



Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003

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Queensland

Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003

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Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003

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

Part 1 Preliminary

1 Short title

This Act may be cited as the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*.

2 Commencement

- (1) This Act, other than part 6, division 1, commences on a day to be fixed by proclamation.
- (2) Part 6, division 1, commences on whichever of the following days applies—
 - (a) 5 April 2005;
 - (b) if the Council of Australian Governments declares an earlier day by notice in the gazette—that earlier day.

3 Object of Act

The object of this Act is to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos—

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

4 Act binds all persons

- (1) This Act binds all persons, including the State, and, as far as the legislative power of the Parliament permits, the Commonwealth and the other States.
- (2) Nothing in this Act makes the Commonwealth or a State liable to be prosecuted for an offence.

5 Definitions

- (1) The dictionary in the schedule defines particular words used in this Act.
- (2) For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human—
 - (a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and
 - (b) it is not necessary to establish that the copy is an identical genetic copy.
- (3) For the purposes of the definition *human embryo* in the schedule, 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.
- (4) For the purposes of the definition *human embryo clone* in the schedule, a human embryo that results from the technological

process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by human sperm.

- (5) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.
- (6) A reference in this Act to a human egg is a reference to a human oocyte.
- (7) 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.
- (8) The following provisions of the *Acts Interpretation Act 1954* do not apply to a reference to a spouse in this Act—
 - section 32DA(6)
 - schedule 1, definition *spouse*.

6 Meaning of *reckless*

- (1) A person is *reckless* in relation to a circumstance if—
 - (a) the person is aware of a substantial risk that the circumstance exists or will exist; and
 - (b) having regard to the circumstances known to the person, it is unjustifiable to take the risk.
- (2) A person is *reckless* in relation to a result if—
 - (a) the person is aware of a substantial risk that the result will happen; and
 - (b) having regard to the circumstances known to the person, it is unjustifiable to take the risk.
- (3) It is a question of fact as to whether taking a risk is unjustifiable.

Part 2 Prohibited practices

Division 1 Practices that are completely prohibited

7 Offence—placing a human embryo clone in the human body or the body of an animal

- (1) 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—15 years imprisonment.

- (2) It is not a defence to an offence under subsection (1) that the human embryo clone did not survive or could not have survived.

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 10.

8 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—15 years imprisonment.

- (2) A defendant does not bear the burden of proving any matter in subsection (1).

9 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—15 years imprisonment.

10 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—15 years imprisonment.

11 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—15 years imprisonment.

(2) In this section—

human cell includes a human embryonal cell, a human fetal cell, human sperm and a human egg.

12 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—15 years imprisonment.

13 Offence—creating a chimeric embryo

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

Maximum penalty—15 years imprisonment.

14 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—15 years imprisonment.

15 Offence—placing of an embryo

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

Maximum penalty—15 years imprisonment.

- (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—15 years imprisonment.

- (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—15 years imprisonment.

16 Offence—placing a prohibited embryo

- (1) 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—15 years imprisonment.

- (2) 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 11) 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.

17 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—15 years imprisonment.

- (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—15 years imprisonment.

- (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 within the meaning of section 22; 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

18 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—10 years imprisonment.

Notes—

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 10.
- 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 7 and 16.

19 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—10 years imprisonment.

Notes—

- 1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 10.
- 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 16.

20 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—10 years imprisonment.

20A Offence—creating a hybrid embryo

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

Maximum penalty—10 years imprisonment.

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

Maximum penalty—10 years imprisonment.

- (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 use a hybrid embryo can only be issued under section 29 for the purposes of testing sperm quality in an accredited ART centre up to, but not including, the first mitotic division.

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

Division 1 Interpretation

21 Definitions for pt 3

In this part—

accredited ART centre means an entity accredited to carry out assisted reproductive technology by an entity prescribed under a regulation.

confidential commercial information means information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

disclose, in relation to information, means give or communicate in any way.

excess ART embryo has the meaning given by section 22.

HREC means a Human Research Ethics Committee.

licence means a licence issued under section 29.

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* (Cwlth) and prescribed under a regulation for the purposes of this definition.

relevant State body means the person or body notified by the State to the chairperson of the NHMRC Licensing Committee for the purposes of the Commonwealth Act, part 2.

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.

22 Meaning of *excess ART embryo*

- (1) In this part—

excess ART embryo means a human embryo that—

- (a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and
 - (b) is excess to the needs of—
 - (i) the woman for whom it was created; and
 - (ii) her spouse (if any) at the time the embryo was created.
- (2) For the purposes of paragraph (b) of the definition *excess ART embryo*, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if—
- (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating

to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or

- (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

Division 2 Offences

23 Offence—use of excess ART embryo

- (1) A person commits an offence if the person intentionally uses an excess ART embryo, unless—
 - (a) the use by the person is authorised by a licence; or
 - (b) the use by the person is an exempt use within the meaning of subsection (2).

Maximum penalty—5 years imprisonment.

- (2) A use of an excess ART embryo by a person is an exempt use for the purposes of subsection (1) if—
 - (a) the use consists only of—
 - (i) storage of the excess ART embryo; or
 - (ii) removal of the excess ART embryo from storage; or
 - (iii) transport of the excess ART embryo; or
 - (b) the use consists only of observation of the excess ART embryo; or
 - (c) the use consists only of allowing the excess ART embryo to succumb; or
 - (d) the use is carried out by an accredited ART centre, and—
 - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created

where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and

- (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; or
 - (e) the use is carried out by an accredited ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
 - (f) the use is of a kind prescribed under a regulation for the purposes of this paragraph.
- (3) A defendant does not bear the burden of proving any matter in subsection (1) or (2).
- (4) In this section—

diagnostic investigation, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created.

observation, in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

23A 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—5 years imprisonment.

Note—

The creation or development of embryos mentioned in this section is prohibited under part 2, unless authorised by a licence.

23B 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—5 years imprisonment.

24 Offence—use of embryo that is not an excess ART embryo

A person commits an offence if—

(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

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried

out by an accredited ART centre, and the person knows or is reckless as to that fact.

Maximum penalty—5 years imprisonment.

25 Offence—breaching a licence condition

- (1) A person commits an offence if the person intentionally engages in conduct, knowing that the conduct contravenes a condition of a licence that applies to the person, or reckless as to whether the conduct contravenes a condition of such a licence.

Maximum penalty—5 years imprisonment.

- (2) In this section—

engage in conduct means—

- (a) do an act; or
- (b) omit to perform an act.

25A Person not liable for conduct purportedly authorised

- (1) To avoid any doubt, it is declared that a person is not criminally responsible for an offence against this part, or section 50(1) to the extent the attempt relates to an offence against this part, 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.

Division 3 Embryo Research Licensing Committee of the NHMRC

26 Functions of committee

The functions of the NHMRC Licensing Committee are—

- (a) to perform functions in relation to licences under division 4; and
- (b) to perform functions in relation to databases under division 5; and
- (c) to perform such other functions as are conferred on it by this Act or any other law.

27 Powers of committee

The NHMRC Licensing Committee has power to do all things necessary or convenient to be done for or in connection with the performance of its functions under this Act.

Division 4 Licensing system

28 Person may apply for licence

- (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;
 - (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 any doubt, it is declared that subsection (1)(a), (b), (c) or (d) does 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.
- (2) An application under subsection (1)—
- (a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and
 - (b) must be accompanied by the fee (if any) prescribed under a regulation.

29 Determination of application by committee

- (1) This section applies if a person has made an application under section 28 for a licence.
- (2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.

- (3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following—
- (a) that appropriate protocols are in place—
 - (i) to enable proper consent to be obtained before an excess ART embryo or human egg is used, or other embryo is created or used under the licence (see section 32(1)(a)); and
 - (ii) to enable compliance with any restrictions on such consent;
 - (c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the NHMRC National Statement on Ethical Conduct in Research Involving Humans (1999), as in force from time to time.
- (4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following—
- (a) restricting the number of excess ART embryos, other embryos or human eggs, to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
 - (b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means;
 - (c) any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC under the *National Health and Medical Research Council Act 1992* (Cwlth) and prescribed under a regulation for the purposes of this paragraph;
 - (d) the HREC assessment of the application mentioned in subsection (3)(c);

- (e) such additional matters (if any) as are prescribed by a regulation.

30 Notification of decision

- (1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 28 to the following—
 - (a) the applicant;
 - (b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in section 29(3)(c);
 - (c) the relevant State body.
- (2) If the NHMRC Licensing Committee decides to issue the licence, it must, in addition to issuing the licence to the applicant, give a copy of the licence to the bodies mentioned in subsection (1)(b) and (c).

31 Period of licence

- (1) A licence—
 - (a) comes into force on the day specified in the licence, or if no day is specified, on the day on which it is issued; and
 - (b) remains in force until the day specified in the licence, unless it is suspended, revoked or surrendered before that day.
- (2) A licence is not in force throughout any period of suspension.

32 Licence is subject to conditions

- (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) A licence is subject to the condition that the use of an excess ART embryo or human egg, or the creation or use of any other embryo, must be in accordance with any restrictions to which the proper consent under subsection (1) is subject.
- (4) A licence is subject to such other conditions as are specified in the licence.
- (5) The conditions specified in the licence may include, but are not limited to, conditions relating to the following—
- (a) the persons authorised by the licence to use excess ART embryos or human eggs, or create or use other embryos;
 - (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;
 - (c) reporting;
 - (d) monitoring;
 - (e) information to be given by the licence holder to persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (6) The licence conditions set out in subsections (1) and (2) apply to all persons who are authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (7) Licence conditions specified in the licence apply to—
- (a) the licence holder; and

- (b) such other persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos, as are specified in the licence.
- (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 *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 the use, under the licence, of the excess ART embryos.

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.

33 Variation of licence

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, vary a licence if the committee believes on reasonable grounds that it is necessary or desirable to do so.
- (2) The NHMRC Licensing Committee may vary a licence under subsection (1) on its own initiative or on application by the licence holder.
- (3) Without limiting subsection (1), the NHMRC Licensing Committee may vary the licence by specifying additional conditions or varying existing conditions.
- (4) The NHMRC Licensing Committee must not vary a licence in such a way that, had a person applied under section 28 for the licence as varied, the committee would not have been permitted by this part to issue the licence.

34 Suspension or revocation of licence

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a licence if the committee believes on reasonable grounds that a condition of the licence has been breached.
- (2) If a licence holder is convicted of an offence under this Act, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

35 Surrender of licence

A licence holder may surrender a licence by written notice given to the NHMRC Licensing Committee.

36 Notification of variation, suspension or revocation of licence

- (1) If the NHMRC Licensing Committee varies, suspends or revokes a licence, the committee must notify—
 - (a) the licence holder; and
 - (b) the HREC and the relevant State body.
- (2) The NHMRC Licensing Committee must also notify the bodies mentioned in subsection (1)(b) if a licence is surrendered.

Division 5 Reporting and confidentiality

37 NHMRC Licensing Committee to make certain information publicly available

- (1) The NHMRC Licensing Committee must maintain a database containing the following information in relation to each licence (including a licence as varied)—
 - (a) the name of the person to whom the licence was issued;

- (b) a short statement about the nature of the uses of excess ART embryos or human eggs, or creation or uses of other embryos, that are authorised by the licence;
 - (c) any conditions to which the licence is subject;
 - (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;
 - (e) the date on which the licence was issued;
 - (f) the period throughout which the licence is to remain in force.
- (2) The database is to be made publicly available.
 - (3) The database may be kept and made publicly available in electronic form.
 - (4) Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.
 - (5) The database may form part of the database maintained by the NHMRC Licensing Committee under the Commonwealth Act, section 29.

38 Confidential commercial information may only be disclosed in certain circumstances

- (1) A person commits an offence if—
 - (a) the person discloses confidential commercial information that the person has only because of performing duties or functions under this part, or under this part and the Commonwealth Act; and
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not made—
 - (i) for the purposes of this Act, a corresponding State law, the Commonwealth Act or the *Prohibition of Human Cloning Act 2002* (Cwlth), to a State

agency, the Commonwealth or a Commonwealth authority; or

- (ii) by order of a court; or
- (iii) with the consent of each person to whom the information has a commercial or other value.

Maximum penalty—2 years imprisonment.

- (2) A person commits an offence if—
- (a) the person discloses confidential commercial information that the person has only because of a disclosure permitted under subsection (1) or this subsection; and
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not made—
 - (i) for the purposes of this Act, a corresponding State law, the Commonwealth Act or the *Prohibition of Human Cloning Act 2002* (Cwlth), to a State agency, the Commonwealth or a Commonwealth authority; or
 - (ii) by order of a court; or
 - (iii) with the consent of each person to whom the information has a commercial or other value.

Maximum penalty—2 years imprisonment.

- (3) In this section—
- court*** includes a tribunal, authority or person having power to require the production of documents or the answering of questions.

State agency means the following—

- (a) a State;
- (b) a Minister of a State;

- (c) a department or a department of Government of another State;
- (d) an instrumentality of a State, including a body corporate established for a public purpose under a law of a State;
- (e) a company in which a controlling interest is held by any 1 of the following persons, or by 2 or more of the following persons together—
 - (i) a State;
 - (ii) a Minister of a State, or a State instrumentality mentioned in paragraph (d);
 - (iii) a person or body covered by subparagraph (i) or (ii).

Division 6 Review provisions

39 Definitions for div 6

In this division—

Administrative Appeals Tribunal means the Administrative Appeals Tribunal established by the *Administrative Appeals Tribunal Act 1975* (Cwlth).

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975* (Cwlth).

eligible person, in relation to a decision of the NHMRC Licensing Committee, means—

- (a) in relation to a decision under section 29 not to issue a licence—the applicant for the licence; or
- (b) in relation to a decision in respect of the period throughout which the licence is to be in force under section 31—the licence holder; or
- (c) in relation to a decision to specify a licence condition under section 32(4)—the licence holder; or

- (ca) in relation to a decision to modify guidelines under section 32(8) in respect of a licence—the licence holder; or
- (d) in relation to a decision to vary or refuse to vary a licence under section 33—the licence holder; or
- (e) in relation to a decision to suspend or revoke a licence under section 34—the person who was the licence holder immediately before the suspension or revocation.

40 Review of decisions

- (1) An eligible person may apply to the Administrative Appeals Tribunal for review of any of the following decisions of the NHMRC Licensing Committee if the decision is declared by the regulations made under the Commonwealth Act to be a reviewable State decision for the purposes of section 45 of that Act—
 - (a) a decision under section 29 not to issue a licence;
 - (b) a decision in respect of the period throughout which the licence is to be in force under section 31;
 - (c) a decision to specify a licence condition under section 32(4);
 - (ca) a decision to modify guidelines under section 32(8) in respect of a licence;
 - (d) a decision to vary or refuse to vary a licence under section 33;
 - (e) a decision to suspend or revoke a licence under section 34.
- (2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975* (Cwlth).
- (3) The *Administrative Appeals Tribunal Act 1975* (Cwlth), other than part IVA, and the regulations in force under that Act apply as laws of the State for the review of a decision under subsection (1).

- (4) For this section, a reference in a provision of the *Administrative Appeals Tribunal Act 1975* (Cwlth), as the provision applies as a law of the State, to all or any part of part IVA of that Act is taken to be a reference to all or part of that part as it has effect as a law of the Commonwealth.

Part 4 Monitoring powers

41 Appointment of inspectors

- (1) The chairperson of the NHMRC Licensing Committee may, by instrument in writing, appoint any of the following persons as inspectors—
- (a) a person who is appointed or employed by the State;
 - (b) a person who is appointed or employed by the Commonwealth.
- (2) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the chairperson of the NHMRC Licensing Committee.
- (3) The chairperson of the NHMRC Licensing Committee must not appoint a person as an inspector under subsection (1) unless he or she is satisfied that the person has appropriate skills and experience.

42 Identity card

- (1) The chairperson of the NHMRC Licensing Committee must issue an identity card to an inspector.
- (2) The identity card—
- (a) must be in the form prescribed by the regulations under the Commonwealth Act; and
 - (b) must contain a recent photograph of the inspector.

- (3) If a person to whom an identity card has been issued ceases to be an inspector, the person must return the identity card to the chairperson of the NHMRC Licensing Committee as soon as practicable.

Maximum penalty—1 penalty unit.

- (4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.

43 Powers available to inspectors for monitoring compliance

- (1) For the purpose of finding out whether this Act has been complied with, an inspector may—

- (a) enter any premises; and
- (b) exercise the monitoring powers set out in section 44.

- (2) An inspector is not authorised to enter premises under subsection (1) unless—

- (a) the occupier of the premises has consented to the entry; or
- (b) the premises are premises at which the occupier of the premises is carrying out activities authorised by a licence issued under section 29, and the entry is at a reasonable time; or
- (c) the entry is made under a warrant under section 45A.

44 Monitoring powers

- (1) The monitoring powers that an inspector may exercise under section 43(1)(b) are as follows—

- (a) to search the premises and any thing on the premises;
- (b) to inspect, examine, take measurements of, conduct tests on, or take samples of, any human embryo, other embryo, human egg or thing on the premises that relates to this Act;

- (c) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises;
 - (d) to inspect any book, record or document on the premises;
 - (e) to take extracts from or make copies of any such book, record or document;
 - (f) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises;
 - (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 45A—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.
- (2) For the purposes of this part, monitoring powers include the power to operate equipment at premises to see whether—
- (a) the equipment; or
 - (b) a disk, tape or other storage device that—
 - (i) is at the premises; and
 - (ii) can be used with the equipment or is associated with it;
- contains information that is relevant to determining whether there has been compliance with this Act.
- (3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information mentioned in subsection (2), the inspector may—
- (a) operate equipment or facilities at the premises to put the information in documentary form and copy the document so produced; or

- (b) if the information can be transferred to a tape, disk or other storage device that—
 - (i) is brought to the premises; or
 - (ii) is at the premises and the use of which has been agreed to in writing by the occupier of the premises;
 - operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.

45 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 afford evidence of the commission of an offence against this Act, the monitoring powers include securing the embryo, the egg or the thing pending the obtaining of a warrant by anyone to seize it.

45A 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 purpose of finding out whether this Act has 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 44 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.

45B Details of warrant to be given to occupier etc.

- (1) If a warrant under section 45A 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.

45C 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.

45D Occupier entitled to be present during search

- (1) If a warrant under section 45A 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.

46 Inspector must produce identity card on request

An inspector is not entitled to exercise any powers under this part in relation to premises if—

- (a) the occupier of the premises has required the inspector to produce his or her identity card for inspection by the occupier; and
- (b) the inspector fails to comply with the requirement.

47 Consent

- (1) Before obtaining the consent of a person for the purposes of section 43(2)(a), the inspector must inform the person that he or she may refuse consent.
- (2) An entry of an inspector by virtue of the consent of a person is not lawful unless the person voluntarily consented to the entry.

48 Compensation for damage

- (1) The owner of equipment or other facilities is entitled to compensation for damage to the equipment or other facilities if—

- (a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this part; and
 - (b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.
- (2) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment or other facilities that was appropriate in the circumstances.

Part 5 Miscellaneous

Division 1 Review of Act

49 Further review of operation of Act

- (1) The Minister must cause a review of the operation of this Act as amended by the *Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007* to be undertaken as soon as possible after the third anniversary of the day on which that Act commenced.
- (2) The review must cover the scope and operation of parts 2 and 3 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) an analysis of any research or clinical practice that has been prevented as a result of legislative restrictions.
- (3) The review may be undertaken as part of the reviews under the Commonwealth Act, section 47A and the *Prohibition of Human Cloning for Reproduction Act 2002* (Cwlth), section 25A.

Division 2 Matters about offences

50 Attempts to commit offences against this Act

- (1) A person who attempts to commit an offence against this Act commits an offence.
- Maximum penalty—the maximum penalty for committing the offence attempted to be committed.
- (2) The Criminal Code, section 4, applies to subsection (1).

51 Crimes and summary offences

- (1) The following offences are crimes—
- (a) an offence mentioned in part 2 or in part 3, division 2;
 - (b) an offence against section 50(1), if the offence attempted to be committed is a crime.
- (2) The offender can not be arrested without warrant.
- (3) Any other offence against this Act is a summary offence.

52 Limitation on time for starting summary proceedings

A proceeding for a summary offence against this Act by way of summary proceeding under the *Justices Act 1886* must start—

- (a) within 1 year after the commission of the offence; or
- (b) within 6 months after the offence comes to the complainant's knowledge, but within 2 years after the commission of the offence.

Division 3 Regulations

53 Regulation-making power

The Governor in Council may make regulations under this Act.

Part 6 Saving provisions

54 Saving provision

- (1) If—
 - (a) at any time before the commencement of this section, a person made an application under subsection 28(1) for a licence; and
 - (b) immediately before that commencement, the NHMRC Licensing Committee had not decided the application;then the person is taken, on and from that commencement, to have applied for the licence under subsection 28(1) of the amended Act.
- (2) To avoid any doubt, it is declared that a licence issued under section 29 that was in force immediately before the

commencement of this section continues in force after that commencement.

(3) In this section—

amended Act means this Act as amended by the *Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007*.

Schedule Dictionary

section 5(1)

accredited ART centre, for part 3, see section 21.

Administrative Appeals Tribunal, for part 3, division 6, see section 39.

animal does not include a human.

ART means assisted reproductive technology.

chimeric embryo means—

- (a) a human embryo into which a cell, or any component part of a cell, of an animal has been introduced; or
- (b) a thing declared under a regulation to be a chimeric embryo.

Commonwealth Act means the *Research Involving Human Embryos Act 2002* (Cwlth).

Commonwealth authority means the following—

- (a) a body corporate established for a public purpose by or under an Act of the Commonwealth;
- (b) a company in which a controlling interest is held by any 1 of the following persons, or by 2 or more of the following persons together—
 - (i) the Commonwealth;
 - (ii) a body covered by paragraph (a);
 - (iii) a body covered by subparagraph (i) or (ii).

confidential commercial information, for part 3, see section 21.

corresponding State law see the Commonwealth Act, section 7(1).

decision, for part 3, division 6, see section 39.

disclose, for part 3, see section 21.

eligible person, for part 3, division 6, see section 39.

excess ART embryo, for part 3, see section 21.

HREC, for part 3, see section 21.

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.

human embryo clone means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.

human sperm includes human spermatids.

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 under a regulation to be a hybrid embryo.

inspector means a person appointed as an inspector under section 41(1).

licence see section 21.

NHMRC Licensing Committee means the committee established by the Commonwealth Act, section 13.

precursor cell means a cell that has the potential to develop into a human egg or human sperm.

proper consent, for part 3, see section 21.

reckless see section 6.

relevant State body, for part 3, see section 21.

responsible person, for part 3, see section 21.

spouse, in relation to a person, includes a person who, although not legally married to the person, is living with the person as the person's spouse on a bona fide domestic basis.

State includes the Australian Capital Territory and the Northern Territory.

the NHMRC means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992* (Cwlth).

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* (Cwlth) and prescribed under a regulation for the purposes of this paragraph.

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

woman means a female human.