

2003

THE LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

(As presented)

(Minister for Health)

Human Cloning and Embryo Research Bill 2003

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2003

THE LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

(As presented)

(Minister for Health)

Human Cloning and Embryo Research Bill 2003

A Bill for

An Act to prohibit human cloning and to regulate certain activities involving the use of human embryos

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

1 **Part 1 Preliminary**

2 **1 Name of Act**

3 This Act is the *Human Cloning and Embryo Research Act 2003*.

4 **2 Commencement**

5 This Act commences on the day after its notification day.

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

8 **3 Dictionary**

9 The dictionary at the end of this Act is part of this Act.

10 *Note 1* The dictionary at the end of this Act defines certain terms used in this
11 Act, and includes references (*signpost definitions*) to other terms
12 defined elsewhere in this Act.

13 For example, the signpost definition '*human embryo*—see section 7.'
14 means that the term 'human embryo' is defined that section.

15 *Note 2* A definition in the dictionary (including a signpost definition) applies to
16 the entire Act unless the definition, or another provision of the Act,
17 provides otherwise or the contrary intention otherwise appears (see
18 Legislation Act, s 155 and s 156 (1)).

19 **4 Notes**

20 A note included in this Act is explanatory and is not part of this Act.

21 *Note* See Legislation Act, s 127 (1), (4) and (5) for the legal status of notes.

1 **5 Offences against Act—application of Criminal Code etc**

2 Other legislation applies in relation to offences against this Act.

3 *Note 1 Criminal Code*

4 The Criminal Code, ch 2 applies to all offences against this Act (see
5 Code, pt 2.1).

6 The chapter sets out the general principles of criminal responsibility
7 (including burdens of proof and general defences), and defines terms
8 used for offences to which the Code applies (eg *conduct*, *intention*,
9 *recklessness* and *strict liability*).

10 *Note 2 Penalty units*

11 The Legislation Act, s 133 deals with the meaning of offence penalties
12 that are expressed in penalty units.

13 **6 Object of Act**

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

17 (a) by prohibiting certain practices; and

18 (b) by regulating activities that involve the use of certain human
19 embryos created by assisted reproductive technology.

20 **7 Meaning of *human embryo***

21 (1) In this Act:

22 *human embryo* means a live embryo that has a human genome or an
23 altered human genome and that has been developing for less than 8
24 weeks since the appearance of 2 pro-nuclei or the initiation of its
25 development by other means.

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

- 1 **8 Meaning of *human embryo clone***
- 2 (1) In this Act:
- 3 *human embryo clone* means a human embryo that is a genetic copy
- 4 of another living or dead human, but does not include a human
- 5 embryo created by the fertilisation of a human egg by human sperm.
- 6 (2) To establish that a human embryo clone is a genetic copy of a living
- 7 or dead human—
- 8 (a) it is sufficient to establish that the set of genes in the nuclei of
- 9 the cells of the living or dead human has been copied; and
- 10 (b) it is not necessary to establish that the copy is an identical
- 11 genetic copy.
- 12 (3) A human embryo that results from the technological process known
- 13 as embryo splitting is taken not to be created by a process of
- 14 fertilisation of a human egg by human sperm.

1 **Part 2** **Prohibited practices**

2 **Division 2.1** **Human cloning**

3 **9** **Offence—creating human embryo clone**

4 A person commits an offence if the person intentionally creates a
5 human embryo clone.

6 Maximum penalty: imprisonment for 15 years.

7 **10** **Offence—placing human embryo clone in body of human**
8 **or animal**

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

12 Maximum penalty: imprisonment for 15 years.

13 **11** **Offence—importing or exporting human embryo clone**

14 (1) A person commits an offence if the person intentionally imports a
15 human embryo clone into the ACT.

16 Maximum penalty: imprisonment for 15 years.

17 (2) A person commits an offence if the person intentionally exports a
18 human embryo clone from the ACT.

19 Maximum penalty: imprisonment for 15 years.

20 **12** **No defence that human embryo clone could not survive**

21 It is not a defence to an offence against section 9, section 10 or
22 section 11 that the human embryo clone did not survive or could not
23 have survived.

Division 2.2 Other prohibited practices

13 Offence—creating human embryo otherwise than by fertilisation etc

A person commits an offence if the person intentionally creates a human embryo by a process other than the fertilisation of a human egg by human sperm, or intentionally develops a human embryo so created.

Maximum penalty: imprisonment for 10 years.

14 Offence—creating human embryo for purpose other than achieving pregnancy

- (1) A person commits an offence if the person intentionally creates a human embryo 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 10 years.

- (2) Despite the Criminal Code, section 58 (3), a defendant does not bear an evidential burden in relation to anything mentioned in subsection (1).

15 Offence—creating etc human embryo containing genetic material from more than 2 people

A person commits an offence if the person intentionally creates or develops a human embryo containing genetic material provided by more than 2 people.

Maximum penalty: imprisonment for 10 years.

-
- 1 **16 Offence—developing human embryo outside body of**
2 **woman for longer than 14 days**
- 3 A person commits an offence if the person intentionally develops a
4 human embryo outside the body of a woman for a period of longer
5 than 14 days, excluding any period when development is suspended.
- 6 Maximum penalty: imprisonment for 10 years.
- 7 **17 Offence—using precursor cells to create human embryo**
8 **etc**
- 9 A person commits an offence if the person uses precursor cells taken
10 from a human embryo or a human foetus, intending to create a
11 human embryo, or intentionally develops an embryo so created.
- 12 Maximum penalty: imprisonment for 10 years.
- 13 **18 Offence—heritable alterations to genome**
- 14 (1) A person commits an offence if—
- 15 (a) the person alters the genome of a human cell in such a way that
16 the alteration is heritable by descendants of the human whose
17 cell was altered; and
- 18 (b) in altering the genome, the person intended the alteration to be
19 heritable by descendants of the human whose cell was altered.
- 20 Maximum penalty: imprisonment for 10 years.
- 21 (2) In this section:
- 22 *human cell* includes a human embryonal cell, a human foetal cell,
23 human sperm and a human egg.

1 **19 Offence—collecting viable human embryo from woman’s**
2 **body**

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

6 Maximum penalty: imprisonment for 10 years.

7 **20 Offence—creating chimeric or hybrid embryo**

8 (1) A person commits an offence if the person intentionally creates a
9 chimeric embryo.

10 Maximum penalty: imprisonment for 10 years.

11 (2) A person commits an offence if the person intentionally creates a
12 hybrid embryo.

13 Maximum penalty: imprisonment for 10 years.

14 **21 Offence—placing of embryo**

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

17 Maximum penalty: imprisonment for 10 years.

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

21 Maximum penalty: imprisonment for 10 years.

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

24 Maximum penalty: imprisonment for 10 years.

22 **Offence—importing, exporting or placing prohibited embryo**

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

Maximum penalty: imprisonment for 10 years.

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

Maximum penalty: imprisonment for 10 years.

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

Maximum penalty: imprisonment for 10 years.

- (4) In this section:

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

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 containing genetic material provided by more than 2 people; or
- (d) a human embryo that has been developing outside the body of a woman for a period of longer than 14 days, disregarding any period when development is suspended; or

- 1 (e) a human embryo created using precursor cells taken from a
2 human embryo or foetus; or
- 3 (f) a human embryo containing a human cell whose genome has
4 been altered in such a way that the alteration is heritable by
5 human descendants of the human whose cell was altered; or
- 6 (g) a human embryo that was removed from the body of a woman
7 by a person intending to collect a viable human embryo; or
- 8 (h) a chimeric embryo or a hybrid embryo.

9 **23 Offence—commercial trading in human eggs etc**

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

13 Maximum penalty: imprisonment for 10 years.

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

17 Maximum penalty: imprisonment for 10 years.

- 18 (3) In this section:

19 *reasonable expenses*—

- 20 (a) in relation to the supply of a human egg or human sperm—
21 includes, for example, expenses relating to the collection,
22 storage or transport of the egg or sperm; and

- 23 (b) in relation to the supply of a human embryo—

- 24 (i) includes, for example, expenses relating to the storage or
25 transport of the embryo; but

1 (ii) does not include any expenses incurred by a person
2 before the embryo became an excess ART embryo.

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

6 ***valuable consideration***, in relation to the supply of a human egg,
7 human sperm or a human embryo by a person, includes any
8 inducement, discount or priority in the provision of a service to the
9 person, but does not include the payment of reasonable expenses
10 incurred by the person in connection with the supply.

- 1 **Part 3** **Regulation of certain uses**
2 **involving excess ART**
3 **embryos**
- 4 **Division 3.1** **Interpretation for pt 3**
- 5 **24** **Definitions for pt 3**
- 6 In this part:
- 7 ***accredited ART centre*** means an entity accredited to carry out
8 assisted reproductive technology by—
- 9 (a) the Reproductive Technology Accreditation Committee of the
10 Fertility Society of Australia; or
- 11 (b) if the regulations prescribe another body or other bodies in
12 addition to, or instead of, the body mentioned in
13 paragraph (a)—that other body or any of those other bodies, as
14 the case requires.
- 15 ***confidential commercial information*** means information that has a
16 commercial or other value that would be, or could reasonably be
17 expected to be, destroyed or diminished if the information were
18 disclosed.
- 19 ***disclose*** information means give or communicate the information in
20 any way.
- 21 ***HREC*** means a human research ethics committee.
- 22 ***licence*** means a licence issued under section 31 (Committee
23 decision on application).

1 **proper consent**, in relation to the use of an excess ART embryo,
2 means—

- 3 (a) consent obtained in accordance with the *Ethical Guidelines on*
4 *Assisted Reproductive Technology* (1996) issued by the
5 NHMRC; or
- 6 (b) if other guidelines are issued by the NHMRC under the
7 *National Health and Medical Research Council Act 1992*
8 (Cwlth) and prescribed under the regulations for this
9 paragraph—consent obtained in accordance with those
10 guidelines, rather than the guidelines mentioned in
11 paragraph (a).

12 **relevant Territory entity** means the entity notified by the Territory
13 to the chairperson of the NHMRC licensing committee for the
14 *Research Involving Human Embryos Act 2002* (Cwlth), part 2.

15 **responsible person**, for an excess ART embryo, means—

- 16 (a) each person who provided the egg or sperm from which the
17 embryo was created; and
- 18 (b) the woman for whom the embryo was created, for the purpose
19 of achieving her pregnancy; and
- 20 (c) anyone who was the domestic partner of a person mentioned in
21 paragraph (a) when the egg or sperm mentioned in that
22 paragraph was provided; and
- 23 (d) anyone who was the domestic partner of the woman mentioned
24 in paragraph (b) when the embryo was created.

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

25 Meaning of excess ART embryo

(1) In this Act:

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 domestic partner (if any) when the embryo was created.

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

(2) For subsection (1) (b), a human embryo is excess to the needs of the people mentioned in that paragraph at a particular time if—

- (a) each of the people 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 of the people has declared in writing that the embryo is excess to their needs, and the declaration is in force at that time.

Division 3.2 Offences

26 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.

Maximum penalty: imprisonment for 5 years.

-
- 1 (2) Despite the Criminal Code, section 58 (3), a defendant does not bear
2 an evidential burden in relation to anything mentioned in this
3 section.
- 4 (3) In this section:
- 5 *diagnostic investigation*, in relation to an excess ART embryo,
6 means any procedure undertaken on embryos for the sole purpose of
7 diagnostic investigations for the direct benefit of the woman for
8 whom it was created.
- 9 *exempt use*—a use of an excess ART embryo by a person is an
10 *exempt use* if—
- 11 (a) the use consists only of—
- 12 (i) storage of the excess ART embryo; or
- 13 (ii) removal of the excess ART embryo from storage; or
- 14 (iii) transport of the excess ART embryo; or
- 15 (iv) observation of the excess ART embryo; or
- 16 (v) allowing the excess ART embryo to succumb; or
- 17 (b) the use is carried out by an accredited ART centre, and—
- 18 (i) the excess ART embryo is not suitable (based only on its
19 biological fitness for implantation) to be placed in the
20 body of the woman for whom it was created; and
- 21 (ii) the use forms part of diagnostic investigations conducted
22 in connection with the assisted reproductive technology
23 treatment of the woman for whom the excess ART
24 embryo was created; or
- 25 (c) the use is carried out by an accredited ART centre and is for
26 the purpose of achieving pregnancy in a woman other than the
27 woman for whom the excess ART embryo was created; or
- 28 (d) the use is prescribed under the regulations.
-

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

4 **27 Offence—use of embryo that is not excess ART embryo**

5 A person commits an offence if—

- 6 (a) the person intentionally uses, outside the body of a woman, a
7 human embryo that is not an excess ART embryo; and
- 8 (b) the use is not for a purpose relating to the assisted reproductive
9 technology treatment of a woman carried out by an accredited
10 ART centre, and the person knows or is reckless about that
11 fact.

12 Maximum penalty: imprisonment for 5 years.

13 **28 Offence—breaching licence condition**

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

18 Maximum penalty: imprisonment for 5 years.

- 19 (2) In this section:

20 *engage in conduct* means—

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

**Division 3.3 Embryo research licensing
 committee of NHMRC**

29 Functions of committee

The functions of the NHMRC licensing committee are—

- (a) to exercise functions in relation to licences under division 3.4 (Licensing system); and
- (b) to exercise functions in relation to databases under division 3.5 (Reporting and confidentiality); and
- (c) to exercise the other functions (if any) that are given to it under this Act or any other law.

Division 3.4 Licensing system

30 Person may apply for licence

- (1) A person may apply to the NHMRC licensing committee for a licence authorising use of excess ART embryos.
- (2) An application under subsection (1) must be made in accordance with the written requirements (if any) of the NHMRC licensing committee.

Note A fee may be determined under s 53 for this section.

31 Committee decision on application

- (1) This section applies if a person has made an application under section 30 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—

- 1 (i) to enable proper consent to be obtained before an excess
2 ART embryo is used under the licence (see
3 section 34 (1) (a)); and
- 4 (ii) to enable compliance with any restrictions on the
5 consent;
- 6 (b) if the use of an excess ART embryo proposed in the
7 application may damage or destroy the embryo—that
8 appropriate protocols are in place to enable compliance with
9 the condition that the use is authorised only in relation to an
10 embryo created before 5 April 2002 (see section 34 (3));
- 11 (c) that the activity or project proposed in the application has been
12 assessed and approved by a HREC that is constituted in
13 accordance with, and acting in compliance with, the NHMRC
14 *National Statement on Ethical Conduct in Research Involving*
15 *Humans* (1999), as in force from time to time.
- 16 (4) In deciding whether to issue the licence, the NHMRC licensing
17 committee must have regard to the following:
- 18 (a) restricting the number of excess ART embryos to that likely to
19 be necessary to achieve the goals of the activity or project
20 proposed in the application;
- 21 (b) the likelihood of significant advance in knowledge or
22 improvement in technologies for treatment as a result of the
23 use of excess ART embryos proposed in the application, that
24 could not reasonably be achieved by other means;
- 25 (c) any relevant guidelines, or relevant parts of guidelines, issued
26 by the NHMRC under the *National Health and Medical*
27 *Research Council Act 1992* (Cwlth) and prescribed under the
28 regulations for this paragraph;
- 29 (d) the HREC assessment of the application mentioned in
30 subsection (3) (c);
- 31 (e) the additional matters (if any) prescribed under the regulations.
-

1 **32 Notification of decision**

- 2 (1) The NHMRC licensing committee must notify its decision on an
3 application for a licence to the following:
- 4 (a) the applicant;
- 5 (b) the HREC that assessed and approved the activity or project
6 proposed in the application as mentioned in section 31 (3) (c);
- 7 (c) the relevant Territory entity.
- 8 (2) If the NHMRC licensing committee decides to issue the licence, it
9 must, in addition to issuing the licence to the applicant, give a copy
10 of the licence to the entities mentioned in subsection (1) (b) and (c).

11 **33 Period of licence**

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

18 **34 Licence is subject to conditions**

- 19 (1) A licence is subject to the condition that before an excess ART
20 embryo is used as authorised by the licence—
- 21 (a) each responsible person in relation to the excess ART embryo
22 must have given proper consent to that use; and
- 23 (b) the licence holder must have reported in writing to the
24 NHMRC licensing committee that the consent has been
25 obtained, and any restrictions to which the consent is subject;
26 and

- 1 (c) if the licence authorises use of an excess ART embryo that
2 may damage or destroy the embryo—the licence holder must
3 have reported in writing to the NHMRC licensing committee
4 that the embryo was created before 5 April 2002.
- 5 (2) A licence is subject to the condition that the use of an excess ART
6 embryo must be in accordance with any restrictions to which the
7 proper consent under subsection (1) is subject.
- 8 (3) If a licence authorises the use of an excess ART embryo that may
9 damage or destroy the embryo, the licence is subject to the condition
10 that the use is authorised only in relation to an embryo created
11 before 5 April 2002.
- 12 (4) A licence is subject to the other conditions (if any) stated in the
13 licence.
- 14 (5) The conditions stated in the licence may include, for example,
15 conditions relating to the following:
- 16 (a) the people authorised by the licence to use excess ART
17 embryos;
- 18 (b) the number of excess ART embryos in relation to which use is
19 authorised by the licence;
- 20 (c) reporting;
- 21 (d) monitoring;
- 22 (e) information to be given by the licence holder to people
23 authorised by the licence to use excess ART embryos.
- 24 *Note* An example is part of the Act, is not exhaustive and may extend, but
25 does not limit, the meaning of the provision in which it appears (see
26 Legislation Act, s 126 and s 132).
- 27 (6) The licence conditions mentioned in subsections (1), (2) and (3)
28 apply to all people who are authorised by the licence to use excess
29 ART embryos.

- 1 (7) Licence conditions stated in the licence apply to—
2 (a) the licence holder; and
3 (b) such other people authorised by the licence to use excess ART
4 embryos as are stated in the licence.

5 **35 Variation of licence**

- 6 (1) The NHMRC licensing committee may, by written notice given to
7 the licence holder, vary a licence if the committee believes on
8 reasonable grounds that it is necessary or desirable to do so.
- 9 (2) The NHMRC licensing committee may vary a licence under
10 subsection (1) on its own initiative or on application by the licence
11 holder.
- 12 (3) Without limiting subsection (1), the NHMRC licensing committee
13 may vary the licence by stating additional conditions or varying
14 existing conditions.
- 15 (4) The NHMRC licensing committee must not vary a licence in such a
16 way that, had a person applied under section 30 for the licence as
17 varied, the committee would not have been permitted under this part
18 to issue the licence.

19 **36 Suspension or revocation of licence**

- 20 (1) The NHMRC licensing committee may, by written notice given to
21 the licence holder, suspend or revoke a licence if the committee
22 believes on reasonable grounds that a condition of the licence has
23 been breached.
- 24 (2) If a licence holder is convicted of an offence against this Act, the
25 NHMRC licensing committee must, by written notice given to the
26 licence holder, revoke each licence held by the licence holder.

1 **37 Surrender of licence**

2 A licence holder may surrender a licence by written notice given to
3 the NHMRC licensing committee.

4 **38 Notice of variation, suspension or revocation of licence**

5 (1) If the NHMRC licensing committee varies, suspends or revokes a
6 licence, the committee must tell—

7 (a) the licence holder; and

8 (b) the HREC and the relevant Territory entity.

9 (2) The NHMRC licensing committee must also tell the entities
10 mentioned in subsection (1) (b) if a licence is surrendered.

11 **Division 3.5 Reporting and confidentiality**

12 **39 NHMRC licensing committee to make certain information**
13 **publicly available**

14 (1) The NHMRC licensing committee must maintain a database
15 containing the following information in relation to each licence
16 (including a licence as varied):

17 (a) the name of the person to whom the licence was issued;

18 (b) a short statement about the nature of the uses of excess ART
19 embryos that are authorised by the licence;

20 (c) any conditions to which the licence is subject;

21 (d) the number of excess ART embryos in relation to which use is
22 authorised by the licence;

23 (e) the date the licence was issued;

24 (f) the period throughout which the licence is to remain in force.

25 (2) The database must be made publicly available.

1 (3) The database may be kept and made publicly available in electronic
2 form.

3 (4) Information mentioned in subsection (1) must not disclose
4 confidential commercial information.

5 **40 Confidential commercial information may only be**
6 **disclosed in certain circumstances**

7 (1) A person commits an offence if—

8 (a) the person discloses confidential commercial information that
9 the person has only because of exercising functions under this
10 Act or under the Commonwealth Act; and

11 (b) the person knows that the information is confidential
12 commercial information; and

13 (c) the disclosure is not—

14 (i) to the Territory, a Territory agency, the Commonwealth,
15 a Commonwealth authority, a State, or a State agency for
16 this Act, a corresponding State law or the Commonwealth
17 Act; or

18 (ii) by order of a court; or

19 (iii) with the consent of each person to whom the information
20 has a commercial or other value.

21 Maximum penalty: imprisonment for 2 years.

22 (2) A person commits an offence if—

23 (a) the person discloses confidential commercial information that
24 the person has only because of a disclosure permitted under
25 subsection (1) or this subsection; and

26 (b) the person knows that the information is confidential
27 commercial information; and

- 1 (c) the disclosure is not—
- 2 (i) to the Territory, a Territory agency, the Commonwealth,
- 3 a Commonwealth authority, a State, or a State agency for
- 4 this Act, a corresponding State law or the Commonwealth
- 5 Act; or
- 6 (ii) by order of a court; or
- 7 (iii) with the consent of each person to whom the information
- 8 has a commercial or other value.

9 Maximum penalty: imprisonment for 2 years.

10 (3) In this section:

11 ***Commonwealth authority*** means—

- 12 (a) a corporation established for a public purpose under a
- 13 Commonwealth Act; or
- 14 (b) a company in which a controlling interest is held by any 1 of
- 15 the following, or by 2 or more of the following together:
- 16 (i) the Commonwealth;
- 17 (ii) a corporation covered by paragraph (a);
- 18 (iii) an entity covered by subparagraph (i) or (ii).

19 ***corresponding State law***—see the Commonwealth Act,

20 section 7 (1).

21 ***court*** includes a tribunal, authority or person having power to

22 require the production of documents or the answering of questions.

1 ***State agency*** means—

- 2 (a) a Minister of a State; or
- 3 (b) a department of government of a State; or
- 4 (c) an instrumentality of a State, including a corporation
- 5 established for a public purpose under a law of a State; or
- 6 (d) a company in which a controlling interest is held by any 1 of
- 7 the following, or by 2 or more of the following together:
- 8 (i) a State;
- 9 (ii) a Minister of a State;
- 10 (iii) an entity covered by subparagraph (i) or (ii).

11 ***Territory agency*** means—

- 12 (a) a Minister; or
- 13 (b) an administrative unit; or
- 14 (c) a Territory instrumentality; or
- 15 (a) a corporation established for a public purpose under a Territory
- 16 Act; or
- 17 (d) a company in which a controlling interest is held by any one of
- 18 the following, or by 2 or more of the following together:
- 19 (i) the Territory;
- 20 (ii) an entity covered by paragraph (a), (c) or (e);
- 21 (iii) an entity covered by subparagraph (i) or (ii).

22 *Note* For the definition of ***confidential commercial information***, see s 24.

1 **Division 3.6 Review provisions**

2 **41 Definitions for div 3.6**

3 In this division:

4 *Commonwealth administrative appeals tribunal* means the
5 Administrative Appeals Tribunal established by the *Administrative*
6 *Appeals Tribunal Act 1975* (Cwlth).

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

9 *eligible person*, in relation to a decision of the NHMRC licensing
10 committee, means:

- 11 (a) in relation to a decision under section 31 not to issue a
12 licence—the applicant for the licence; or
- 13 (b) in relation to a decision about the period throughout which the
14 licence is to be in force under section 33—the licence holder;
15 or
- 16 (c) in relation to a decision to state a licence condition under
17 section 34 (4)—the licence holder; or
- 18 (d) in relation to a decision to vary or refuse to vary a licence
19 under section 35—the licence holder; or
- 20 (e) in relation to a decision to suspend or revoke a licence under
21 section 36—the person who was the licence holder
22 immediately before the suspension or revocation.

1 **42 Review of decisions**

2 (1) An eligible person may apply to the Commonwealth administrative
3 appeals tribunal for review of the following decisions of the
4 NHMRC licensing committee:

- 5 (a) a decision under section 31 not to issue a licence;
6 (b) a decision about the period throughout which the licence is to
7 be in force under section 33;
8 (c) a decision to state a licence condition under section 34 (4);
9 (d) a decision to vary or refuse to vary a licence under section 35;
10 (e) a decision to suspend or revoke a licence under section 36.

11 (2) This section has effect subject to the *Administrative Appeals*
12 *Tribunal Act 1975* (Cwlth).

(1) The chairperson of the NHMRC licensing committee may, by instrument in writing, appoint any of the following as inspectors:

- (a) a person who is appointed or employed by the Territory;
- (b) a person who is appointed or employed by a State;
- (c) a person who is appointed or employed by the Commonwealth.

- (2) The Legislation Act, part 19.3 (Appointments) does not apply to appointments under this section.

- (3) In exercising functions as an inspector, an inspector must comply with any directions of the chairperson of the NHMRC licensing committee.

- (4) The chairperson of the NHMRC licensing committee must not appoint a person as an inspector under subsection (1) unless the chairperson is satisfied that the person has appropriate skills and experience.

- (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 approved form; and
- (b) must contain a recent photograph of the inspector.

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

4 Maximum penalty: 1 penalty unit.

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

7 **45 Powers available to inspectors for monitoring compliance**

- 8 (1) To find out whether this Act has been complied with, an inspector
9 may—

10 (a) enter any premises; and

11 (b) exercise the monitoring powers set out in section 46.

12 *Note* A reference to an Act includes a reference to the statutory instruments
13 made or in force under the Act, including regulations (see Legislation
14 Act, s 104).

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

17 (a) the occupier of the premises has consented to the entry; or

18 (b) the premises are premises where the occupier of the premises is
19 carrying out activities authorised by a licence issued under
20 section 31, and the entry is at a reasonable time.

21 **46 Monitoring powers**

- 22 (1) The monitoring powers that an inspector may exercise under
23 section 45 (1) (b) are as follows:

24 (a) to search the premises and anything on the premises;

25 (b) to inspect, examine, take measurements of, conduct tests on, or
26 take samples of, any human embryo or thing on the premises
27 that relates to this Act;

- 1 (c) to take photographs, make video or audio recordings or make
2 sketches of the premises or anything on the premises;
- 3 (d) to inspect any book, record or document on the premises;
- 4 (e) to take extracts from or make copies of any such book, record
5 or document;
- 6 (f) to take onto the premises the equipment and materials that the
7 inspector requires to exercise powers in relation to the
8 premises.
- 9 (2) For this part, monitoring powers include the power to operate
10 equipment at premises to see whether—
- 11 (a) the equipment; or
- 12 (b) a disk, tape or other storage device that—
- 13 (i) is at the premises; and
- 14 (ii) can be used with the equipment or is associated with it;
- 15 contains information that is relevant to deciding whether there has
16 been compliance with this Act.
- 17 *Note* A reference to an Act includes a reference to the statutory instruments
18 made or in force under the Act, including regulations (see Legislation
19 Act, s 104).
- 20 (3) If the inspector, after operating equipment at the premises, finds that
21 the equipment, or that a disk, tape or other storage device at the
22 premises, contains information mentioned in subsection (2), the
23 inspector may—
- 24 (a) operate equipment or facilities at the premises to put the
25 information in documentary form and copy the document
26 produced; or
- 27 (b) if the information can be transferred to a tape, disk or other
28 storage device that—
- 29 (i) is brought to the premises; or

- 1 (ii) is at the premises and the use of which has been agreed to
2 in writing by the occupier of the premises;
3 operate the equipment or other facilities to copy the
4 information to the storage device, and remove the storage
5 device from the premises.

6 **47 Power to secure**

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

13 *Note* A reference to an offence against a Territory law includes a reference to
14 a related ancillary offence, eg attempt (see Legislation Act, s 189).

15 **48 Inspector must produce identity card on request**

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

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

22 **49 Consent**

- 23 (1) Before obtaining the consent of a person for section 45 (2) (a), the
24 inspector must tell the person that he or she may refuse consent.
25 (2) An entry of an inspector with the consent of a person is not lawful
26 unless the person voluntarily consented to the entry.

- 1 **50 Compensation for damage**
- 2 (1) The owner of equipment or other facilities is entitled to
- 3 compensation for damage to the equipment or other facilities if—
- 4 (a) the damage was caused to the equipment or other facilities
- 5 because of it being operated by an inspector as mentioned in
- 6 this part; and
- 7 (b) the damage was caused because insufficient care was exercised
- 8 by the inspector operating the equipment or other facilities.
- 9 (2) In deciding the amount of compensation payable, regard is to be had
- 10 to whether the occupier of the premises and his or her employees
- 11 and agents, if they were available at the time, had provided any
- 12 warning or guidance as to the operation of the equipment or other
- 13 facilities that was appropriate in the circumstances.

Part 5 Miscellaneous

51 Reports to Legislative Assembly

As soon as practicable after receiving a copy of a report from the NHMRC licensing committee under the Commonwealth Act, section 19, the Minister must present a copy of the report to the Legislative Assembly.

52 Review of operation of Act

- (1) The Minister must review the operation of this Act as soon as practicable after the 2nd anniversary of the day the Act commences.
- (2) The review must consider and report on the scope and operation of this Act, part 2 and part 3 taking into account the following:
 - (a) developments in technology in relation to assisted reproductive technology;
 - (b) developments in medical research and scientific research and the potential therapeutic applications of such research;
 - (c) community standards;
 - (d) the applicability of establishing a national stem cell bank.
- (3) The review may be undertaken as part of the reviews mentioned in the *Research Involving Human Embryos Act 2002* (Cwlth), section 47 and the *Prohibition of Human Cloning Act 2002* (Cwlth), section 25.

1 **53 Determination of fees**

2 (1) The Minister may, in writing, determine fees for this Act.

3 *Note* The Legislation Act contains provisions about the making of
4 determinations and regulations relating to fees (see pt 6.3)

5 (2) A determination is a disallowable instrument.

6 *Note* A disallowable instrument must be notified, and presented to the
7 Legislative Assembly, under the Legislation Act.

8 **54 Approved forms**

9 (1) The Minister may, in writing, approve forms for this Act.

10 *Note* For other provisions about forms, see Legislation Act, s 255.

11 (2) If the Minister approves a form for a particular purpose, the
12 approved form must be used for that purpose.

13 (3) An approved form is a notifiable instrument.

14 *Note* A notifiable instrument must be notified under the Legislation Act.

15 **55 Regulation-making power**

16 The Executive may make regulations for this Act.

17 *Note* Regulations must be notified, and presented to the Legislative
18 Assembly, under the Legislation Act.

19 **56 Expiry of certain provisions**

20 (1) This section applies to the following provisions:

- 21 • section 31 (3) (b)
22 • section 34 (1) (c)
23 • section 34 (3)
24 • this section.

25 (2) The provisions expire on the earlier of the following:

- 26 (a) 5 April 2005;

1 (b) if an earlier expiry date is fixed by the Minister under
2 subsection (3)—that day.

3 (3) If the Council of Australian Governments declares an expiry date
4 earlier than 5 April 2005 by notice in the Commonwealth Gazette
5 (as mentioned in the Commonwealth Act, section 46), the Minister
6 must, in writing, fix that day as the expiry date.

7 (4) An instrument under subsection (2) is a notifiable instrument.

8 *Note* A notifiable instrument must be notified under the Legislation Act.

Dictionary

(see s 3)

Note 1 The Legislation Act contains definitions and other provisions relevant to this Act.

Note 2 For example, the Legislation Act, dict, pt 1, defines the following terms:

- corporation
- entity
- exercise
- functions
- State
- under.

accredited ART centre—see section 24.

animal does not include a human.

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) anything declared under the regulations to be a chimeric embryo.

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

Commonwealth administrative appeals tribunal—see section 41.

confidential commercial information—see section 24.

decision, for division 3.6 (Review provisions)—see section 41.

disclose information, for part 3 (Regulation of certain uses involving excess ART embryos)—see section 24.

eligible person, for division 3.6 (Review provisions)—see section 41.

1 **excess ART embryo**—see section 25.

2 **HREC**—see section 24.

3 **human embryo**—see section 7.

4 **human embryo clone**—see section 8.

5 **human sperm** includes human spermatids.

6 **hybrid embryo** means—

7 (a) an embryo created by the fertilisation of a human egg by
8 animal sperm; or

9 (b) an embryo created by the fertilisation of an animal egg by
10 human sperm; or

11 (c) a human egg into which the nucleus of an animal cell has been
12 introduced; or

13 (d) an animal egg into which the nucleus of a human cell has been
14 introduced; or

15 (e) a thing declared under the regulations to be a hybrid embryo.

16 **inspector** means a person appointed as an inspector under
17 section 43 (1).

18 **licence**, for part 3 (Regulation of certain uses involving excess ART
19 embryos)—see section 24.

20 **NHMRC licensing committee** means the committee established by
21 the *Research Involving Human Embryos Act 2002* (Cwlth),
22 section 13.

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

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

- 1 ***proper consent***, for part 3 (Regulation of certain uses involving
2 excess ART embryos)—see section 24.
- 3 ***relevant Territory entity***, for part 3 (Regulation of certain uses
4 involving excess ART embryos)—see section 24.
- 5 ***responsible person***, for part 3 (Regulation of certain uses involving
6 excess ART embryos), see section 24.
- 7 ***woman*** means a female human.
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Endnotes

- 1 **Presentation speech**
Presentation speech made in Legislative Assembly on 2003.
- 2 **Notification**
Notified under the Legislation Act on 2003.
- 3 **Republications of amended laws**
For the latest republication of amended laws, see www.legislation.act.gov.au.
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