

2004

THE LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

(As presented)

(Minister for Health)

Human Embryo (Research) Bill 2004

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THE LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

(As presented)

(Minister for Health)

Human Embryo (Research) Bill 2004

A Bill for

An Act 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 Embryo (Research) Act 2004*.

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.

5 Offences against Act—application of Criminal Code etc

Other legislation applies in relation to offences against this Act.

Note 1 Criminal Code

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

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

Note 2 Penalty units

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

6 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 by regulating activities that involve the use of certain human embryos created by assisted reproductive technology.

7 Meaning of *human embryo*

(1) In this Act:

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

(2) 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.

- 1 **Part 2** Regulation of certain uses
2 involving excess ART embryos
- 3 **Division 2.1** Interpretation for pt 2
- 4 **8** Definitions for pt 2
- 5 In this part:
- 6 *accredited ART centre* means an entity accredited to carry out
7 assisted reproductive technology by—
- 8 (a) the Reproductive Technology Accreditation Committee of the
9 Fertility Society of Australia; or
- 10 (b) if the regulations prescribe another body or other bodies in
11 addition to, or instead of, the body mentioned in
12 paragraph (a)—that other body or any of those other bodies, as
13 the case requires.
- 14 *confidential commercial information* means information that has a
15 commercial or other value that would be, or could reasonably be
16 expected to be, destroyed or diminished if the information were
17 disclosed.
- 18 *disclose* information means give or communicate the information in
19 any way.
- 20 *HREC* means a human research ethics committee.
- 21 *licence* means a licence issued under section 15 (Committee
22 decision on application).

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

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

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

responsible person, for an excess ART embryo, means—

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

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

9 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 2.2 Offences

10 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

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

1 (c) the use is carried out by an accredited ART centre and is for
2 the purpose of achieving pregnancy in a woman other than the
3 woman for whom the excess ART embryo was created; or

4 (d) the use is prescribed under the regulations.

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

8 **11 Offence—use of embryo that is not excess ART embryo**

9 A person commits an offence if—

10 (a) the person intentionally uses, outside the body of a woman, a
11 human embryo that is not an excess ART embryo; and

12 (b) the use is not for a purpose relating to the assisted reproductive
13 technology treatment of a woman carried out by an accredited
14 ART centre, and the person knows or is reckless about that
15 fact.

16 Maximum penalty: imprisonment for 5 years.

17 **12 Offence—breaching licence condition**

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

22 Maximum penalty: imprisonment for 5 years.

23 (2) In this section:

24 **engage in conduct** means—

25 (a) do an act; or

26 (b) omit to perform an act.

The functions of the NHMRC licensing committee are—

- ## Division 2.4 Licensing system

- (1) A person may apply to the NHMRC licensing committee for a licence authorising use of excess ART embryos.

- Note* A fee may be determined under s 37 for this section.

(1) This section applies if a person has made an application under section 14 for a licence.

- (2) The NHMRC licensing committee must decide, in accordance with this section, whether or not to issue the licence.

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

1 (d) the HREC assessment of the application mentioned in
2 subsection (3) (c);

3 (e) the additional matters (if any) prescribed under the regulations.

4 **16 Notification of decision**

5 (1) The NHMRC licensing committee must notify its decision on an
6 application for a licence to the following:

7 (a) the applicant;

8 (b) the HREC that assessed and approved the activity or project
9 proposed in the application as mentioned in section 15 (3) (c);

10 (c) the relevant Territory entity.

11 (2) If the NHMRC licensing committee decides to issue the licence, it
12 must, in addition to issuing the licence to the applicant, give a copy
13 of the licence to the entities mentioned in subsection (1) (b) and (c).

14 **17 Period of licence**

15 (1) A licence—

16 (a) comes into force on the day stated in the licence or, if no day is
17 stated, on the day it is issued; and

18 (b) remains in force until the day stated in the licence, unless it is
19 suspended, revoked or surrendered before that day.

20 (2) A licence is not in force throughout any period of suspension.

21 **18 Licence is subject to conditions**

22 (1) A licence is subject to the condition that before an excess ART
23 embryo is used as authorised by the licence—

24 (a) each responsible person in relation to the excess ART embryo
25 must have given proper consent to that use; and

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

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

8 **19 Variation of licence**

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

22 **20 Suspension or revocation of licence**

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

1 **21 Surrender of licence**

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

4 **22 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 2.5 Reporting and confidentiality**

12 **23 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 **24 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, a
15 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, a
- 3 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.
- 23 ***State agency*** means—
- 24 (a) a Minister of a State; or
- 25 (b) a department of government of a State; or
- 26 (c) an instrumentality of a State, including a corporation
- 27 established for a public purpose under a law of a State; or

(d) a company in which a controlling interest is held by any 1 of the following, or by 2 or more of the following together:

(i) a State;

(ii) a Minister of a State;

(iii) an entity covered by subparagraph (i) or (ii).

Territory agency means—

(a) a Minister; or

(b) an administrative unit; or

(c) a Territory instrumentality; or

(d) a corporation established for a public purpose under a Territory Act; or

(e) a company in which a controlling interest is held by any one of the following, or by 2 or more of the following together:

(i) the Territory;

(ii) an entity covered by paragraph (a), (c) or (d);

(iii) an entity covered by subparagraph (i) or (ii).

Note For the definition of ***confidential commercial information***, see s 8.

Division 2.6 Review provisions

25 Definitions for div 2.6

In this division:

Commonwealth 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 15 not to issue a licence—the applicant for the licence; or
- (b) in relation to a decision about the period throughout which the licence is to be in force under section 17—the licence holder; or
- (c) in relation to a decision to state a licence condition under section 18 (4)—the licence holder; or
- (d) in relation to a decision to vary or refuse to vary a licence under section 19—the licence holder; or
- (e) in relation to a decision to suspend or revoke a licence under section 20—the person who was the licence holder immediately before the suspension or revocation.

26 Review of decisions

- (1) An eligible person may apply to the Commonwealth administrative appeals tribunal for review of the following decisions of the NHMRC licensing committee:
 - (a) a decision under section 15 not to issue a licence;
 - (b) a decision about the period throughout which the licence is to be in force under section 17;
 - (c) a decision to state a licence condition under section 18 (4);
 - (d) a decision to vary or refuse to vary a licence under section 19;
 - (e) a decision to suspend or revoke a licence under section 20.
- (2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975* (Cwlth).

Part 3 Monitoring powers

27 Appointment of inspectors

- (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.

28 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 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 **29 Powers available to inspectors for monitoring compliance**

- 8 (1) To find out whether this Act or the *Human Cloning (Prohibition)*
9 *Act 2004* has been complied with, an inspector may—

10 (a) enter any premises; and

11 (b) exercise the monitoring powers set out in section 30.

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 15, and the entry is at a reasonable time.

21 **30 Monitoring powers**

- 22 (1) The monitoring powers that an inspector may exercise under
23 section 29 (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 or the *Human Cloning (Prohibition)*
28 *Act 2004*;

- 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 or the *Human Cloning (Prohibition)*
17 *Act 2004*.
- 18 *Note* A reference to an Act includes a reference to the statutory instruments
19 made or in force under the Act, including regulations (see Legislation
20 Act, s 104).
- 21 (3) If the inspector, after operating equipment at the premises, finds that
22 the equipment, or that a disk, tape or other storage device at the
23 premises, contains information mentioned in subsection (2), the
24 inspector may—
- 25 (a) operate equipment or facilities at the premises to put the
26 information in documentary form and copy the document
27 produced; or

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

9 **31 Power to secure**

10 If an inspector, during a search of premises, believes on reasonable
11 grounds that there is at the premises a human embryo or a thing that
12 may provide evidence of the commission of an offence against this
13 Act or the *Human Cloning (Prohibition) Act 2004*, the monitoring
14 powers include securing the embryo or thing while a warrant to
15 seize it is obtained (whether by the inspector or by another person).

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

18 **32 Inspector must produce identity card on request**

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

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

25 **33 Consent**

- 26 (1) Before obtaining the consent of a person for section 29 (2) (a), the
27 inspector must tell the person that he or she may refuse consent.

- 1 (2) An entry of an inspector with the consent of a person is not lawful
2 unless the person voluntarily consented to the entry.

3 **34 Compensation for damage**

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

1 **Part 4 Miscellaneous**

2 **35 Reports to Legislative Assembly**

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

7 **36 Review of operation of Act**

- 8 (1) The Minister must review the operation of this Act as soon as
9 practicable after the 2nd anniversary of the day the Act commences.
- 10 (2) The review must consider and report on the scope and operation of
11 this Act, part 2 taking into account the following:
- 12 (a) developments in technology in relation to assisted reproductive
13 technology;
- 14 (b) developments in medical research and scientific research and
15 the potential therapeutic applications of such research;
- 16 (c) community standards;
- 17 (d) the applicability of establishing a national stem cell bank.
- 18 (3) The review may be undertaken as part of the review mentioned in
19 the Commonwealth Act, section 47.

20 **37 Determination of fees**

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

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

- 24 (2) A determination is a disallowable instrument.

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

38 Approved forms

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

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

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

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

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

39 Regulation-making power

The Executive may make regulations for this Act.

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

40 Expiry of certain provisions

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

- section 15 (3) (b)
- section 18 (1) (c)
- section 18 (3)
- this section.

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

(a) 5 April 2005;

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

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

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

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

- 1 **41 Legislation amended—sch 1**
- 2 (1) Despite section 2 (Commencement), this section commences on the
- 3 later of the following:
- 4 (a) the commencement of the *Human Cloning (Prohibition)*
- 5 *Act 2004*;
- 6 (b) the commencement of this Act.
- 7 (2) On the commencement of this section, this Act is taken to be
- 8 amended in accordance with schedule 1, part 1.1.
- 9 (3) Schedule 1, part 1.2 amends the *Human Cloning (Prohibition)*
- 10 *Act 2004*.
- 11 (4) On the commencement of this section, the *Human Cloning*
- 12 *(Prohibition) Act 2004* (as amended by this Act) is repealed.
- 13 (5) This section and schedule 1 expire at the end of 6 months after the
- 14 commencement of this Act if the *Human Cloning (Prohibition)*
- 15 *Act 2004* has not commenced before then.
- 16 (6) To remove any doubt, subsection (4) does not affect the operation of
- 17 the Legislation Act, section 89 (Automatic repeal of certain laws
- 18 and provisions).

Schedule 1 Amendments

(see s 41)

Part 1.1 Amendments of this Act

[1.1] Long title

substitute

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

[1.2] Section 1

substitute

1 Name of Act

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

[1.3] Section 6

substitute

6 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.

- 1 **[1.4] Section 29 (1)**
- 2 *omit*
- 3 or the *Human Cloning (Prohibition) Act 2004*
- 4 **[1.5] Section 30 (1) (b)**
- 5 *omit*
- 6 or the *Human Cloning (Prohibition) Act 2004*
- 7 **[1.6] Section 30 (2)**
- 8 *omit*
- 9 or the *Human Cloning (Prohibition) Act 2004*
- 10 **[1.7] Section 31**
- 11 *omit*
- 12 or the *Human Cloning (Prohibition) Act 2004*
- 13 **[1.8] Section 36 (2)**
- 14 *before*
- 15 part 2
- 16 *insert*
- 17 part 1A and
- 18 **[1.9] Section 36 (3)**
- 19 *substitute*
- 20 (3) The review may be undertaken as part of the reviews mentioned in
- 21 the *Research Involving Human Embryos Act 2002* (Cwlth),
- 22 section 47 and the *Prohibition of Human Cloning Act 2002* (Cwlth),
- 23 section 25.

1 **[1.10] Act—renumbering**
2 *renumber provisions when Act next republished under Legislation*
3 *Act*

4 **Part 1.2 Amendments of the Human**
5 **Cloning (Prohibition) Act 2004**

6 **[1.11] Section 8**
7 *relocate to this Act as section 7A*

8 **[1.12] Part 2**
9 *relocate to this Act as part 1A*

10 **[1.13] Dictionary definitions (other than definitions of excess**
11 **ART embryo, human embryo and woman)**
12 *relocate to this Act, dictionary*

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 8.

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

Commonwealth administrative appeals tribunal—see section 25.

confidential commercial information—see section 8.

decision, for division 2.6 (Review provisions)—see section 25.

disclose information, for part 2 (Regulation of certain uses involving excess ART embryos)—see section 8.

eligible person, for division 2.6 (Review provisions)—see section 25.

excess ART embryo—see section 9.

HREC—see section 8.

human embryo—see section 7.

inspector means a person appointed as an inspector under section 27 (1).

- 1 *licence*, for part 2 (Regulation of certain uses involving excess ART
2 embryos)—see section 8.
- 3 *NHMRC licensing committee* means the committee established by
4 the *Research Involving Human Embryos Act 2002* (Cwlth),
5 section 13.
- 6 *NHMRC* means the National Health and Medical Research Council
7 established by the *National Health and Medical Research Council*
8 *Act 1992* (Cwlth).
- 9 *proper consent*, for part 2 (Regulation of certain uses involving
10 excess ART embryos)—see section 8.
- 11 *relevant Territory entity*, for part 2 (Regulation of certain uses
12 involving excess ART embryos)—see section 8.
- 13 *responsible person*, for part 2 (Regulation of certain uses involving
14 excess ART embryos)—see section 8.
- 15 *woman* means a female human.

Endnotes

1 **Presentation speech**

Presentation speech made in the Legislative Assembly on 2004.

2 **Notification**

Notified under the Legislation Act on 2004.

3 **Republications of amended laws**

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