EXPLANATORY STATEMENT

Select Legislative Instrument 2008 No. 80

Research Involving Human Embryos Act 2002

Research Involving Human Embryos Amendment Regulations 2008 (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 purpose of the Regulations is to make consequential amendments to the *Research Involving Human Embryos Regulations 2003* (the Principal Regulations) arising from those amendments to the Act.

One of the amendments to the Act was the inclusion of a definition of 'unsuitable for implantation' which means a human embryo that:

(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the CEO of the NHMRC; or

(b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* (the NHMRC Act) and prescribed by the regulations for the purposes of this paragraph.

On 6 December 2007, the *Objective Criteria for determining Embryos that are Unsuitable for Implantation* (2007) (the Objective Criteria) were issued as guidelines by the CEO of the NHMRC in accordance with the NHMRC Act; and the Regulations prescribe those guidelines in the Principal Regulations for the purposes of paragraph (b) of the definition of 'unsuitable for implantation'.

The 2006 amendment to the Act allows the NHMRC Embryo Research Licensing Committee to modify the consent process in relation to excess Assisted Reproductive Technology (ART) embryos that are unsuitable for implantation according to the Objective Criteria. An explanation of the intent and consequences of this amendment is at Attachment A, which is an excerpt from the Explanatory Memorandum to the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006.*

Details of the Regulations are set out in Attachment B.

As required by subsection 48(2) of the Act, the States and Territories were consulted, and their views taken into consideration before making these regulations. Moreover, the guidelines prescribed by the regulations were made following a period of public consultation as required under the *National Health and Medical Research Council Act 1992*.

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 the day after they are registered on the Federal Register of Legislative Instruments.

ATTACHMENT A

Excerpt from the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 - EXPLANATORY MEMORANDUM

Item 24 (Page 21)

This item inserts a new subsection (8) at the end of section 24 which provides that a licence in relation to embryos that are unsuitable for implantation (as defined) may provide that the NHMRC guidelines referred to in the definition of proper consent may apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation.

The purpose of this provision is to address Lockhart Recommendations 20, 21 and 22. The Lockhart Committee recommended that fresh ART embryos that are unsuitable for implantation, as defined by objective criteria, be able to be licensed for use for training and research.

Currently the *Research Involving Human Embryos Act 2002* does not expressly prohibit this. However, there is a statutory condition of licence that the responsible people in relation to an excess ART embryo must give proper consent to any research, in accordance with NHMRC guidelines. The relevant guidelines are the Australian Health Ethics Committee (AHEC) *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research* (2004). These Guidelines provide that:

"A person responsible for an embryo must be free at any time to withdraw consent to further involvement in the research. In view of the fact that once an embryo has been destroyed it cannot be restored, it is recommended that the consent of the persons responsible to a use that will damage or destroy an embryo must not be acted upon until a suitable fixed period of time for reconsideration has been allowed, normally at least two weeks after their consent to such research. This 'cooling-off' period before consent becomes effective must be explained to the persons responsible when consent is obtained." (page 53)

Based on the Lockhart Committee discussion of the issue, it would appear that researchers and the NHMRC Licensing Committee has been interpreting this requirement such that embryos that are unsuitable for implantation and are not frozen (because they are unable to be frozen or because they are unsuitable for implantation), cannot be used for research because the 14 day cooling-off period would preclude this.

In order to address this issue, it is proposed that a new sub-clause be added into section 24 (subsection 24(8)) that clarifies that if the NHMRC Licensing Committee considers it appropriate, they may approve the use of embryos that are unsuitable for implantation and alter the cooling-off period that would be "normally at least two weeks" as recommended by the NHMRC. This would allow the use of excess ART embryos that are unsuitable for implantation and would still ensure that appropriate consent is obtained from the responsible people. In no circumstances would embryos that are not excess be able to be used.

It is proposed that the NHMRC develop clear and objective criteria defining those embryos that are unsuitable for implantation.

ATTACHMENT B

Details of the *Research Involving Human Embryos Amendment Regulations 2008 (No. 1)*

Regulation 1 identifies the Regulations as the *Research Involving Human Embryos Amendment Regulations 2008 (No. 1).*

Regulation 2 provides that the item 1 of Schedule 1 to the Regulations will commence on the day after the Regulations are registered on the Federal Register of Legislative Instruments. Items 2 to 4 of Schedule 1 will commence immediately after item 1 of that Schedule.

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

Schedule 1 – Amendments

Item 1 renumbers current regulations 2.1A, 2.1 and 2.2 of the Principal Regulations in order to accommodate a new regulation 2.2 to be inserted by item 3.

Item 2 amends regulation 1.3 of the Principal Regulations to include and define the phrase *Objective Criteria for Unsuitable Embryos* to mean the *Objective Criteria for determining embryos that are unsuitable for implantation*, issued by the CEO of the NHMRC on 6 December 2007.

Item 3 amends the Principal Regulations to insert a new regulation 2.2 that prescribes the *Objective Criteria for Unsuitable Embryos* as the guidelines referred to in paragraph (b) of the definition of *unsuitable for implantation* in section 7 of the Act.

Item 4 amends the heading of Schedule 1 to the Principal Regulations to correspond with the renumbering of current regulation 2.2 to 2.3.