

PURPOSE, SCOPE AND LIMITS OF THIS DOCUMENT

PURPOSE

The purpose of this National Statement is to promote ethically good 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 therefore designed to clarify the responsibilities of:

- institutions and researchers for the ethical design, conduct and dissemination of results of human research; and
- review bodies in the ethical review of research.

The National Statement will help them to meet their responsibilities: to identify issues of ethics that arise in the design, review and conduct of human research, to deliberate about those ethical issues, and to justify decisions about them.

Use of this National Statement

This National Statement must be used to inform the design, ethical review and conduct of human research that is funded by, or takes place under the auspices of, any of the bodies that have developed this National Statement (NHMRC, ARC, AVCC).

In addition, the National Statement sets national standards for use by any individual, institution or organisation conducting human research. This includes human research undertaken by governments, industry, private individuals, organisations, or networks of organisations.

What is research?

There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers. The British Research Assessment Exercise (RAE) definition of research is somewhat wider:

'Research'... includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.²

² Higher Education Funding Council for England, Scottish Higher Education Funding Council, Higher Education Funding Council for Wales, & Department for Employment and Learning Northern Ireland (2005) *RAE 2008: Guidance to Panels*, p.28. At <http://www.rae.ac.uk/pubs/2005/01/rae0105.doc>, accessed 27th October 2006

To enable comparative assessment of academic activity, this definition sought to include the widest range of creative and experimental activities. Many items in the definition are uncontroversial, but there may be disagreement about some – for example, ‘the invention and generation of new...images, performances, artefacts...where these lead to new or substantially improved insights’ – since this could count poetry, painting and performing arts as research.

For the purposes of this National Statement, two further questions are more important than any definition of research:

- What is *human* research?
- When and by what means does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review? (See *When does quality assurance in health care require independent ethical review?* NHMRC 2003.)

What is human research?

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term ‘participants’ is therefore used very broadly in this National Statement to include those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a Human Research Ethics Committee (HREC).

In addition, the conduct of human research often has an impact on the lives of others who are not participants. When this impact is reasonably foreseeable, it may raise ethical questions for researchers and for those ethically reviewing research.

When is ethical review needed?

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see *Section 2: Themes in research ethics: risk and benefit, consent, and Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*). Research with more than a low level of risk (as defined in paragraph 2.1.6, page 18) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21 (page 79). Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23, page 79).

A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

Ethics and law in human research

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants. Contractual arrangements may impose obligations on research funders and institutions.

This National Statement focuses on the ethical aspects of the design, review and conduct of human research. Research ethics is only part of an institution's responsibilities for research governance. Compliance with legal obligations (statutory or otherwise) forms another part, which is not within the scope of the National Statement.

Some human research is subject to specific statutory regulation, at Commonwealth and State and Territory levels. The National Statement identifies some specific Commonwealth legislation that refers to the National Statement. The National Statement does not identify State and Territory laws that may be relevant to human research, such as those relating to use of information held by state or territory authorities, use of human tissues, guardianship, and illegal and unprofessional conduct.

The responsibilities set out in this National Statement are intended to be consistent with the international human rights instruments that Australia has ratified.

It is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant.