

Infertility Treatment Amendment Act 2007

No. 15 of 2007

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Victoria

Infertility Treatment Amendment Act 2007[†]

No. 15 of 2007

[Assented to 15 May 2007]

The Parliament of Victoria enacts:

1 Purpose

The main purpose of this Act is to amend the **Infertility Treatment Act 1995** to modify the existing regulatory framework to allow the use of somatic cell nuclear transfer in stem cell research, while retaining the existing prohibition on human cloning for reproduction.

2 Commencement

This Act comes into operation on 12 June 2007.

3 Principal Act

In this Act, the **Infertility Treatment Act 1995** is called the Principal Act.

See:
Act No.
63/1995.
Reprint No 2
as at
16 October
2003 and
amending
Act Nos
108/2004,
10/2005,
97/2005,
24/2006,
45/2006 and
80/2006.
Law Today
www.
legislation.
vic.gov.au

4 Definition

- (1) For the definition of *human embryo* in section 3(1) of the Principal Act **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;".

(2) After section 3(1D) of the Principal Act **insert**—

"(1E) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.

(1F) A reference in this Act to a human egg is a reference to a human oocyte.

(1G) 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."

5 Amendment of heading to Part 2A

In the heading to Part 2A of the Principal Act after "**EMBRYOS**" **insert** ", **OTHER EMBRYOS AND HUMAN EGGS**".

6 Definitions for Part 2A

In section 21A of the Principal Act—

(a) for the 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 guidelines issued by the Chief Executive Officer of the NHMRC under the National Health and Medical Research Council Act 1992 of the Commonwealth and prescribed by the regulations under the Commonwealth Act for the purposes of the definition of proper consent in section 8 of that Act;"

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- (b) in the definition of *responsible person*—
- (i) **omit** ", in relation to an excess ART embryo,";
 - (ii) for paragraph (a) **substitute**—
 - "(a) in relation to an excess ART embryo—
 - (i) each person who provided the egg or sperm from which the embryo was created; and";
 - (iii) for "(b)" (where first occurring) **substitute** "(i)";
 - (iv) for "(c)" **substitute** "(iii)";
 - (v) for "paragraph (a)" **substitute** "subparagraph (i)";
 - (vi) for "(d)" **substitute** "(iv)";
 - (vii) for "paragraph (b)" **substitute** "subparagraph (ii)";
 - (vii) for "the time the embryo was created." **substitute** the following—
 - "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;"
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(c) **insert** the following definitions—

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

- (a) is diagnosed by pre-implantation 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 Chief Executive Officer 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 Chief Executive Officer of the NHMRC under the National Health and Medical Research Council Act 1992 of the Commonwealth and prescribed by the regulations under the Commonwealth Act for the purposes of paragraph (b) of the definition of unsuitable for implantation in section 7(1) of that Act;

use includes develop, or development, as the case requires;".

7 New sections 21CA and 21CB inserted

After section 21C of the Principal Act **insert—**

"21CA Offence—use of other embryos

- (1) 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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.

Note

The creation or development of embryos mentioned in this section is prohibited under Part 4A, unless authorised by a licence.

21CB Offence—certain activities involving use of human eggs

- (1) 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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years."

8 Use of embryo that was created by fertilisation and is not an excess ART embryo

- (1) In the heading to section 21D of the Principal Act after "**embryo**" (where first occurring) **insert "that was created by fertilisation and"**.
- (2) For section 21D(1)(a) of the Principal Act **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"

9 Insertion of new section 21EA in Division 2 of Part 2A

In Division 2 of Part 2A of the Principal Act after section 21E **insert—**

"21EA Person not liable for conduct purportedly authorised

- (1) To avoid doubt, a person is not criminally responsible for an offence against this Division 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."

10 Application for licence

For section 21H(1) of the Principal Act **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;

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- (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;
 - (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, 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."
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11 Determination of application by Committee

- (1) In section 21I(3)(a)(i) of the Principal Act for "is used" **substitute** "or human egg is used, or other embryo is created or used".
- (2) In section 21I(4)(a) of the Principal Act after "excess ART embryos" **insert** ", other embryos or human eggs".
- (3) In section 21I(4)(b) of the Principal Act, after "excess ART embryos" **insert** "or human eggs, or the creation or use of other embryos,".

12 Conditions of licence

- (1) In section 21L(1) of the Principal Act for "is used" **substitute** "or human egg is used, or any other embryo is created or used,".
 - (2) In section 21L(1)(a) of the Principal Act after "excess ART embryo" **insert** ", human egg or other embryo".
 - (3) In section 21L(2) of the Principal Act after "excess ART embryo" **insert** "or human egg, or the creation or use of any other embryo,".
 - (4) In section 21L(5)(a) and (e) and (6) of the Principal Act after "excess ART embryos" (wherever occurring) **insert** "or human eggs, or to create or use other embryos".
 - (5) For section 21L(5)(b) of the Principal Act **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;".
 - (6) In section 21L(7)(b) of the Principal Act after "excess ART embryos" **insert** "or human eggs, or to create or use other embryos,".
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(7) After section 21L(7) of the Principal Act **insert**—

- "(8) For the purposes of applying the condition referred to in subsection (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.

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."

13 NHMRC Licensing Committee to make certain information publicly available

- (1) In section 21Q(1)(b) of the Principal Act after "excess ART embryos" **insert** "or human eggs, and creations or uses of any other embryos,".
- (2) For section 21Q(1)(d) of the Principal Act **substitute**—
 - "(d) 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;".

14 Definitions for Division 6 of Part 2A

In section 21S of the Principal Act after paragraph (c) of the definition of *eligible person* insert—

"(ca) in relation to a decision to modify guidelines under section 21L(8) in respect of a licence—the licence holder; or".

15 Review of decisions

After section 21T(1)(c) of the Principal Act insert—

"(ca) a decision to modify guidelines under section 21L(8) in respect of a licence;".

16 Powers available to inspectors for monitoring compliance

(1) In section 21U(2)(b) of the Principal Act for "time." substitute "time; or".

(2) After section 21U(2)(b) of the Principal Act insert—

"(c) the entry is made under a warrant under section 21WA."

17 Monitoring powers

(1) In section 21V(1)(b) of the Principal Act after "human embryo" insert ", other embryo, human egg".

(2) In section 21V(1)(f) of the Principal Act for "premises." substitute "premises;".

(3) After section 21V(1)(f) of the Principal Act 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 21WA—to require any person in or on the premises to—

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- (i) answer any questions put by the inspector; and
 - (ii) produce any book, record or document requested by the inspector."

18 Power to secure

- (1) In section 21W of the Principal Act after "human embryo" **insert** ", another embryo, a human egg".
- (2) In section 21W of the Principal Act after "the embryo" **insert** ", the egg".

19 New sections 21WA to 21WD inserted

After section 21W of the Principal Act **insert**—

"21WA Monitoring warrants

- (1) An inspector may apply to a magistrate for the issue of 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 evidence on oath, whether oral or by affidavit, that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether this Part or the regulations made for the purposes of this Part 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.
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- (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 21V 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.
- (5) Except as provided by this Act, the rules to be observed with respect to search warrants under the **Magistrates' Court Act 1989** extend and apply to warrants under this section.

21WB Details of warrant to be given to occupier etc.

- (1) If a warrant under section 21WA 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.

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- (3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

21WC 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.

21WD Occupier entitled to be present during search

- (1) If a warrant under section 21WA 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."

20 New section 21ZA inserted in Division 7 of Part 2A

In Division 7 of Part 2A of the Principal Act after section 21Z insert—

"21ZA Extended operation of Division

A reference in this Division to this Part includes a reference to Part 4A, and a reference in this Division to regulations made for the purposes of this Part includes a

reference to regulations made for the purposes of Part 4A."

21 Replacement of heading to Part 4A

For the heading to Part 4A of the Principal Act **substitute—**

**"PART 4A—PROHIBITED PRACTICES
INCLUDING PROHIBITION ON HUMAN
CLONING FOR REPRODUCTION".**

22 Replacement of heading to Division 1 of Part 4A

For the heading to Division 1 of Part 4A of the Principal Act **substitute—**

**"Division 1—Practices that are completely
prohibited".**

23 Repeal of section 38A

Section 38A of the Principal Act **is repealed.**

24 No defence that human embryo clone could not survive

In section 38D of the Principal Act **omit "38A,".**

25 Repeal of heading to Division 2 of Part 4A

The heading to Division 2 of Part 4A of the Principal Act **is repealed.**

26 Repeal of section 38E

Section 38E of the Principal Act **is repealed.**

27 Offence of creating a human embryo for a purpose other than achieving pregnancy in a woman

- (1) In section 38F(1) of the Principal Act after "human embryo" **insert "by a process of the fertilisation of a human egg by a human sperm".**
- (2) In section 38F(2) of the Principal Act for "10 years" **substitute "15 years".**

28 Offence of creating or developing a human embryo by fertilisation that contains genetic material provided by more than 2 persons

- (1) In the heading to section 38G of the Principal Act for "**containing**" substitute "**by fertilisation that contains**".
- (2) For section 38G(1) of the Principal Act substitute—

"(1) 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."
- (3) In section 38G(2) of the Principal Act for "10 years" substitute "15 years".

29 Increase in penalty for offence for developing a human embryo outside the body of a woman for more than 14 days

In section 38H(2) of the Principal Act for "10 years" substitute "15 years".

30 Repeal of section 38I

Section 38I of the Principal Act is **repealed**.

31 Increase in penalty for offence for heritable alterations to genome

In section 38J(3) of the Principal Act for "10 years" substitute "15 years".

32 Increase in penalty for offence for collecting a viable human embryo from the body of a woman

In section 38K(2) of the Principal Act for "10 years" **substitute** "15 years".

33 Increase in penalty for offence for creating a chimeric embryo

For section 38L(2) and (3) of the Principal Act **substitute—**

"(2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 15 years."

34 Insertion of new section 38LA

After section 38L of the Principal Act **insert—**

"38LA Offence—developing a hybrid embryo

- (1) 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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 15 years."

35 Increase in penalty for offence for placing of an embryo

In section 38M(4) of the Principal Act for "10 years" **substitute** "15 years".

36 Increase in penalty for offence for importing, exporting or placing a prohibited embryo

In section 38N(5) of the Principal Act for "10 years" **substitute** "15 years".

37 Increase in penalty for offence for commercial trading in human eggs, human sperm or human embryos

In section 38O(4) of the Principal Act for "10 years" **substitute** "15 years".

38 Insertion of new Division 2 in Part 4A

After section 38O of the Principal Act **insert—**

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

380A Offence—creating a human embryo other than by fertilisation, or developing such an embryo

- (1) 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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

Notes

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 38H.
- 2 The placement in the human body 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 38B and 38N.

38OB Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons

- (1) 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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

Notes

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 38H.
- 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 38N.

38OC Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo

- (1) 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
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- (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.
- (2) An offence against subsection (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38OD 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.
- (4) An offence against subsection (1) or (2) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

Note

A licence to create or develop a hybrid embryo can be issued under section 211—

- (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 a hybrid embryo created by introducing the nucleus of a human cell into an animal egg—for not longer than 14 days."

39 Search warrants

In section 162(1) and (3)(a) of the Principal Act after "Part 2A" (wherever occurring) **insert** "or Part 4A".

40 Insertion of new Division 4 in Part 14

After section 203 of the Principal Act **insert—**

"Division 4—Savings and transitional provisions (2007 Act)

204 Definition

In this Division—

commencement means the commencement of the **Infertility Treatment Amendment Act 2007**.

205 Existing applications for licences

- (1) This section applies if—
- (a) before the commencement a person had applied for a licence under section 21H of this Act; and
 - (b) immediately before the commencement, the NHMRC Licensing Committee had not decided the application.
- (2) On and after the commencement, the application is to be decided under this Act as if it had been made after the commencement.

206 Existing licences

A licence issued under section 21I that was in force immediately before the commencement continues in force on and after the commencement.

207 Offences

- (1) The amendments of this Act made by the **Infertility Treatment Amendment Act 2007** apply only to offences alleged to have been committed on or after the commencement.
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- (2) For the purposes of subsection (1), if an offence is alleged to have been committed between two dates, one before and one after the commencement, the offence is alleged to have been committed before the commencement."

41 Repeal of Act

This Act is **repealed** on 12 June 2008.

ENDNOTES

- † *Minister's second reading speech—*
Legislative Assembly: 14 March 2007
Legislative Council: 19 April 2007

The long title for the Bill for this Act was "A Bill for an Act to amend the **Infertility Treatment Act 1995** to allow human cloning under licence for research purposes while retaining the existing prohibition on human cloning for reproduction and for other purposes."