



What is new in the *National Statement on Ethical Conduct in Human Research 2007*

The *National Statement on Ethical Conduct in Human Research 2007* contains Australia's primary guidelines for the ethical conduct of research involving human participants.

The *National Statement* has been co-issued by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee.

What is the purpose of the National Statement?

The purpose of the *National Statement* is to promote ethical human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

The *National Statement* is organised around four values:

- respect for human beings;
- research merit and integrity;
- justice; and
- beneficence.

These values provide a comprehensive framework of principles to guide the design, review and conduct of human research.

The *National Statement* also contains specific guidance for very different types of research (for example, research using qualitative methods and research using human tissue samples) as well as guidance for research involving particular kinds of participants (such as children and people in dependent relationships).

In addition, the *National Statement* contains detailed guidance for research institutions (for example, hospitals and universities) and their human research ethics committees (HRECs) regarding processes for ethical review of all research involving human participants.

What is new in the *National Statement on Ethical Conduct in Human Research 2007*?

The *National Statement 2007* consists of five parts:

1. *Values and Principles of Ethical Conduct* sets out ethical values and principles that apply to all research involving humans.
2. *Themes in research ethics: risk and benefit, consent* contains a discussion of, and guidelines for, the identification and assessment of risks and benefits of human research. It also contains guidelines about consent to participation in and withdrawal from, research.

3. *Ethical considerations specific to research methods or fields* provides more detailed guidance on ethical considerations specific to different research methods and disciplines, such as human tissue samples, clinical trials and databanks.
4. *Ethical considerations specific to participants* provides more detailed guidance on ethical considerations that need to be taken into account for different types of participants, such as children and people in other countries.
5. *Processes of research governance and ethical review* sets out the responsibilities of institutions for research and for the establishment and functioning of processes for ethical review of research, including HRECs. It also provides guidelines for minimising duplication of ethical review, managing conflicts of interest, monitoring approved research, handling complaints and the accountability of researchers, HRECs and institutions.

The main changes from the 1999 *National Statement* are as follows:

1. The following chapters address issues related to research methods, participants, and responsibilities that were not included in the 1999 *National Statement*:
 - 2.1 Risk
 - 3.1 Qualitative methods
 - 3.2 Databanks
 - 3.6 Human stem cells
 - 4.1 Women who are pregnant and the human foetus
 - 4.6 People who may be involved in illegal activities
 - 4.8 People in other countries
 - 5.1 Institutional responsibilities.
2. All chapters have been revised in the light of submissions received in the first and second rounds of consultation (and the order, titles and numbering of some chapters have changed). However, some chapters have significant revisions. These are:
 - 2.2 General requirements for consent
 - 2.3 Qualifying or waiving conditions for consent
 - 4.2 Children and young people
 - 4.7 Aboriginal and Torres Strait Islander Peoples.
3. Some chapters in the 1999 *National Statement* have been deleted because the ethical matters are now addressed in other guidelines or have been incorporated in other chapters of the *National Statement* 2007. These are:
 - Research involving ionising radiation – responsibility for this research is now managed by the Australian Radiation Protection and Nuclear Safety Agency (website: <http://www.arpansa.gov.au/index.htm>);
 - Research involving assisted reproductive technology – the NHMRC has developed separate guidelines for this type of research: *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2004* (website: <http://www.nhmrc.gov.au/ethics/human/issues/art.htm#2>). These

guidelines are currently being revised and will be available following completion of public consultation and issue by the NHMRC, expected shortly;

- Research involving collectivities –has been covered in other chapters in the *National Statement 2007*; and
- Epidemiological research - has been covered in other chapters in the *National Statement 2007*.

4. Section 5 makes provision for institutions to establish different levels of ethical review for research with different levels of risk.

The *National Statement* is also one of the key documents that support the new legislative regime arising from the passage of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*.

Is the NHMRC planning to hold information sessions on the new *National Statement*?

- NHMRC will be holding national information sessions on the new *National Statement* over the coming months. Further advice on information sessions will be provided on the NHMRC website as it becomes available.
- The National Research Ethics Conference to be held in Melbourne from 16-18 October 2007 will provide further opportunities for information and discussion about the *National Statement*.

When do HRECs have to comply with the new *National Statement*?

- Institutions and their HRECs and other review bodies should acquaint themselves with, and meet, the requirements in the new *National Statement* as soon as possible.
- The 2006-2007 annual reporting round will be based on use of the 1999 *National Statement* and will cover activities of the HREC from 1 July 2006 to 30 June 2007.
- After the 2006-2007 annual reporting round, reporting about compliance with the *National Statement 2007* will commence from 1 January 2008.

Which *National Statement* applies if my research proposal research involves human embryos, stem cells or requires a licence from the NHMRC's Licensing Committee?

- Research that involves stem cells, human embryos or other licensable activities is expected to conform to the requirements of the 2007 *National Statement*.
- Ethics applications for such research, therefore, will need to satisfy the requirements of the 2007 *National Statement*.

What will happen to NEAF?

- The National Ethics Application Form is being revised to take account of the new *National Statement*, and will be available before the end of 2007.