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## 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 Universities Australia (formerly 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.

### 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.

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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.

## 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 a Beta version of NEAF 2007 is available now. This version can be accessed at [www.neaf.gov.au](http://www.neaf.gov.au). We welcome user feedback and comments at [neafassist@nhmrc.gov.au](mailto:neafassist@nhmrc.gov.au)

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