



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

**No. 172, 2006**

**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**

Note: An electronic version of this Act is available in ComLaw (<http://www.comlaw.gov.au/>)



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**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**

[Assented to 12 December 2006]

The Parliament of Australia enacts:

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## 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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<b>Commencement information</b>		
<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.	12 December 2006
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.	12 June 2007

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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.

- (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.

## 3 Schedule(s)

- (1) Each Act, and each set of regulations, that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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

## Schedule 1—Prohibition of Human Cloning Act 2002

### 1 Title

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

### 2 Section 1

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

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

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

Repeal the definition, substitute:

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

- (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

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

### 4 Subsection 8(1)

Insert:

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

### 5 Subsection 8(1)

Insert:

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



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

Add:

- (6) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.
- (7) A reference in this Act to a human egg is a reference to a human oocyte.
- (8) A reference in this Act to a human embryo does not include a reference to:
  - (a) a hybrid embryo; or
  - (b) a human embryonic stem cell line.

## **7 Part 2**

Repeal the Part, substitute:

## **Part 2—Prohibited practices**

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

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

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

Maximum penalty: Imprisonment for 15 years.

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

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

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

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

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

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

Maximum penalty: Imprisonment for 15 years.

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

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

A person commits an offence if:

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

Maximum penalty: Imprisonment for 15 years.

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

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

Maximum penalty: Imprisonment for 15 years.

**15 Offence—heritable alterations to genome**

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

Maximum penalty: Imprisonment for 15 years.

- (2) In this section:

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

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

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

Maximum penalty: Imprisonment for 15 years.

**17 Offence—creating a chimeric embryo**

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

Maximum penalty: Imprisonment for 15 years.

**18 Offence—developing a hybrid embryo**

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

Maximum penalty: Imprisonment for 15 years.

**19 Offence—placing of an embryo**

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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(4) In this section:

***prohibited embryo*** means:

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

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

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

(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.

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

A person commits an offence if:

- (a) the person intentionally creates or develops a human embryo by a process other than the fertilisation of a human egg by a human sperm; and
- (b) the human embryo contains genetic material provided by more than 2 persons; and
- (c) 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 created other than by the fertilisation of a human egg by a human sperm is prohibited by section 20.

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

A person commits an offence if:

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

Maximum penalty: Imprisonment for 10 years.

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

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

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

Maximum penalty: Imprisonment for 10 years.

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

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

### 23C Regulations under Customs Act

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

## 8 After section 25

Insert:

### 25A Further review of operation of Act

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



- (4) The persons undertaking the review must consider and report on the scope and operation of this Act as amended by the amending Act, taking into account the following:
- (a) developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
  - (b) developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
  - (c) community standards;
  - (d) a brief analysis of international developments and legislation relating to the use of human embryos and related research;
  - (e) an analysis of research resulting from the licenses granted;
  - (f) any National Stem Cell Centre and any national register of donated excess ART embryos;
  - (g) an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;
  - (h) an evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;
  - (i) an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;
  - (j) the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings;
  - (k) the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.
- (5) The report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned in subsection (4).
- (6) The persons undertaking the review must consult:
- (a) the Commonwealth and the States; and

(b) a broad range of persons with expertise in or experience of relevant disciplines;  
and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

## **Schedule 2—Research Involving Human Embryos Act 2002**

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

Add “or by other means”.

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

Repeal the definition, substitute:

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

- (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

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

### **3 Subsection 7(1)**

Insert:

*hybrid embryo* means:

- (a) an embryo created by the fertilisation of a human egg by animal sperm; or
- (b) an embryo created by the fertilisation of an animal egg by human sperm; or
- (c) a human egg into which the nucleus of an animal cell has been introduced; or
- (d) an animal egg into which the nucleus of a human cell has been introduced; or
- (e) a thing declared by the regulations to be a hybrid embryo.

### **4 Subsection 7(1)**

Insert:

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

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

## **5 Subsection 7(1)**

Insert:

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

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

Add:

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

## **7 Part 2 (heading)**

Repeal the heading, substitute:

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

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

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Repeal the definition, substitute:

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

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

***responsible person*** means:

- (a) in relation to an excess ART embryo:
  - (i) each person who provided the egg or sperm from which the embryo was created; and
  - (ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and
  - (iii) any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that subparagraph was provided; and
  - (iv) any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or
- (b) in relation to an embryo other than an excess ART embryo—each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or
- (c) in relation to a human egg—the woman who was the biological donor of the egg.

## **10 After section 10**

Insert:

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

A person commits an offence if:

- (a) the person intentionally uses an embryo; and
- (b) the embryo is:
  - (i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or

- (ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons; or
  - (iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or
  - (iv) a hybrid embryo; and
- (c) the use by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 5 years.

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

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

A person commits an offence if:

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

Maximum penalty: Imprisonment for 5 years.

### **11 Paragraph 11(a)**

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

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

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

Add:

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

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

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

(2) In this section:

*licence* includes a purported licence.

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

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

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

Add:

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

### **15 Subsection 20(1)**

Repeal the subsection, substitute:

- (1) A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:
    - (a) use of excess ART embryos;
    - (b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
    - (c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;
    - (d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
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- (e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART;
- (f) creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, if:
  - (i) the creation or use is for the purposes of testing sperm quality; and
  - (ii) the creation or use will occur in an accredited ART centre.

(1A) To avoid doubt, paragraphs (1)(a), (b), (c) and (d) do not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.

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

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

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

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

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

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

**19 Subsection 24(1)**

Repeal the subsection, substitute:

- (1) A licence is subject to the condition that before an excess ART embryo or human egg is used, or any other embryo is created or used, as authorised by the licence:
  - (a) each responsible person in relation to the excess ART embryo, human egg or other embryo must have given proper consent to that creation or use; and



- (b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject.

**20 Subsection 24(2)**

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

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

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

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

Repeal the paragraph, substitute:

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

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

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

**24 At the end of section 24**

Add:

- (8) For the purposes of applying the condition referred to in paragraph (1)(a):
- (a) a licence may provide that the guidelines referred to in the definition of *proper consent* apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation; and
- (b) if a licence so provides, the guidelines as modified by the licence have effect in relation to the giving of consent for such creation or use.

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

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

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

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

Repeal the paragraph, substitute:

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

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

Insert:

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

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

Insert:

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

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

Add:

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

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

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

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

Add:

- ; (g) in addition to the powers mentioned in paragraphs (a) to (f), if the inspector was authorised to enter the premises by a warrant under section 37A—to require any person in or on the premises to:
    - (i) answer any questions put by the inspector; and
    - (ii) produce any book, record or document requested by the inspector.
-

**32 Section 37**

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

**33 Section 37**

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

**34 After section 37**

Insert:

**37A Monitoring warrants**

- (1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.
  - (2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied by information on oath or affirmation that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether this Act or the regulations have been complied with.
  - (3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.
  - (4) The warrant must:
    - (a) authorise one or more inspectors (whether or not named in the warrant) with such assistance and by such force as is necessary and reasonable:
      - (i) to enter the premises; and
      - (ii) to exercise the powers set out in section 36 in relation to the premises; and
    - (b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night; and
    - (c) specify the day (not more than 15 days after the issue of the warrant) on which the warrant ceases to have effect; and
    - (d) state the purpose for which the warrant is issued.
-

**37B Details of warrant to be given to occupier etc.**

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

**37C Announcement before entry**

An inspector must, before entering premises under a warrant:

- (a) announce that he or she is authorised to enter the premises;  
and
- (b) give any person at the premises an opportunity to allow entry to the premises.

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

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

**35 After section 47**

Insert:

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

- (1) The Minister must cause an independent review of the operation of this Act as amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the **amending Act**) to be undertaken as soon
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as possible after the third anniversary of the day on which the amending Act received the Royal Assent.

- (2) The review must be:
  - (a) undertaken by the persons who undertake the Prohibition of Human Cloning for Reproduction Act further review; and
  - (b) undertaken concurrently with that Prohibition of Human Cloning for Reproduction Act further review.
- (3) The persons undertaking the review must give the Council of Australian Governments and both Houses of the Parliament a written report of the review before the fourth anniversary of the day on which the amending Act received the Royal Assent.
- (4) The persons undertaking the review must consider and report on the scope and operation of this Act as amended by the amending Act, taking into account the following:
  - (a) developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
  - (b) developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
  - (c) community standards;
  - (d) a brief analysis of international developments and legislation relating to the use of human embryos and related research;
  - (e) an analysis of research resulting from the licenses granted;
  - (f) any National Stem Cell Centre and any national register of donated excess ART embryos;
  - (g) an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;
  - (h) an evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;
  - (i) an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;

- (j) the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings;
  - (k) the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.
- (5) The report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned in subsection (4).
- (6) The persons undertaking the review must consult:
- (a) the Commonwealth and the States; and
  - (b) a broad range of persons with expertise in or experience of relevant disciplines;
- and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.
- (7) In this section:

*Prohibition of Human Cloning for Reproduction Act further review* means the review mentioned in section 25A of the *Prohibition of Human Cloning for Reproduction Act 2002*.

#### **47B Minister to report to Parliament**

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

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

### **36 After section 47**

Insert:

#### **47C Study of non-blood human tissue based therapies**

- (1) The Minister must cause to be prepared a report on the feasibility of establishing a national legislative or regulatory approach for effective governance of non-blood human tissue based therapies.
- (2) The review must be undertaken by persons chosen by the Minister with the agreement of each State.
- (3) The report of the review must contain recommendations for a national legislative or regulatory framework.
- (4) The persons undertaking the review must give to the Council of Australian Governments and both Houses of the Parliament a written report of the review.
- (5) The report must be completed not later than 18 months after the day on which the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* receives the Royal Assent.
- (6) The Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of that House after the day on which the report was completed.

## 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.



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

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

#### **1 Regulation 7**

Repeal the regulation.

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*[Second reading speech made in—  
Senate on 19 October 2006  
House of Representatives on 30 November 2006]*

(160/06)

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