

EXPLANATORY STATEMENT

Select Legislative Instrument 2007 No. 255

Subject: *Research Involving Human Embryos Act 2002*

Research Involving Human Embryos Amendment Regulations 2007 (No. 1)

Subsection 48(1) of the *Research Involving Human Embryos Act 2002* (the Act) provides that the Governor-General may make regulations, prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

In December 2006, the Parliament passed the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*, which amended the Act to expand the range of activities permitted under licences issued by the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee.

The amendments allow a person to apply to the NHMRC Embryo Research Licensing Committee for a licence permitting the following additional activities:

- creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
- creation of human embryos (by a process other than fertilisation of human egg by human sperm) containing genetic material provided by more than 2 persons, and use of such embryos;
- creation of human embryos using precursor cells from a human embryo or a human foetus, and use of such embryos;
- research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training in Assisted Reproductive Technology (ART);
- creation of hybrid embryos by the fertilisation of an animal egg by human sperm and use of such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre.

The CEO of the NHMRC issued the *National Statement on Ethical Conduct in Human Research* in March 2007 and the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* in June 2007. Both of these documents are updated versions of ethical guidelines currently prescribed by the *Research Involving Human Embryos Regulations 2003* (the Principal Regulations).

The purpose of the Regulations is to make consequential amendments to the Principal Regulations arising from the amendments to the Act and to replace references to earlier versions of ethical guidelines with references to the revised versions of the ethical guidelines.

Details of the Regulations are set out in the Attachment.

Subsection 48(2) of the Act requires that before making regulations under the Act, the Minister must be satisfied that the States have been consulted in relation to the regulations and that the regulations have been prepared having regard to the views expressed by the States in those consultations. "State" is defined in the Act to include the Australian Capital Territory and the Northern Territory.

The Act specifies no other conditions need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on 24 August 2007.

ATTACHMENT

Details of the *Research Involving Human Embryos Amendment Regulations 2007 (No. 1)*

Regulation 1 identifies the Regulations as the *Research Involving Human Embryos Amendment Regulations 2007 (No. 1)*.

Regulation 2 provides that the Regulations commences on 24 August 2007.

Regulation 3 specifies that Schedule 1 amends the *Research Involving Human Embryos Regulations 2003* (the Principal Regulations).

Schedule 1 – Amendments

Item 1 amends regulation 1.3 of the Principal Regulations to define the phrase “ART Guidelines” to mean the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* since these guidelines are mentioned a number of times in the Principal Regulations.

Item 2 amends the heading of Part 2 of the Principal Regulations to correspond with the heading of Part 2 of the Act.

Item 3 amends regulation 2.1A of the Principal Regulations to correct a reference to a paragraph that no longer exists in the Act because of recent amendments to the Act. Item 3 will also replace a reference to an earlier version of the ART Guidelines with a reference to the revised version of the ART Guidelines.

Item 4 amends regulation 2.2 to replace references to superseded ethical guidelines with references to the revised versions of the guidelines.

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