

2004-2005-2006

The Parliament of the  
Commonwealth of Australia

THE SENATE

*Presented and read a first time*

**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**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provision(s)</b>	<b>Commencement</b>	<b>Date/Details</b>
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)**

9

(1) Each Act, and each set of regulations, that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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

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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.

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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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1                    ***reasonable expenses:***

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

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

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

18                    **22 Offence—creating a human embryo other than by fertilisation, or**  
19                    **developing such an embryo**

20                    A person commits an offence if:

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

26                    Maximum penalty: Imprisonment for 10 years.

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

29                    Note 2: The placement in the body of a woman of a human embryo clone, or  
30                    any other human embryo created other than by the fertilisation of a  
31                    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
-

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.

1  
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:

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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
-

- 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;
-

- 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
-

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;
-

- 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**

4  
**1 Saving provision**

5 (1) If:

6 (a) at any time before the commencement of this item, a person  
7 made an application under subsection 20(1) of the *Research*  
8 *Involving Human Embryos Act 2002* for a licence; and

9 (b) immediately before the commencement of this item, the  
10 NHMRC Licensing Committee had not decided the  
11 application;

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

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

18 (3) In this item:

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

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## **Schedule 4—Amendment of regulations**

4

### ***Customs (Prohibited Exports) Regulations 1958***

5

#### **1 Regulation 7**

6

Repeal the regulation.