

2004-2005-2006

The Parliament of the
Commonwealth of Australia

THE SENATE

**Prohibition of Human Cloning for
Reproduction and the Regulation of
Human Embryo Research Amendment
Bill 2006**

No. , 2006

(Senator Patterson)

**A Bill for an Act to amend the *Prohibition of
Human Cloning Act 2002* and the *Research
Involving Human Embryos Act 2002* based on the
Lockhart Review recommendations, and for related
purposes**

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A Bill for an Act to amend the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* based on the Lockhart Review recommendations, and for related purposes

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*.

2 Commencement

- (1) Each provision of this Act 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.

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Commencement information

Column 1	Column 2	Column 3
Provision(s)	Commencement	Date/Details
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent.	
2. Schedules 1, 2, 3 and 4	On the day after the end of the period of 6 months beginning on the day on which this Act receives the Royal Assent.	

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Note: This table relates only to the provisions of this Act as originally passed by both Houses of the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

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(2) Column 3 of the table contains additional information that is not part of this Act. Information in this column may be added to or edited in any published version of this Act.

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3 Schedule(s)

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(1) Each Act, and each set of regulations, that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

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(2) The amendment of any regulation under subsection (1) does not prevent the regulation, as so amended, from being amended or repealed by the Governor-General.

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2 **Schedule 1—Prohibition of Human Cloning**
3 **Act 2002**
4

5 **1 Title**

6 After “**human cloning**”, insert “**for reproduction**”.

7 **2 Section 1**

8 After “*Cloning*”, insert “*for Reproduction*”.

9 Note: This item amends the short title of the Act. If another amendment of the Act is
10 described by reference to the Act’s previous short title, that other amendment has effect
11 after the commencement of this item as an amendment of the Act under its amended
12 short title (see section 10 of the *Acts Interpretation Act 1901*).

13 **3 Subsection 8(1) (definition of *human embryo*)**

14 Repeal the definition, substitute:

15 ***human embryo*** means a discrete entity that has arisen from either:

16 (a) the first mitotic division when fertilisation of a human oocyte
17 by a human sperm is complete; or

18 (b) any other process that initiates organised development of a
19 biological entity with a human nuclear genome or altered
20 human nuclear genome that has the potential to develop up
21 to, or beyond, the stage at which the primitive streak appears;

22 and has not yet reached 8 weeks of development since the first
23 mitotic division.

24 **4 Subsection 8(1)**

25 Insert:

26 ***licence*** means a licence issued under section 21 of the *Research*
27 *Involving Human Embryos Act 2002*.

28 **5 Subsection 8(1)**

29 Insert:

30 ***NHMRC Licensing Committee*** means the Committee established
31 under section 13 of the *Research Involving Human Embryos Act*
32 *2002*.

1 **6 At the end of section 8**

2 Add:

3 (6) A reference in this Act to an embryo (including a human embryo)
4 is a reference to a living embryo.

5 (7) A reference in this Act to a human egg is a reference to a human
6 oocyte.

7 (8) A reference in this Act to a human embryo does not include a
8 reference to:

9 (a) a hybrid embryo; or

10 (b) a human embryonic stem cell line.

11 **7 Part 2**

12 Repeal the Part, substitute:

13 **Part 2—Prohibited practices**

14 **Division 1—Practices that are completely prohibited**

15 **9 Offence—placing a human embryo clone in the human body or the**
16 **body of an animal**

17 A person commits an offence if the person intentionally places a
18 human embryo clone in the body of a human or the body of an
19 animal.

20 Maximum penalty: Imprisonment for 15 years.

21 Note: The development of a human embryo (including a human embryo
22 clone) outside the body of a woman for more than 14 days is
23 prohibited by section 14.

24 **10 Offence—importing or exporting a human embryo clone**

25 (1) A person commits an offence if the person intentionally imports a
26 human embryo clone into Australia.

27 Maximum penalty: Imprisonment for 15 years.

1 (2) A person commits an offence if the person intentionally exports a
2 human embryo clone from Australia.

3 Maximum penalty: Imprisonment for 15 years.

4 **11 No defence that human embryo clone could not survive**

5 It is not a defence to an offence under section 9 or 10 that the
6 human embryo clone did not survive or could not have survived.

7 **12 Offence—creating a human embryo for a purpose other than**
8 **achieving pregnancy in a woman**

9 (1) A person commits an offence if the person intentionally creates a
10 human embryo by a process of the fertilisation of a human egg by a
11 human sperm outside the body of a woman, unless the person's
12 intention in creating the embryo is to attempt to achieve pregnancy
13 in a particular woman.

14 Maximum penalty: Imprisonment for 10 years.

15 (2) Despite subsection 13.3(3) of the *Criminal Code*, a defendant does
16 not bear an evidential burden in relation to any matter in
17 subsection (1) of this section.

18 **13 Offence—creating or developing a human embryo by fertilisation**
19 **that contains genetic material provided by more than 2**
20 **persons**

21 A person commits an offence if:

- 22 (a) the person intentionally creates or develops a human embryo
23 by a process of the fertilisation of a human egg by a human
24 sperm outside the body of a woman; and
25 (b) the human embryo contains genetic material provided by
26 more than 2 persons.

27 Maximum penalty: Imprisonment for 10 years.

1 **14 Offence—developing a human embryo outside the body of a**
2 **woman for more than 14 days**

3 A person commits an offence if the person intentionally develops a
4 human embryo outside the body of a woman for a period of more
5 than 14 days, excluding any period when development is
6 suspended.

7 Maximum penalty: Imprisonment for 10 years.

8 **15 Offence—heritable alterations to genome**

- 9 (1) A person commits an offence if:
10 (a) the person alters the genome of a human cell in such a way
11 that the alteration is heritable by descendants of the human
12 whose cell was altered; and
13 (b) in altering the genome, the person intended the alteration to
14 be heritable by descendants of the human whose cell was
15 altered.

16 Maximum penalty: Imprisonment for 10 years.

- 17 (2) In this section:

18 *human cell* includes a human embryonal cell, a human fetal cell,
19 human sperm or a human egg.

20 **16 Offence—collecting a viable human embryo from the body of a**
21 **woman**

22 A person commits an offence if the person removes a human
23 embryo from the body of a woman, intending to collect a viable
24 human embryo.

25 Maximum penalty: Imprisonment for 10 years.

26 **17 Offence—creating a chimeric embryo**

27 A person commits an offence if the person intentionally creates a
28 chimeric embryo.

29 Maximum penalty: Imprisonment for 10 years.

1 **18 Offence—developing a hybrid embryo**

2 A person commits an offence if the person intentionally develops a
3 hybrid embryo for a period of more than 14 days, excluding any
4 period when development is suspended.

5 Maximum penalty: Imprisonment for 10 years.

6 **19 Offence—placing of an embryo**

7 (1) A person commits an offence if the person intentionally places a
8 human embryo in an animal.

9 Maximum penalty: Imprisonment for 10 years.

10 (2) A person commits an offence if the person intentionally places a
11 human embryo in the body of a human, other than in a woman's
12 reproductive tract.

13 Maximum penalty: Imprisonment for 10 years.

14 (3) A person commits an offence if the person intentionally places an
15 animal embryo in the body of a human for any period of gestation.

16 Maximum penalty: Imprisonment for 10 years.

17 **20 Offence—importing, exporting or placing a prohibited embryo**

18 (1) A person commits an offence if the person intentionally imports an
19 embryo into Australia knowing that, or reckless as to whether, the
20 embryo is a prohibited embryo.

21 Maximum penalty: Imprisonment for 10 years.

22 (2) A person commits an offence if the person intentionally exports an
23 embryo from Australia knowing that, or reckless as to whether, the
24 embryo is a prohibited embryo.

25 Maximum penalty: Imprisonment for 10 years.

26 (3) A person commits an offence if the person intentionally places an
27 embryo in the body of a woman knowing that, or reckless as to
28 whether, the embryo is a prohibited embryo.

29 Maximum penalty: Imprisonment for 10 years.

1 (4) In this section:

2 *prohibited embryo* means:

- 3 (a) a human embryo created by a process other than the
4 fertilisation of a human egg by human sperm; or
5 (b) a human embryo created outside the body of a woman, unless
6 the intention of the person who created the embryo was to
7 attempt to achieve pregnancy in a particular woman; or
8 (c) a human embryo that contains genetic material provided by
9 more than 2 persons; or
10 (d) a human embryo that has been developing outside the body
11 of a woman for a period of more than 14 days, excluding any
12 period when development is suspended; or
13 (e) a human embryo created using precursor cells taken from a
14 human embryo or a human fetus; or
15 (f) a human embryo that contains a human cell (within the
16 meaning of section 15) whose genome has been altered in
17 such a way that the alteration is heritable by human
18 descendants of the human whose cell was altered; or
19 (g) a human embryo that was removed from the body of a
20 woman by a person intending to collect a viable human
21 embryo; or
22 (h) a chimeric embryo or a hybrid embryo.

23 **21 Offence—commercial trading in human eggs, human sperm or**
24 **human embryos**

25 (1) A person commits an offence if the person intentionally gives or
26 offers valuable consideration to another person for the supply of a
27 human egg, human sperm or a human embryo.

28 Maximum penalty: Imprisonment for 10 years.

29 (2) A person commits an offence if the person intentionally receives,
30 or offers to receive, valuable consideration from another person for
31 the supply of a human egg, human sperm or a human embryo.

32 Maximum penalty: Imprisonment for 10 years.

33 (3) In this section:

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reasonable expenses:

- (a) in relation to the supply of a human egg or human sperm— includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and
- (b) in relation to the supply of a human embryo:
 - (i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and
 - (ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo.

valuable consideration, in relation to the supply of a human egg, human sperm or a human embryo by a person, includes any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply.

Division 2—Practices that are prohibited unless authorised by a licence

22 Offence—creating a human embryo other than by fertilisation, or developing such an embryo

A person commits an offence if:

- (a) the person intentionally creates a human embryo by a process other than the fertilisation of a human egg by a human sperm, or develops a human embryo so created; and
- (b) the creation or development of the human embryo by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 10 years.

Note 1: The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 14.

Note 2: The placement in the body of a woman of a human embryo clone, or any other human embryo created other than by the fertilisation of a human egg by a human sperm, is prohibited by sections 9 and 20.

1 **23 Offence—creating or developing a human embryo containing**
2 **genetic material provided by more than 2 persons**

3 A person commits an offence if:

- 4 (a) the person intentionally creates or develops a human embryo
5 by a process other than the fertilisation of a human egg by a
6 human sperm; and
7 (b) the human embryo contains genetic material provided by
8 more than 2 persons; and
9 (c) the creation or development of the human embryo by the
10 person is not authorised by a licence.

11 Maximum penalty: Imprisonment for 10 years.

12 Note 1: The development of a human embryo outside the body of a woman for
13 more than 14 days is prohibited by section 14.

14 Note 2: The placement in the body of a woman of a human embryo created
15 other than by the fertilisation of a human egg by a human sperm is
16 prohibited by section 20.

17 **23A Offence—using precursor cells from a human embryo or a**
18 **human fetus to create a human embryo, or developing**
19 **such an embryo**

20 A person commits an offence if:

- 21 (a) the person uses precursor cells taken from a human embryo
22 or a human fetus, intending to create a human embryo, or
23 intentionally develops an embryo so created; and
24 (b) the person engages in activities mentioned in paragraph (a)
25 without being authorised by a licence, and the person knows
26 or is reckless as to that fact.

27 Maximum penalty: Imprisonment for 10 years.

28 **23B Offence—creating a hybrid embryo**

- 29 (1) A person commits an offence if the person intentionally creates a
30 hybrid embryo.
31 (2) A person commits an offence if the person intentionally develops a
32 hybrid embryo.

- 1 (3) A person does not commit an offence against subsection (1) or (2)
2 if the creation or development of the hybrid embryo by the person
3 is authorised by a licence.

4 Maximum penalty: Imprisonment for 10 years.

5 Note: A licence to create or develop a hybrid embryo can only be issued
6 under section 21 of the *Research Involving Human Embryos Act 2002*:

- 7 (a) for the purposes of testing sperm quality in an accredited ART
8 centre—up to, but not including, the first mitotic division; or
9 (b) in the case of hybrid embryo created by introducing the nucleus
10 of a human cell into an animal egg—for not longer than 14 days.

11 **23C Regulations under Customs Act**

12 The Minister who administers the *Customs Act 1901* must take all
13 reasonable steps to ensure that regulations are made, within 6
14 months after the commencement of this section, permitting, subject
15 to appropriate conditions or restrictions, the import and export of
16 human embryonic stem cell lines which have been derived from
17 human embryo clones using practices consistent with Australian
18 legislation.

19 **8 After section 25**

20 Insert:

21 **25A Further review of operation of Act**

- 22 (1) The Minister must cause an independent review of the operation of
23 this Act as amended by the *Prohibition of Human Cloning for*
24 *Reproduction and the Regulation of Human Embryo Research*
25 *Amendment Act 2006* (the **amending Act**) to be undertaken as soon
26 as possible after the third anniversary of the day on which the
27 amending Act received the Royal Assent.
- 28 (2) The review is to be undertaken by persons chosen by the Minister,
29 with the agreement of each State.
- 30 (3) The persons undertaking the review must give the Council of
31 Australian Governments and both Houses of the Parliament a
32 written report of the review before the fourth anniversary of the
33 day on which the amending Act received the Royal Assent.

- 1 (4) The persons undertaking the review must consider and report on
2 the scope and operation of this Act as amended by the amending
3 Act, taking into account the following:
4 (a) developments in assisted reproductive technology, including
5 technological, medical and scientific developments, and the
6 actual or potential clinical and therapeutic applications of
7 such research;
8 (b) developments in embryonic stem cell research, including
9 technological, medical and scientific developments, and the
10 actual or potential clinical and therapeutic applications of
11 such research;
12 (c) community standards;
13 (d) a brief analysis of international developments and legislation
14 relating to the use of human embryos and related research;
15 (e) an analysis of research resulting from the licenses granted;
16 (f) any National Stem Cell Centre and any national register of
17 donated excess ART embryos;
18 (g) an evaluation of the effectiveness of legislative provisions
19 and NHMRC guidelines relating to proper consent;
20 (h) an evaluation of the range of matters for which the NHMRC
21 Licensing Committee may issue a licence and any
22 recommendations to increase, decrease or alter these arising
23 from the evaluation;
24 (i) an analysis of any research or clinical practice which has
25 been prevented as a result of legislative restrictions;
26 (j) the extent to which the NHMRC Licensing Committee has
27 effectively used information and education tools to assist
28 researchers working in the field, and any ongoing need for
29 legally binding rulings;
30 (k) the extent of Commonwealth/State cooperation in the area of
31 human embryo research and the requirement for further
32 Commonwealth or State legislation on the matter.
- 33 (5) The report must contain recommendations about amendments that
34 should be made to this Act, having regard to the matters mentioned
35 in subsection (4).
- 36 (6) The persons undertaking the review must consult:
37 (a) the Commonwealth and the States; and
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1 (b) a broad range of persons with expertise in or experience of
2 relevant disciplines;
3 and the views of the Commonwealth, the States and the persons
4 mentioned in paragraph (b) must be set out in the report to the
5 extent that it is reasonably practicable to do so.

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2 **Schedule 2—Research Involving Human**
3 **Embryos Act 2002**
4

5 **1 At the end of section 3**

6 Add “or by other means”.

7 **2 Subsection 7(1) (definition of *human embryo*)**

8 Repeal the definition, substitute:

9 ***human embryo*** means a discrete entity that has arisen from either:

10 (a) the first mitotic division when fertilisation of a human oocyte
11 by a human sperm is complete; or

12 (b) any other process that initiates organised development of a
13 biological entity with a human nuclear genome or altered
14 human nuclear genome that has the potential to develop up
15 to, or beyond, the stage at which the primitive streak appears;

16 and has not yet reached 8 weeks of development since the first
17 mitotic division.

18 **3 Subsection 7(1)**

19 Insert:

20 ***hybrid embryo*** means:

21 (a) an embryo created by the fertilisation of a human egg by
22 animal sperm; or

23 (b) an embryo created by the fertilisation of an animal egg by
24 human sperm; or

25 (c) a human egg into which the nucleus of an animal cell has
26 been introduced; or

27 (d) an animal egg into which the nucleus of a human cell has
28 been introduced; or

29 (e) a thing declared by the regulations to be a hybrid embryo.

30 **4 Subsection 7(1)**

31 Insert:

1 ***unsuitable for implantation***, in relation to a human embryo, means
2 a human embryo that:

- 3 (a) is diagnosed by preimplantation genetic diagnosis as
4 unsuitable for implantation, in accordance with the *Ethical*
5 *Guidelines on the Use of Assisted Reproductive Technology*
6 *in Clinical Practice and Research (2004)*, issued by the CEO
7 of the NHMRC; or
8 (b) is determined to be unsuitable for implantation in the body of
9 a woman, in accordance with objective criteria specified in
10 guidelines issued by the CEO of the NHMRC under the
11 *National Health and Medical Research Council Act 1992* and
12 prescribed by the regulations for the purposes of this
13 paragraph.

14 **5 Subsection 7(1)**

15 Insert:

16 *use* includes develop, or development, as the case requires.

17 **6 At the end of section 7**

18 Add:

- 19 (3) A reference in this Act to an embryo (including a human embryo)
20 is a reference to a living embryo.
21 (4) A reference in this Act to a human egg is a reference to a human
22 oocyte.
23 (5) A reference in this Act to a human embryo does not include a
24 reference to:
25 (a) a hybrid embryo; or
26 (b) a human embryonic stem cell line.

27 **7 Part 2 (heading)**

28 Repeal the heading, substitute:

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

31 **8 Section 8 (definition of *proper consent*)**

1 Repeal the definition, substitute:

2 *proper consent*, in relation to the use of an excess ART embryo or
3 a human egg, or the creation or use of any other embryo, means
4 consent obtained in accordance with guidelines issued by the CEO
5 of the NHMRC under the *National Health and Medical Research*
6 *Council Act 1992* and prescribed by the regulations for the
7 purposes of this definition.

8 **9 Section 8 (definition of *responsible person*)**

9 *responsible person* means:

- 10 (a) in relation to an excess ART embryo:
- 11 (i) each person who provided the egg or sperm from which
12 the embryo was created; and
13 (ii) the woman for whom the embryo was created, for the
14 purpose of achieving her pregnancy; and
15 (iii) any person who was the spouse of a person mentioned
16 in subparagraph (i) at the time the egg or sperm
17 mentioned in that subparagraph was provided; and
18 (iv) any person who was the spouse of the woman
19 mentioned in subparagraph (ii) at the time the embryo
20 was created; or
- 21 (b) in relation to an embryo other than an excess ART embryo—
22 each person whose reproductive material, genetic material or
23 cell was used, or is proposed to be used, in the creation or use
24 of the embryo; or
- 25 (c) in relation to a human egg—the woman who was the
26 biological donor of the egg.

27 **10 After section 10**

28 Insert:

29 **10A Offence—use of other embryos**

30 A person commits an offence if:

- 31 (a) the person intentionally uses an embryo; and
32 (b) the embryo is:
33 (i) a human embryo created by a process other than the
34 fertilisation of a human egg by a human sperm; or
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- 1 (ii) a human embryo created by a process other than the
2 fertilisation of a human egg by a human sperm that
3 contains genetic material provided by more than 2
4 persons; or
5 (iii) a human embryo created using precursor cells taken
6 from a human embryo or a human fetus; or
7 (iv) a hybrid embryo; and
8 (c) the use by the person is not authorised by a licence.

9 Maximum penalty: Imprisonment for 5 years.

10 Note: The creation or development of embryos mentioned in this section is
11 prohibited under Part 2 of the *Prohibition of Human Cloning for*
12 *Reproduction Act 2002*, unless authorised by a licence under this Act.

13 **10B Offence—certain activities involving use of human eggs**

14 A person commits an offence if:

- 15 (a) the person undertakes research or training involving the
16 fertilisation of a human egg by a human sperm up to, but not
17 including, the first mitotic division, outside the body of a
18 woman for the purposes of research or training in ART; and
19 (b) the person is not authorised by a licence to undertake the
20 research or training.

21 Maximum penalty: Imprisonment for 5 years.

22 **11 Paragraph 11(a)**

23 Omit all the words after “human”, substitute “embryo:

- 24 (i) that was created by fertilisation of a human egg by a
25 human sperm; and
26 (ii) that is not an excess ART embryo; and”.

27 **12 At the end of Division 2 of Part 2**

28 Add:

29 **12A Person not liable for conduct purportedly authorised**

- 30 (1) To avoid doubt, a person is not criminally responsible for an
31 offence against this Act in respect of particular conduct if:

- 1 (a) the conduct by the person is purportedly authorised by a
2 provision of a licence; and
3 (b) the licence or the provision is invalid, whether because of a
4 technical defect or irregularity or for any other reason; and
5 (c) the person did not know, and could not reasonably be
6 expected to have known, of the invalidity of the licence or
7 the provision.

8 (2) In this section:

9 *licence* includes a purported licence.

10 **13 Paragraph 16(3)(c)**

11 After “embryos”, insert “or human eggs, or creation or uses of other
12 embryos”.

13 **14 At the end of section 16**

14 Add:

- 15 (7) It is the intention of the Parliament that any vacancy on the
16 NHMRC Licensing Committee be filled as soon as possible.
- 17 (8) If there is a vacancy in the membership of the NHMRC Licensing
18 Committee for a period of 3 months the Minister must, within 3
19 sitting days of the expiration of that 3 months, table in each House
20 of the Parliament a written statement of reasons for the failure to
21 fill the vacancy.

22 **15 Subsection 20(1)**

23 Repeal the subsection, substitute:

- 24 (1) A person may apply to the NHMRC Licensing Committee for a
25 licence authorising one or more of the following:
- 26 (a) use of excess ART embryos;
27 (b) creation of human embryos other than by fertilisation of a
28 human egg by a human sperm, and use of such embryos;
29 (c) creation of human embryos other than by fertilisation of a
30 human egg by a human sperm that contain genetic material
31 provided by more than 2 persons, and use of such embryos;
32 (d) creation of human embryos using precursor cells from a
33 human embryo or a human fetus, and use of such embryos;
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- 1 (e) research and training involving the fertilisation of a human
2 egg by a human sperm up to, but not including, the first
3 mitotic division, outside the body of a woman for the
4 purposes of research or training in ART;
5 (f) creation of hybrid embryos by the fertilisation of an animal
6 egg by a human sperm, and use of such embryos up to, but
7 not including, the first mitotic division, if:
8 (i) the creation or use is for the purposes of testing sperm
9 quality; and
10 (ii) the creation or use will occur in an accredited ART
11 centre;
12 (g) creation of hybrid embryos by introducing the nucleus of a
13 human cell into an animal egg, and use of such embryos.
- 14 (1A) To avoid doubt, paragraphs (1)(a), (b), (c), (d) and (g) do not
15 permit the NHMRC Licensing Committee to authorise any use of
16 an excess ART embryo or other embryo that would result in the
17 development of the embryo for a period of more than 14 days,
18 excluding any period when development is suspended.

19 **16 Subparagraph 21(3)(a)(i)**

20 Omit “is used”, substitute “or human egg is used, or other embryo is
21 created or used”.

22 **17 Paragraph 21(4)(a)**

23 After “excess ART embryos”, insert “, other embryos or human eggs,”.

24 **18 Paragraph 21(4)(b)**

25 After “excess ART embryos”, insert “or human eggs, or the creation or
26 use of other embryos,”.

27 **19 Subsection 24(1)**

28 Repeal the subsection, substitute:

- 29 (1) A licence is subject to the condition that before an excess ART
30 embryo or human egg is used, or any other embryo is created or
31 used, as authorised by the licence:
32 (a) each responsible person in relation to the excess ART
33 embryo, human egg or other embryo must have given proper
34 consent to that creation or use; and
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1 (b) the licence holder must have reported in writing to the
2 NHMRC Licensing Committee that such consent has been
3 obtained, and any restrictions to which the consent is subject.

4 **20 Subsection 24(2)**

5 After “excess ART embryo”, insert “or human egg, or the creation or
6 use of any other embryo,”.

7 **21 Paragraph 24(5)(a)**

8 After “excess ART embryos”, insert “or human eggs, or create or use
9 other embryos”.

10 **22 Paragraph 24(5)(b)**

11 Repeal the paragraph, substitute:

12 (b) the number of excess ART embryos or human eggs
13 authorised to be used under the licence, or the number of
14 other embryos authorised to be created or used under the
15 licence;

16 **23 Paragraph 24(5)(e) and subsections 24(6) and (7)**

17 After “excess ART embryos” (wherever occurring), insert “or human
18 eggs, or to create or use other embryos”.

19 **24 At the end of section 24**

20 Add:

21 (8) For the purposes of applying the condition referred to in
22 paragraph (1)(a):

23 (a) a licence may provide that the guidelines referred to in the
24 definition of *proper consent* apply in a modified form in
25 relation to the use, under the licence, of excess ART embryos
26 that are unsuitable for implantation; and

27 (b) if a licence so provides, the guidelines as modified by the
28 licence have effect in relation to the giving of consent for
29 such creation or use.

30 Note: For example, the guidelines could apply to a particular licence in a
31 modified form, to alter the cooling-off period required in relation to
32 the use of excess ART embryos that are unsuitable for implantation.

1 **25 Paragraph 29(1)(b)**

2 After “excess ART embryos”, insert “or human eggs, and creations or
3 uses of other embryos,”.

4 **26 Paragraph 29(1)(d)**

5 Repeal the paragraph, substitute:

6 (d) the number of ART embryos or human eggs authorised to be
7 used under the licence, and the number of other embryos
8 authorised to be created or used under the licence;

9 **27 Section 31 (after paragraph (c) of the definition of *eligible***
10 ***person*)**

11 Insert:

12 (ca) in relation to a decision to modify guidelines under
13 subsection 24(8) in respect of a licence—the licence holder;
14 or

15 **28 After paragraph 32(1)(c)**

16 Insert:

17 (ca) a decision to modify guidelines under subsection 24(8) in
18 respect of a licence;

19 **29 At the end of subsection 35(2)**

20 Add:

21 ; or (c) the entry is made under a warrant under section 37A.

22 **30 Paragraph 36(1)(b)**

23 After “human embryo”, insert “, other embryo, human egg”.

24 **31 At the end of subsection 36(1)**

25 Add:

26 ; (g) in addition to the powers mentioned in paragraphs (a) to (f),
27 if the inspector was authorised to enter the premises by a
28 warrant under section 37A—to require any person in or on
29 the premises to:

30 (i) answer any questions put by the inspector; and

31 (ii) produce any book, record or document requested by the
32 inspector.

1 **32 Section 37**

2 After “human embryo”, insert “, another embryo, a human egg”.

3 **33 Section 37**

4 Omit “the embryo or thing”, substitute “the embryo, the egg or the
5 thing”.

6 **34 After section 37**

7 Insert:

8 **37A Monitoring warrants**

- 9 (1) An inspector may apply to a magistrate for a warrant under this
10 section in relation to premises.
- 11 (2) Subject to subsection (3), the magistrate may issue the warrant if
12 the magistrate is satisfied by information on oath or affirmation
13 that it is reasonably necessary that one or more inspectors should
14 have access to the premises for the purposes of finding out whether
15 this Act or the regulations have been complied with.
- 16 (3) The magistrate must not issue the warrant unless the inspector or
17 some other person has given to the magistrate, either orally or by
18 affidavit, such further information (if any) as the magistrate
19 requires concerning the grounds on which the issue of the warrant
20 is being sought.
- 21 (4) The warrant must:
- 22 (a) authorise one or more inspectors (whether or not named in
23 the warrant) with such assistance and by such force as is
24 necessary and reasonable:
- 25 (i) to enter the premises; and
26 (ii) to exercise the powers set out in section 36 in relation to
27 the premises; and
- 28 (b) state whether the entry is authorised to be made at any time
29 of the day or night or during specified hours of the day or
30 night; and
- 31 (c) specify the day (not more than one month after the issue of
32 the warrant) on which the warrant ceases to have effect; and
33 (d) state the purpose for which the warrant is issued.
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1 **37B Details of warrant to be given to occupier etc.**

- 2 (1) If a warrant under section 37A is being executed and the occupier
3 of the premises or another person who apparently represents the
4 occupier is present at the premises, the inspector must make
5 available to that person a copy of the warrant.
- 6 (2) The inspector must identify himself or herself to that person.
- 7 (3) The copy of the warrant referred to in subsection (1) need not
8 include the signature of the magistrate who issued the warrant.

9 **37C Announcement before entry**

- 10 An inspector must, before entering premises under a warrant:
11 (a) announce that he or she is authorised to enter the premises;
12 and
13 (b) give any person at the premises an opportunity to allow entry
14 to the premises.

15 **37D Occupier entitled to be present during search**

- 16 (1) If a warrant under section 37A is being executed and the occupier
17 of the premises, or another person who apparently represents the
18 occupier is present at the premises, the person is entitled to observe
19 the search being conducted.
- 20 (2) The right to observe the search being conducted ceases if the
21 person impedes the search.
- 22 (3) This section does not prevent 2 or more areas of the premises being
23 searched at the same time.

24 **35 After section 47**

25 Insert:

26 **47A Further review of operation of Act**

- 27 (1) The Minister must cause an independent review of the operation of
28 this Act as amended by the *Prohibition of Human Cloning for*
29 *Reproduction and the Regulation of Human Embryo Research*
30 *Amendment Act 2006* (the **amending Act**) to be undertaken as soon

- 1 as possible after the third anniversary of the day on which the
2 amending Act received the Royal Assent.
- 3 (2) The review must be:
- 4 (a) undertaken by the persons who undertake the Prohibition of
5 Human Cloning for Reproduction Act further review; and
6 (b) undertaken concurrently with that Prohibition of Human
7 Cloning for Reproduction Act further review.
- 8 (3) The persons undertaking the review must give the Council of
9 Australian Governments and both Houses of the Parliament a
10 written report of the review before the fourth anniversary of the
11 day on which the amending Act received the Royal Assent.
- 12 (4) The persons undertaking the review must consider and report on
13 the scope and operation of this Act as amended by the amending
14 Act, taking into account the following:
- 15 (a) developments in assisted reproductive technology, including
16 technological, medical and scientific developments, and the
17 actual or potential clinical and therapeutic applications of
18 such research;
- 19 (b) developments in embryonic stem cell research, including
20 technological, medical and scientific developments, and the
21 actual or potential clinical and therapeutic applications of
22 such research;
- 23 (c) community standards;
- 24 (d) a brief analysis of international developments and legislation
25 relating to the use of human embryos and related research;
- 26 (e) an analysis of research resulting from the licenses granted;
- 27 (f) any National Stem Cell Centre and any national register of
28 donated excess ART embryos;
- 29 (g) an evaluation of the effectiveness of legislative provisions
30 and NHMRC guidelines relating to proper consent;
- 31 (h) an evaluation of the range of matters for which the NHMRC
32 Licensing Committee may issue a licence and any
33 recommendations to increase, decrease or alter these arising
34 from the evaluation;
- 35 (i) an analysis of any research or clinical practice which has
36 been prevented as a result of legislative restrictions;
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- 1 (j) the extent to which the NHMRC Licensing Committee has
2 effectively used information and education tools to assist
3 researchers working in the field, and any ongoing need for
4 legally binding rulings;
- 5 (k) the extent of Commonwealth/State cooperation in the area of
6 human embryo research and the requirement for further
7 Commonwealth or State legislation on the matter.
- 8 (5) The report must contain recommendations about amendments that
9 should be made to this Act, having regard to the matters mentioned
10 in subsection (4).
- 11 (6) The persons undertaking the review must consult:
12 (a) the Commonwealth and the States; and
13 (b) a broad range of persons with expertise in or experience of
14 relevant disciplines;
15 and the views of the Commonwealth, the States and the persons
16 mentioned in paragraph (b) must be set out in the report to the
17 extent that it is reasonably practicable to do so.
- 18 (7) In this section:
19 *Prohibition of Human Cloning for Reproduction Act further*
20 *review* means the review mentioned in section 25A of the
21 *Prohibition of Human Cloning for Reproduction Act 2002*.

22 **47B Minister to report to Parliament**

- 23 (1) The Minister must prepare a report on the following matters:
24 (a) the establishment of a National Stem Cell Centre and a
25 national register of donated excess ART embryos; and
26 (b) the making of guidelines referred to in this Act, to the extent
27 that those guidelines were not in force on the day on which
28 this Act commenced.
- 29 (2) The report must be completed not later than 6 months after the day
30 on which *Prohibition of Human Cloning for Reproduction and the*
31 *Regulation of Human Embryo Research Amendment Act 2006*
32 commenced.

- 1 (3) The Minister must cause a copy of the report to be tabled in each
2 House of the Parliament within 15 sitting days of that House after
3 the day on which the report was completed.

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Schedule 3—Saving provision

1 Saving provision

(1) If:

- (a) at any time before the commencement of this item, a person made an application under subsection 20(1) of the *Research Involving Human Embryos Act 2002* for a licence; and
- (b) immediately before the commencement of this item, the NHMRC Licensing Committee had not decided the application;

then the person is taken, on and from the commencement of this item, to have applied for the licence under subsection 20(1) of the amended Act.

(2) To avoid doubt, a licence issued under section 21 of the *Research Involving Human Embryos Act 2002* that was in force immediately before the commencement of this item continues in force after that commencement.

(3) In this item:

amended Act means the *Research Involving Human Embryos Act 2002* as amended by this Act.

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Schedule 4—Amendment of regulations

Customs (Prohibited Exports) Regulations 1958

1 Regulation 7

Repeal the regulation.