Research Involving Human Embryos Regulations 2017

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 18 September 2017

Peter Cosgrove
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

Contents

Part 1—Preliminary

1 Name

This instrument is the *Research Involving Human Embryos Regulations 2017*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	20 September 2017

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Research Involving Human Embryos Act 2002*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

5 Definitions

In this instrument:

Act means the *Research Involving Human Embryos Act 2002*.

ART Guidelines means the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017*, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992*, as existing at the time when this instrument commences.

Note: The ART Guidelines could in 2017 be viewed on the website of the NHMRC (https://www.nhmrc.gov.au).

Section 5

National Statement means the *National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015)*, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992*, as existing at the time when this instrument commences.

Note: The National Statement could in 2017 be viewed on the website of the NHMRC (https://www.nhmrc.gov.au).

Objective Criteria for Unsuitable Embryos means the *Objective Criteria for determining embryos that are unsuitable for implantation*, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992*, as existing at the time when this instrument commences.

Note: The Objective Criteria for Unsuitable Embryos could in 2017 be viewed on the website of the NHMRC (https://www.nhmrc.gov.au).

Part 2—Regulation of the use of excess ART embryos, other embryos and human eggs

6 Definition of *unsuitable for implantation*—prescribed guidelines

For the purposes of paragraph (b) of the definition of ***unsuitable for implantation*** in subsection 7(1) of the Act, the Objective Criteria for Unsuitable Embryos are prescribed.

7 Definition of *proper consent*—prescribed guidelines

For the purposes of the definition of ***proper consent*** in section 8 of the Act, the ART Guidelines are prescribed.

8 Membership of NHMRC Licensing Committee—prescribed bodies from which nominations must be sought

For the purposes of paragraph 16(3)(a) of the Act, the bodies mentioned in the following table are prescribed.

Prescribed bodies

Item	Body
1	Access Australia's National Infertility Network Limited
2	Association of Australian Medical Research Institutes Limited
3	Australasian Association of Bioethics and Health Law
4	Australian Academy of Health and Medical Sciences Limited
5	Australian Academy of Science
6	Australian College of Nursing Ltd
7	Australian College of Rural and Remote Medicine
8	Australian Consumers' Association
9	Australian Federation of Disability Organisations (AFDO) Ltd
10	Australian Research Council
11	The Australian Society for Medical Research
12	Consumers Health Forum of Australia Ltd
13	The Fertility Society of Australia
14	Human Genetics Society of Australasia
15	Law Council of Australia Ltd
16	National Association of Specialist Obstetricians and Gynaecologists
17	National Stem Cell Foundation of Australia
18	Rare Voices Australia Ltd
19	The Royal Australasian College of Physicians
20	The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
21	The Royal Australian College of General Practitioners

Section 9

Prescribed bodies

Item	Body
22	Society for Reproductive Biology Incorporated
23	Universities Australia

9 Determination by NHMRC Licensing Committee of licence applications—prescribed guidelines

For the purposes of paragraph 21(4)(c) of the Act, the following guidelines are prescribed:

(a) the ART Guidelines;

(b) the National Statement.

Part 3—Miscellaneous

10 Form of identity card

For the purposes of paragraph 34(2)(a) of the Act:

(a) an inspector's identity card must state the date of issue of the card and the period of validity of the card; and

(b) the card's recent photograph of the inspector must be substantially a photograph of the inspector's face.

Part 4—Transitional, savings and application provisions

11 Licence applications

(1) 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* (the ***old regulations***).

(2) The following provisions of this instrument do not apply to the application:
  (a) the definition of ***ART Guidelines*** in section 5;
  (b) section 7;
  (c) section 9.

(3) Despite the repeal of the old regulations, the following provisions, as in force immediately before the repeal of the old regulations, continue to apply, on and after the commencement of this instrument, in relation to the application as if the repeal had not happened:
  (a) the definition of ***ART Guidelines*** in regulation 1.3;
  (b) regulation 2.1;
  (c) regulation 2.4.

Schedule 1—Repeals

Research Involving Human Embryos Regulations 2003

1 The whole of the regulations

Repeal the regulations.