



Australian Capital Territory

Human Cloning and Embryo Research Amendment Act 2008

A2008-8

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Australian Capital Territory

Human Cloning and Embryo Research Amendment Act 2008

A2008-8

An Act to amend the *Human Cloning and Embryo Research Act 2004*

The Legislative Assembly for the Australian Capital Territory enacts as follows:

1 Name of Act

This Act is the *Human Cloning and Embryo Research Amendment Act 2008*.

2 Commencement

This Act commences on the day after its notification day.

Note The naming and commencement provisions automatically commence on the notification day (see Legislation Act, s 75 (1)).

3 Legislation amended

This Act amends the *Human Cloning and Embryo Research Act 2004*.

4 Long title

substitute

An Act to prohibit human cloning for reproduction and other unacceptable practices associated with reproductive technology and to regulate certain activities involving the use of human embryos

**5 Object of Act
Section 5 (b)**

substitute

- (b) by regulating activities that involve the use of certain human embryos created by assisted reproductive technology or by other means.

6 Section 6

substitute

6 Meaning of *human embryo*—Act

(1) In this Act:

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.

(2) However, ***human embryo*** does not include a—

- (a) hybrid embryo; or
- (b) human embryonic stem cell line.

(3) In working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

7 **Part 2**

substitute

Part 2 **Prohibited practices**

Division 2.1 **Practices that are completely prohibited**

8 **Offence—placing human embryo clone in human body or 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 s 12.

9 **No defence that human embryo clone could not survive**

It is not a defence to an offence against section 8 that the human embryo clone did not survive or could not have survived.

10 Offence—creating human embryo for purpose other than achieving pregnancy in 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 the Criminal Code, section 58 (3), a defendant does not bear an evidential burden in relation to anything mentioned in subsection (1).

11 Offence—creating or developing human embryo by fertilisation that contains genetic material provided by more than 2 people

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 people.

Maximum penalty: imprisonment for 15 years.

12 Offence—developing human embryo outside body of 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.

13 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 foetal cell, human sperm or a human egg.

14 Offence—collecting viable human embryo from body of 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.

15 Offence—creating chimeric embryo

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

Maximum penalty: imprisonment for 15 years.

16 Offence—developing 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.

17 Offence—placing of 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.

18 Offence—importing, exporting or placing prohibited embryo

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

Maximum penalty: imprisonment for 15 years.

- (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 people; 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 foetus; or
- (f) a human embryo that contains a human cell (within the meaning of section 13) 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.

19 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—

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 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 2.2 Practices that are prohibited unless authorised by licence

20 Offence—creating human embryo other than by fertilisation, or developing 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 s 12.

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 s 8 and s 18.

21 Offence—creating or developing human embryo containing genetic material provided by more than 2 people

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 people; 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 s 12.

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 s 18.

22 Offence—using precursor cells from human embryo or human foetus to create 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 foetus, 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 about that fact.

Maximum penalty: imprisonment for 10 years.

22A Offence—creating 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.

8 Part 3 heading

substitute

**Part 3 Regulation of the use of excess
ART embryos, other embryos
and human eggs**

**9 Definitions for pt 3
Section 23, definition of *licence***

omit

10 Section 23, definition of *proper consent*

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—

- (a) the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research issued by the CEO of the NHMRC in 2007, and existing on 24 August 2007; or

Note These guidelines are available on the internet—see <http://www.nhmrc.gov.au>

- (b) if other guidelines are issued by the CEO of the NHMRC and prescribed by the *Research Involving Human Embryos Regulations 2003* (Cwlth)—those guidelines, rather than the guidelines mentioned in paragraph (a).

11 Section 23, definition of *responsible person*

substitute

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) anyone who was the domestic partner of a person mentioned in subparagraph (i) when the egg or sperm mentioned in that subparagraph was provided; and
 - (iv) anyone who was the domestic partner of the woman mentioned in subparagraph (ii) when the embryo was created; or

Note For the meaning of ***domestic partner***, see the Legislation Act, s 169.

- (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.

12 Section 23, new definitions of *unsuitable for implantation* and *use*

insert

unsuitable for implantation—a human embryo is ***unsuitable for implantation*** if it—

- (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* issued by the CEO of the NHMRC in 2007, and existing on 24 August 2007; or

Note These guidelines are available on the internet—see <http://www.nhmrc.gov.au>

- (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 and prescribed by the *Research Involving Human Embryos Regulations 2003* (Cwlth).

use includes develop.

Note If an Act defines a term, other parts of speech and grammatical forms of the term have a corresponding meaning (see Legislation Act, s 157).

13 New sections 25A and 25B

insert

25A 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 people; or
 - (iii) a human embryo created using precursor cells taken from a human embryo or a human foetus; 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 pt 2, unless authorised by a licence.

25B 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.

**14 Offence—use of embryo that is not excess ART embryo
Section 26 (a)**

substitute

- (a) the person intentionally uses, outside the body of a woman, a human 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

15 New section 27A

in division 3.2, insert

27A Person not liable for conduct purportedly authorised

- (1) To remove any doubt, a person is not criminally responsible for an offence against this part in relation to 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.

**16 Person may apply for licence
Section 29 (1)***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 people, and use of such embryos;
 - (d) creation of human embryos using precursor cells from a human embryo or a human foetus, and use of such embryos;
 - (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 remove any doubt, subsection (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.

**17 Committee decision on application
Section 30 (3) (a) (i)**

omit

embryo is used

substitute

embryo or human egg is used, or other embryo is created or used,

18 Section 30 (4) (a)

omit

ART embryos

substitute

ART embryos, other embryos or human eggs,

19 Section 30 (4) (b)

omit

ART embryos

substitute

ART embryos or human eggs, or the creation or use of other embryos,

20 Section 30 (4) (c)

omit

prescribed under the regulations

substitute

prescribed by the *Research Involving Human Embryos Regulations 2003* (Cwlth)

**21 Licence is subject to conditions
Section 33 (1)**

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 the consent has been obtained, and any restrictions to which the consent is subject.

22 Section 33 (2)

omit

ART embryo

substitute

ART embryo or human egg, or the creation or use of any other embryo,

23 Section 33 (4) (a)

omit

ART embryos

substitute

ART embryos or human eggs, or create or use other embryos

24 Section 33 (4) (b)

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;

25 Section 33 (4) (e), (5) and (6) (b)

omit

ART embryos

substitute

ART embryos or human eggs, or to create or use other embryos

26 New section 33 (7)

insert

- (7) For the purposes of applying the condition mentioned in subsection (1) (a)—
- (a) a licence may provide that the guidelines mentioned 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.

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.

Note An example is part of the Act, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

**27 NHMRC licensing committee to make certain information publicly available
Section 38 (1) (b)**

omit

ART embryos

substitute

ART embryos or human eggs, and creations or uses of other embryos,

28 Section 38 (1) (d)

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;

**29 Definitions for div 3.6
Section 40, definition of *eligible person*, new paragraph (ca)**

insert

(ca) in relation to a decision to modify guidelines under section 33 (7) in relation to a licence—the licence holder; or

**30 Review of decisions
New section 41 (1) (ca)**

insert

(ca) a decision to modify guidelines under section 33 (7) in relation to a licence;

**31 Powers available to inspectors for monitoring compliance
New section 44 (2) (c)**

insert

(c) the entry is made under a warrant under section 46A.

**32 Monitoring powers
Section 45 (1) (b)**

omit

human embryo

substitute

human embryo, other embryo, human egg

33 New section 45 (1) (g)

insert

(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 46A—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.

34 Section 46*substitute***46 Power to secure**

If an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a human embryo, another embryo, a human egg or a thing that may provide evidence of the commission of an offence against this Act, the monitoring powers include securing the embryo, the egg or the thing while a warrant to seize it is obtained (whether by the inspector or by another person).

35 New sections 46A, 46B, 46C and 46D*insert***46A 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 that it is reasonably necessary that 1 or more inspectors should have access to the premises for the purposes of finding out whether this Act has been complied with.

Note 1 **Oath** includes affirmation, and **take** an oath includes make an affirmation (see Legislation Act, dict, pt 1).

Note 2 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).

- (3) The magistrate must not issue the warrant unless the inspector or someone else has given to the magistrate, either orally or by affidavit, any further information the magistrate requires about the grounds on which the issue of the warrant is being sought.

- (4) The warrant must—
- (a) authorise 1 or more inspectors (whether or not named in the warrant) with the assistance and force that is necessary and reasonable—
 - (i) to enter the premises; and
 - (ii) to exercise the powers set out in section 45 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 stated hours of the day or night; and
 - (c) state 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.

46B Details of warrant to be given to occupier etc

- (1) If a warrant under section 46A 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 mentioned in subsection (1) need not include the signature of the magistrate who issued the warrant.

46C 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.

46D Occupier entitled to be present during search

- (1) If a warrant under section 46A 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.

36 Section 51

substitute

51 Report on operation of Act

- (1) This section applies to—
 - (a) a report of the review mentioned in the *Prohibition of Human Cloning for Reproduction Act 2002* (Cwlth), section 25A; and
 - (b) a report of the review mentioned in the *Research Involving Human Embryos Act 2002* (Cwlth), section 47A.
- (2) The Minister must present a copy of the report to the Legislative Assembly as soon as practicable after it is tabled in a house of the Commonwealth Parliament.

37 New part 10

insert

Part 10 Transitional

100 Existing applications for licences

- (1) In this section:

amended Act means this Act as amended by the *Human Cloning and Embryo Research Amendment Act 2008*.

commencement day means the day the *Human Cloning and Embryo Research Amendment Act 2008* commences.

- (2) This section applies if, before the commencement day—
- (a) a person had applied for a licence under section 29; and
 - (b) the NHMRC licensing committee had not decided the application.
- (3) The application is taken to have been made under the amended Act.

101 Expiry—pt 10

This part expires 1 year after the day it commences.

38 Dictionary, definition of *disclose*

substitute

disclose information, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

39 Dictionary, new definition of *embryo*

insert

embryo means a living embryo, and includes a human embryo.

40 Dictionary, new definition of *human egg*

insert

human egg means a human oocyte.

41 Dictionary, definition of *licence*

substitute

licence means a licence issued under section 30 (Committee decision on application).

42 Dictionary, definitions of *proper consent*, *relevant Territory entity* and *responsible person*

substitute

proper consent, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

relevant Territory entity, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

responsible person, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

43 Dictionary, new definitions of *unsuitable for implantation* and *use*

insert

unsuitable for implantation, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

use, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

Endnotes

1 Presentation speech

Presentation speech made in the Legislative Assembly on 6 December 2007.

2 Notification

Notified under the Legislation Act on 17 April 2008.

3 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.

I certify that the above is a true copy of the Human Cloning and Embryo Research Amendment Bill 2008, which originated in the Legislative Assembly as the Human Cloning and Embryo Research Amendment Bill 2007 and was passed by the Assembly on 8 April 2008.

Clerk of the Legislative Assembly

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