National Statement - Summary of Updates

Version 6.0

Title/status	Amendment details	Date of effect	Supporting documents and relevant links
National Statement on Ethical Conduct in Human Research (2007 – Updated May 2015) **Current**	**Guideline:** Minor amendments made to Chapter 2.3 to make it easier for users to ensure the requirements of the *Privacy Act 1988* are met following revisions made to the Act on 12 March 2014.	14 May 2015	
National Statement on Ethical Conduct in Human Research (2007 – Updated March 2014)	**Guideline:** Insertion of new guidelines into Chapter 2.3 to include guidance on an opt-out approach. Consequent amendment to the introduction of Chapter 2.3 and inclusion of the term 'opt-out approach' in the Glossary. **Editorial:** Removal of page numbers throughout the document and updates to chapter references. Update reference to *Ethical Considerations in Quality Assurance and Evaluation Activities, 2014.*	27 March 2014	Ethical considerations in quality assurance and evaluation activities Further information on the revision of Chapter 2.3
National Statement on Ethical Conduct in Human Research (2007 – Updated December 2013) **Archived**	**Guideline:** Inserted new *Chapter 3.4: Human biospecimens in laboratory based research*. Revoked (in full) existing *Chapter 3.4: Human tissue samples; and Chapter 3.6: Human stem cells*. Inclusion of the terms 'cell line' and 'community' in the Glossary.	11 December 2013	Further information on the revision of Chapter 3.4 & 3.6
National Statement on Ethical Conduct in Human Research (2007 – Updated May 2013) **Archived**	**Guideline:** Inserted new paragraph 4.1.11. Revoked existing paragraph 4.1.11[1].	28 May 2013	
National Statement on Ethical Conduct in Human Research (2007 – Updated 2013) **Archived**	**Guideline:** Amendments to change spelling of foetus to fetus throughout the document in accordance with §14B (1)(b) of the *NHMRC Act 1992*.	13 February 2013	
National Statement on Ethical Conduct in Human Research (2007 – Updated 2009) **Archived**	**Guideline:** Amendments to paragraph 4.5.5 (split into paragraphs 4.5.5 and 4.5.6)[2].	10 August 2009	

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National Statement (2007) **Archived**		28 March 2007	The *Research Involving Human Embryos Act Regulations 2003*, Part 2.4 refer to this version of the *National Statement*.
National Statement on Ethical Conduct in Human Research (1999) **Rescinded**		1999	Section 21(3)(c) of the *Research Involving Human Embryos Act 2002* refers to this version of the National Statement.
NHMRC Statement on Human Experimentation and Supplementary Notes 1992 **Rescinded**		1992	Replaced by *National Statement* (1999) with the exception of **Supplementary Note 5 – Revoked** Issued in October 1983, revoked 26 March 2007 **Supplementary Note 7 – Rescinded** Issued November 1992, rescinded 1 January 2000 *Guidelines for ethical review of research proposals for human somatic cell gene therapy and related therapies 1999* (**rescinded 24 April 2003**) replaced *Supplementary Note 7*.

Details of Amendments

Date of effect 28 May 2013

[1]Inserted:

4.1.11 Research involving a fetus or fetal tissue should be conducted in a manner that maintains a clear separation between the woman's clinical care and the research. Where a treating health professional is also involved in the research, any conflict of interest (for example, one which may arise from a financial or contractual relationship) will need to be managed in accordance with paragraph 5.4.3 of this National Statement. In cases where pregnancy is to be terminated, the possibility of contributing fetal tissue to research must not be raised until a decision to terminate has been made. Proposals for research must include procedures to ensure that the process of providing information and obtaining consent for involvement in the research is clearly separated from clinical care. For example:

- A researcher who is also the treating health professional should not be the person who seeks the consent of the potential participant unless there is a specific justification for doing so (see paragraph 3.3.17)
- Information sheets for research projects must be completely separate from, and capable of being read independently of, written information provided to a patient in the course of routine clinical care.

Revoked:

4.1.11 Those conducting research involving the human fetus ex utero or fetal tissue, after termination of pregnancy, should have no involvement in the clinical care of the woman from whom the fetus or fetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in a location that maintains a separation of the woman's clinical care from research.

Date of effect 10 August 2009

[2]Chapter 4.5 *People with a cognitive impairment, an intellectual disability or a mental illness*.

4.5.5 – split into 4.5.5 and 4.5.6

Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

4.5.6 Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.