

## EXPLANATORY STATEMENT

### Select Legislative Instrument No.

#### Issued by Authority of the Minister for Health

#### *Research Involving Human Embryos Act 2002* Research Involving Human Embryos Regulations 2017

The *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) establish a regulatory framework to prohibit unacceptable practices, including human cloning, and to regulate the use of excess human embryos created through assisted reproductive technology (ART). In addition, the RIHE Act establishes the Embryo Research Licensing Committee (Licensing Committee) as a Principal Committee of the National Health and Medical Research Council (NHMRC). NHMRC is established as a statutory agency under the *National Health and Medical Research Council Act 1992* (NHMRC Act).

Subsection 48(1) provides that the Governor-General may make regulations prescribing matters either required or permitted by the RIHE Act to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the RIHE Act.

Subsection 48(2) provides that before the Governor-General may make regulations under the RIHE Act, the Minister must be satisfied that the States (which includes the internal Territories) have been consulted in relation to the proposed regulations, and that the proposed regulations have been prepared having regard to the views expressed by the States (including the internal Territories) in those consultations.

The *Research Involving Human Embryos Regulations 2003* (the Principal Regulations) prescribe the following documents for the purpose of licencing activities:

- The *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007* (ART guidelines) and *National Statement on Ethical Conduct in Human Research 2007* (National Statement) are those that are ‘as existing on 24 August 2007’.
- The Objective Criteria for Unsuitable Embryos (Objective Criteria) are those ‘as existing on 6 December 2007’.

The Principal Regulations also list the bodies from which nominations to Licensing Committee must be sought.

The National Statement provides ethical guidance for researchers, participants and Human Research Ethics Committees involved in human research. The ART guidelines provide ethical guidance for the use of ART in clinical treatment and research. Both the National Statement and the ART guidelines are developed and

issued in accordance with the NHMRC Act, with public consultation required under section 13. The Objective Criteria provide guidance on the criteria to be used when deciding that embryos can be donated for use in licensed activities because they are unsuitable for implantation.

The purpose of the *Research Involving Human Embryos Regulations 2017* is to:

- Update the references to the National Statement and ART guidelines. This ensures that the more recent version of each document is prescribed.
- Update the list of Prescribed Bodies from which nominations for membership on Licensing Committee is to be sought. The list is moved from a schedule and included in the body of the Regulations.
- Provide for transitional arrangements which would enable applications for licences made but not finally determined before the repeal of the Principal Regulations, to be determined as if the proposed Regulations had not been made.

The Objective Criteria remain unchanged.

Consultation with all the States, the Australian Capital Territory and the Northern Territory (the States) under subsection 48(2) of the RIHE Act was undertaken by NHMRC and considered by the Minister for Health. The States either supported or had no issue with the changes. The Regulations were prepared having regard to the views expressed by the States in those consultations.

Consultation under section 17 of the *Legislation Act 2003* was undertaken with Professor Anne Kelso, NHMRC Chief Executive Officer.

Details of the Regulation are set out in the [Attachment](#).

The Regulation commenced on the day after registration on the Federal Register of Legislation.

The Office of Best Practice Regulation has advised that a Regulation Impact Statement is not required.

The Regulation is a legislative instrument and is subject to the *Legislation Act 2003*.

**Details of the *Research Involving Human Embryos Regulations 2017***

**Section 1 - Name of Regulations**

This section provides that the title of the Regulation is the *Research Involving Human Embryos Regulations 2017*.

**Section 2 – Commencement**

This section provides for the Regulations to commence on the day after this instrument receives registration.

**Section 3 – Authority**

This section provides that the *Research Involving Human Embryos Regulations 2017* are made under the *Research Involving Human Embryos Act 2002* (RIHE Act).

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

**Schedule 1 - Amendments**

**Regulation of the use of excess ART embryos, other embryos and human eggs**

**Section 5 – Definitions**

This section provides definitions of the terms and expressions used in this instrument.

**Section 6 – Definition of *unsuitable for implantation* – prescribed guidelines**

This section prescribes the Objective Criteria for Unsuitable Embryos for the definition of unsuitable for implantation for the purposes of subsection 7(1) of the RIHE Act.

**Section 7 – Definition of *proper consent* – prescribed guidelines**

This section prescribes the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017* (ART guidelines) for the definition of proper consent for the purposes of section 8 of the RIHE Act.

**Section 8 – Membership of NHMRC Licensing Committee – prescribed bodies from which nominations must be sought**

This section prescribes the bodies from which nominations must be sought for the membership of the NHMRC Licensing Committee for the purposes of paragraph 16(3)(a) of the RIHE Act.

**Section 9 – Determination by NHMRC Licensing Committee of licence applications – prescribed guidelines**

This section prescribes the ART guidelines and the *National Statement on Ethical Conduct in Human Research 2007* for the purposes of paragraph 21(4)(c) of the RIHE Act.

**Part 3- Miscellaneous**

**Section 10 – Form of identity card**

This section prescribes the form of identity card required for the purposes of paragraph 32(2)(a) of the RIHE Act.

**Part 4- Transitional, savings and application provisions**

**Section 11 – Licence applications**

This section applies in relation to an application for a licence made, but not finally determined, before the repeal of the *Research Involving Human Embryos Regulations 2003*.

**SCHEDULE 1 – Repeals**

**Item 1 The whole of the Regulations**

This item repeals the whole of the *Research Involving Human Embryos Regulations 2003*.

## **Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### ***Research Involving Human Embryos Regulations 2017***

This Regulation is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Regulation**

The *Research Involving Human Embryos Regulations 2003* (the Principal Regulations) prescribe the following documents for the purpose of licensing activities:

- The *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007* (ART guidelines) and *National Statement on Ethical Conduct in Human Research 2007* (National Statement) ‘as existing on 24 August 2007’.
- The Objective Criteria for Unsuitable Embryos (Objective Criteria) - means the *Objective Criteria for determining embryos that are unsuitable for implantation* ‘as existing on 6 December 2007’.

In addition, the Principal Regulations at Schedule 1 list the bodies from which nominations to Licensing Committee must be sought.

The purpose of the *Research Involving Human Embryos Regulations 2017* is to:

- Update the references to the National Statement and ART guidelines. This ensures that the more recent version of each document is prescribed.
- Update the list of Prescribed Bodies from which nominations for membership on Licensing Committee is to be sought. The list is moved from a schedule and included in the body of the Regulations.
- Provide for transitional arrangements.

#### **Human rights implications**

This Regulation does not engage any of the applicable rights or freedoms.

#### **Conclusion**

This Regulation is compatible with human rights as it does not raise any human rights issues.