: Respect for human beings, justice, research merit and integrity, and beneficence

The ANF recommends that there is further explanation in the Statement of the application of the ethical principle of 'beneficence'. There is no explanation of the translation of the ethical principle of beneficence into the way it is used in the document that is, 'balancing benefits and risks in research'. While this is explained in the *Human Research Ethics Handbook* it is not so explicitly dealt with in the Draft Statement and it is here that the primary guidance is required.

RECOMMENDATION 2:

More explicit recognition that the ethical principle of beneficence is expressed in researchers' responsibility to minimise risks of harm or discomfort to participants in research projects, and is expressed as 'balancing benefits and risks in research' throughout the Statement.

- 3.2 Any research involving humans has the potential to cause some harm, be it physical, psychological, social or other harm. There should be acknowledgement in the Statement of this inevitable risk of harm as well as the necessity to identify and minimise the risks of harm to participants and others involved in the research.

RECOMMENDATION 3:

The Statement includes a statement that researchers have a responsibility to acknowledge that it is inevitable that any research involving humans will entail the risk of some harm to participants.

3.3 **Section 1.2: Consent to participation in research**

The ANF is of the view that there is inadequate detail in the Statement concerning obtaining consent for the collection and retention of different forms of data such as photographs, aural and audio visual recording. We are concerned that the ethical implications of these are often overlooked in research.

RECOMMENDATION 4:

The Statement should make clear the necessity to obtain consent for the collection and retention of the different forms of data such as photographs, aural and audio visual recording, participant diaries etc.

- 3.4 Sub-section 1.2.10 outlining the use of participants' data or tissue in future unspecified research requires further guidance as to when obtaining such extended consent is likely to be sought. Consent to unfettered use of participants' data or tissue in the future is ethically objectionable and unlikely to obtain the approval of a HREC without very good reasons. There must be much more clarity around the intent of this section.
- 3.5 If consent to re-contact a person outside the context of the original research project that they had consented to participate in was not intended in 1.2.10, then several issues should be explicitly addressed. Firstly, the privacy issues around the holding of identifiable information to enable re-contact. Secondly the ethics of obtaining consent to re-contact a participant outside the terms of the consent obtained for participation in the original research project.

RECOMMENDATION 5:

The Statement should provide further guidance as to when obtaining such extended consent is likely to be sought.

RECOMMENDATION 6:

Specific guidance should be given as to the consent issues around recontacting a person outside the context of the original research project that they had consented to participate in.

- 3.6 Subsection 1.2.16 dealing with the waiving of the requirement for a researcher to obtain consent from participants should provide more guidance than it does. The discretion that this provides has the potential to be exploited without some very clear direction.

RECOMMENDATION 7:

A brief summary should be provided outlining those conditions when disclosure and consent are not necessary.

- 3.7 There is little guidance in the Draft Statement on the necessary requirements around indigenous health research protocols and consent. While the ANF accepts that there are other sources for this information as the Statement is assumed to be the definitive statement on the subject, we are strongly of the view that there needs to be a new section in part 1.2 that briefly discusses the specific issues of consent as applied to research involving individual indigenous community members and whole communities.

RECOMMENDATION 8:

A new section should be added to part 1.2 outlining the specific issues in relation to consent as it applies to research involving individual indigenous community members and whole communities.

3.8 **Section 2: Ethical Considerations Specific to Research Methods or Disciplines**

The ANF is of the view that the order of the sub-sections in this section is not logical. For example the information in the sub-sections on data and data banks, and epidemiology are fundamental to all kinds of research, be they quantitative or qualitative.

Also, the sub-section on research involving deception of participants, concealment or covert observation is given too great an emphasis as section 2.2. As this is a most unusual type of research and is generally regarded as ethically objectionable, it should be at the end of this section.

RECOMMENDATION 9:

The sequencing of Part 2 is changed as follows:

- 2.1. Ethical considerations specific to data and data banks
- 2.2. Ethical considerations specific to epidemiological research
- 2.3. Ethical considerations specific to research involving qualitative methodologies
- 2.4. Ethical considerations specific to human genetic research
- 2.5. Ethical considerations specific to research using human tissue samples
- 2.6. Ethical considerations specific to clinical research and clinical trials
- 2.7. Ethical considerations specific to research involving deception of participants, concealment or covert observation.

3.9 The following comments are made in relation to the sub-sections as they currently appear in the Draft Statement.

3.10 **Section 2.1: Ethical considerations specific to research involving qualitative methods**

The ANF is of the view that this section requires further detail and explanation. While we applaud the addition of the section the variety of types of research in this genre are not adequately dealt with in the document. This area of research has also seen remarkable developments in the last decade. This is of particular interest to the ANF as the majority of nursing research is necessarily qualitative research.

RECOMMENDATION 10:

The Committee work with an organisation (such as a university) that is recognised as having broad experience and expertise in qualitative research to ensure that Section 2.1 is a more comprehensive account of this important form of research.

- 3.11 It should be noted here that the language in this section identifies 'cases' rather than people or participants. The use of 'case' is dehumanising and ethically improper.

RECOMMENDATION 11:

All reference to 'cases' be removed and replaced with people, persons or participants.

- 3.12 In Section 2.3 the numbering in document after 2.3.1 goes to 3.32 – 3.35.

3.13 **Section 3: Ethical Considerations Specific to Participants**

The ANF is strongly of the view that this section should be moved within the document and become Section 2 as it recognises the critical importance of participants to any form of research. Its location towards the end of the document de-values the role of participants.

RECOMMENDATION 12:

The section *Ethical Considerations Specific to Participants* to be brought forward in the document to become Section 2.

3.14 Section 3.5: Ethical considerations specific to research involving Aboriginal and Torres Trait Islander peoples

As with the lack of information relating to consent and research involving Aboriginal and Torres Trait Islander peoples, this section is currently far too brief and lacking in detail to adequately represent the national position. While it is acknowledged once again that there are existing guidelines, it is important that there is an outline of the issues they deal with in this National Statement. As stated above, it is important that the National Statement is as comprehensive as possible.

- 3.15 There is increasing research that goes across national borders. This raises particular ethical challenges that confront researchers. While there may be different ethical frameworks that are culturally based there must be a strong statement that the level of ethical review and conditions of approval by a HREC must be as rigorous as research conducted in Australia. While this is dealt with briefly in the earlier part of the Draft Statement, it is the ANF's view that this should be dealt with as a separate part.

RECOMMENDATION 13:

The addition of a separate section dealing with the ethical issues pertaining to research that is conducted across national boundaries.

3.16 Section 4: Ethical Review of Research Involving Humans

Section 4.1: Responsibilities for ethical review of research

In 4.1.1 dealing with the composition of a HREC, the ANF is of the view that there is no need to mandate that a lawyer is a permanent member of a HREC. It is critical that the research is reviewed for its lawfulness but this is a governance responsibility of the organisation(s) hosting the research, not a role for an HREC.

It is improper to require that a single lawyer on the HREC be responsible for this role. There are certainly many fine lawyers who have the capacity to contribute to the deliberations of a HREC because of their understanding and interest in ethics. In which case, they could be potentially be considered as one of the lay members. Some thought should be given to increasing the number of lay members to achieve a more balanced committee with greater independent membership.

RECOMMENDATION 14:

Remove the requirement of having a lawyer as a member of a HREC and increase the number of lay persons on the committee.

- 3.17 Some HRECs have had burdensome responsibilities to be the body responsible for the overall governance of some research projects. This is not appropriate, nor is it the role of an ethics committee. For example they have had responsibility to review the methodology from a scientific point of view, the legality of different aspects of research etc.
- 3.18 The role of any researchers on a HREC is not for the purpose of methodological review but to explain to the Committee any impact of the Committee's decisions to the research proposed. Methodological review, like the testing of lawfulness of research is a governance responsibility of the organisation(s) hosting the research and should be reviewed independently of the HREC, prior to review by the HREC as changes to the methodology can impact on the ethical issues that may arise from a proposal.

3.19 There has also been some criticism of the role of the HREC in approval of all documents and materials. There is a need for more guidance in this section in relation to the matters of substance that should be referred to the HREC for approval as opposed to minor semantic and grammar changes to improve the document. It is the view of ANF that some HRECs spend far too much time debating the minutiae of single documents when it is the ethical appropriateness of the documents that is their responsibility. The steering committee with oversight responsibility for the research, delegated by the host organisation should have the role of ensuring the detail is fitting. Once again this is a governance responsibility that seems to have been taken up by some HRECs. The issues here should also be dealt with in more depth in the Handbook.

RECOMMENDATION 15:

The responsibilities of the HREC are more clearly limited to ethical review and monitoring, while the governance responsibilities, including the review of the scientific calibre of the research methodology and the review for lawfulness are more formally dealt and signed off by the host organisation(s).

3.20 The ANF strongly supports the addition of sub-sections 4.1.37 – 4.1.38 emphasising the importance of much stronger working partnerships or relationships of mutual trust, confidence in and open communication between the organisation, the HREC and the researchers. While these relationships must be conducted in such a way that they do not create conflicts of interest for any of the parties, better conduits for discussion, debate and negotiation can only improve the processes of ethical review and monitoring of research.

3.21 Section 4.2 – Multiple ethical review of research

One of the single most challenging issues confronting researchers conducting research across more than one organisational boundary in 2005 is the demand for multiple ethical reviews by each organisation's HREC. While this section gives some recognition of this dilemma and provides some guidance to enable single review to occur, it is the view of the ANF that a much stronger position needs to be taken to positively encourage review by only one lead HREC.

3.22 This can be done in different ways, for example:

- Providing strong guidance to all HRECs on their institutional policies and processes to improve the consistency and robustness across organisations. This is alluded to in 4.2.2 but requires some significant strengthening if the current inconsistencies are to be removed and lack of trust between HRECs is to be dispelled;
- By designating lead HRECs or setting up regional HRECs that cross boundaries. If the current governance, legal review (including contractual arrangements), methodological review and management responsibilities of the research projects devolve to the organisational agents more appropriate to undertake these tasks, then arguably the current very heavy load that some HRECs have should be reduced appreciably.

RECOMMENDATION 16:

That single review by a recognised HREC is all that is required for a research project that crosses organisational boundaries.

3.23 4.5 - Accountability

The ANF strongly endorses the concept of shared accountability for the ethical conduct of research and recognises the importance of the new subsection on accountability for all parties involved in ethical review, for example, researchers, HRECs, organisations hosting research, funding bodies and governments. This is in keeping with the notion of the overall good governance of research.

3.24 While research governance is dealt with in the Preamble of the Draft Statement a more complete account of what it involves is not clearly outlined in Section 4.5 or other parts of the document.

3.25 While the Draft Statement does emphasise the responsibilities for ethical research must be shared across the organisation(s) hosting the research, the individual researchers and the HREC, there are not adequate guidelines as to the organisation's responsibility for this. The effect of this in many cases is that the HREC carries the burden.

This makes the task of the HREC extremely onerous and has the potential to enable them to wield great power. Yet, as discussed in several places in this submission, a number of core responsibilities should be carried by the organisation(s). For example, responsibility for: the testing of the methodological robustness of the research; the lawfulness of the research; the employment of suitably educated, experienced and ethical researchers; the relationships and contractual arrangements where the research crosses organisations; and the day-to-day decision making and management of the research project are generally the responsibility of the host organisation.

RECOMMENDATION 17:

The guidelines outlining the governance responsibilities for host organisations where research is being conducted are more clearly articulated and have the same degree of formality as an HREC has in relation to research ethics.

4. Conclusion

- 4.1 Finally to reiterate some remarks made in the ANF's preliminary response to the Review.
- 4.2 Often, requests are made of nurses to collect information for research purposes as part of the routine activities of their work. It is vitally important that nurses involved in such research are made fully aware of the ethical conduct required when doing this on behalf of primary researchers. The ANF recommends that reference be made to this 3rd party collection process in the National Statement, making it clear that education must be given to all data collectors, regardless of their number or location.
- 4.3 Nurses may also be made aware of ethical concerns regarding clinical research, either by direct observation or by comments from patients involved in the research. It is even more critical in this instance that nurses involved at that level are made aware of processes whereby they or other concerned people can communicate such concerns in a formal or informal manner, and receive feedback on the outcome of that communication.

RECOMMENDATION 18:

There is guidance provided in the National Statement and Handbook for clinicians who as third parties have a role in research as part of their clinical work.

- 4.4 The ANF looks forward to hearing of the outcomes of the formal consultation process and receiving the revised National Statement.

REFERENCE:

Kerridge I, Lowe M and McPhee 1998 *Ethics and Law for the Health Professions*, Social Science Press, Katoomba.

National Health and Medical Research Council, Australian Research Council and the Australian Vice-Chancellors' Committee 2004 *Review of the National Statement on Ethical Conduct in Research Involving Humans: First Consultation Draft*, December. Available: <http://www.nhmrc.gov.au/issues/pdf/nsec.pdf>. Accessed: 30 January 2005.

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