

House of Assembly

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South Australia

Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research Involving Human Embryos) Bill 2009

A BILL FOR

An Act to amend the *Prohibition of Human Cloning Act 2003* and the *Research Involving Human Embryos Act 2003*.

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The Parliament of South Australia enacts as follows:

Part 1—Preliminary

1—Short title

This Act may be cited as the *Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research Involving Human Embryos) Act 2009*.

2—Commencement

This Act will come into operation on a day to be fixed by proclamation.

3—Amendment provisions

In this Act, a provision under a heading referring to the amendment of a specified Act amends the Act so specified.

Part 2—Amendment of *Prohibition of Human Cloning Act 2003*

4—Amendment of long title

Long title—after "cloning" insert:
for reproduction

5—Amendment of section 1—Short title

Section 1—after "*Cloning*" insert:
for Reproduction

6—Amendment of section 3—Interpretation

- (1) Section 3(1), definition of *human embryo*—delete the definition and 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) Section 3(1)—after the definition of *inspector* insert:

licence means a licence under Part 2 Division 3 of the *Research Involving Human Embryos Act 2003*;
- (3) Section 3(1), definition of *related Commonwealth Act*, (a)—after "*Cloning*" insert:

for Reproduction
- (4) Section 3—after subsection (5) insert:
 - (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—Substitution of Part 2

Part 2—delete the Part and substitute:

Part 2—Prohibited practices

Division 1—Practices that are completely prohibited

5—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 9.

6—No defence that human embryo clone could not survive

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

7—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 section 30, a defendant does not bear an evidential burden in relation to any matter in subsection (1).

8—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.

9—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.

10—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.

11—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.

12—Offence—creating a chimeric embryo

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

Maximum penalty: Imprisonment for 15 years.

13—Offence—developing a hybrid embryo

A person commits an offence if the person intentionally develops a hybrid embryo that has undergone the first mitotic division.

Maximum penalty: Imprisonment for 15 years.

14—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.

15—Offence—importing, exporting or placing a prohibited embryo

- (1) A person commits an offence if the person intentionally imports an embryo into South 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 South 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.

- (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 10) 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.

16—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 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

17—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.

Notes—

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 9.
- 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 5 and 15.

18—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.

Notes—

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 9.
- 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 section 15.

19—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.

19A—Offence—creating a hybrid embryo

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

Maximum penalty: Imprisonment for 10 years.

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

Maximum penalty: Imprisonment for 10 years.

- (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.

Note—

A licence to create or develop a hybrid embryo can only be issued under Part 2 Division 3 of the *Research Involving Human Embryos Act 2003*—

- (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.

Part 3—Amendment of *Research Involving Human Embryos Act 2003*

8—Amendment of section 3—Interpretation

- (1) Section 3(1), definition of *human embryo*—delete the definition and 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) Section 3(1)—after the definition of *human sperm* 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;
- (3) Section 3(1), definition of *proper consent*—delete the definition and 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 *Research Involving Human Embryos Act 2002* of the Commonwealth for the purposes of the definition of *proper consent* in that Act;
- (4) Section 3(1), definition of *related Commonwealth Act*, (a)—after "Cloning" insert:
- for Reproduction*
- (5) Section 3(1), definition of *responsible person*—delete the definition and 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

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- (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;
- (6) Section 3(1)—after the definition of *State* 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 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 *Research Involving Human Embryos Act 2002* of the Commonwealth for the purposes of the definition of ***unsuitable for implantation*** in that Act;

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

- (7) Section 3—after subsection (3) insert:
- (4) A reference in this Act to an ***embryo*** (including a human embryo) is a reference to a living embryo.
 - (5) A reference in this Act to a ***human egg*** is a reference to a human oocyte.
 - (6) 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.

9—Substitution of heading to Part 2

Heading to Part 2—delete the heading and substitute:

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

10—Insertion of sections 5A and 5B

After section 5 insert:

5A—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 2003*, unless authorised by a licence under this Act.

5B—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—Amendment of section 6—Offence—use of embryo that is not an excess ART embryo

Section 6(a)—delete paragraph (a) and 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

12—Insertion of section 7A

After section 7 insert:

7A—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—Amendment of section 10—Person may apply for licence

Section 10(1)—delete subsection (1) and substitute:

- (1) A person may apply to the NHMRC Licensing Committee for a licence authorising 1 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;
 - (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.

14—Amendment of section 11—Determination of application by Committee

- (1) Section 11(3)(a)(i)—delete "is used" and substitute:
 - or human egg is used, or other embryo is created or used,
- (2) Section 11(4)(a)—after “excess ART embryos” insert:
 - , other embryos or human eggs,
- (3) Section 11(4)(b)—after “excess ART embryos” insert:
 - or human eggs, or the creation or use of other embryos,
- (4) Section 11(4)(c)—delete paragraph (c) and substitute:
 - (c) any relevant guidelines, or relevant parts of guidelines, issued by the Chief Executive Officer of the NHMRC under the *National Medical and Research Council Act 1992* of the Commonwealth and prescribed by the regulations for the purposes of the corresponding provision of the *Research Involving Human Embryos Act 2002* of the Commonwealth;

15—Amendment of section 14—Licence is subject to conditions

- (1) Section 14(1)—delete subsection (1) and 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.
- (2) Section 14(2)—after “excess ART embryo” insert:
 - or human egg, or the creation or use of any other embryo,

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- (3) Section 14(5)(a)—after "excess ART embryos" insert:
or human eggs, or create or use other embryos
- (4) Section 14(5)(b)—delete paragraph (b) and 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;
- (5) Section 14(5)(e)—after "excess ART embryos" insert:
or human eggs, or to create or use other embryos
- (6) Section 14(6)—after "excess ART embryos" insert:
or human eggs, or to create or use other embryos
- (7) Section 14(7)—after "excess ART embryos" insert:
or human eggs, or to create or use other embryos,
- (8) Section 14—after subsection (7) 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.

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.

16—Amendment of section 16—Suspension or revocation of licence

Section 16(2)—after "*Cloning*" insert:

for Reproduction

17—Amendment of section 19—NHMRC Committee to make certain information publicly available

- (1) Section 19(1)(b)—after "excess ART embryos" insert:
or human eggs, and creations or uses of other embryos,
- (2) Section 19(1)(d)—delete paragraph (d) and 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;

18—Amendment of section 21—Interpretation

- (1) Section 21, definition of *eligible person*—after paragraph (c) insert:
 - (ca) in relation to a decision to modify guidelines under section 14(8) in respect of a licence—the licence holder; or
- (2) Section 21, definition of *reviewable decision*—after paragraph (c) insert:
 - (ca) a decision to modify guidelines under section 14(8) in respect of a licence;

19—Amendment of section 22—Review of decisions

Section 22(2)(b)—delete "section 13, 14(4) or 15" and substitute:
section 13, 14(4), 14(8) or 15

20—Amendment of section 23—Powers of inspectors

- (1) Section 23(5)—after "human embryo" insert:

, another embryo, a human egg
- (2) Section 23(5)(a)—after "embryo," insert:

the egg,

21—Amendment of section 30—NHMRC guidelines

Section 30(2)(b)—delete "3" and substitute:
6

Part 4—Transitional provision

22—Transitional provision

If an application for a licence under section 10 of the *Research Involving Human Embryos Act 2003* made before the commencement of this section has not been determined at the commencement of this section, the application is to be determined as if it had been made after that commencement.