



Research Involving Human Embryos Act 2002

Act No. 145 of 2002 as amended

This compilation was prepared on 22 December 2008
taking into account amendments up to Act No. 144 of 2008

The text of any of those amendments not in force
on that date is appended in the Notes section

The operation of amendments that have been incorporated may be
affected by application provisions that are set out in the Notes section

[Note: Subsections 21(3)(b), 24(1)(c) and 24(3) are taken to have been
repealed on 5 April 2005, *see* section 46]

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An Act to regulate certain activities involving the use of human embryos, and for related purposes

Part 1—Preliminary

1 Short title *[see Note 1]*

This Act may be cited as the *Research Involving Human Embryos Act 2002*.

2 Commencement

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, on the day or at the time specified in column 2 of the table.

Commencement information		
Column 1	Column 2	Column 3
Provision(s)	Commencement	Date/Details
1. Sections 1 and 2 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent	19 December 2002
2. Sections 3 to 9	The 28th day after the day on which this Act receives the Royal Assent	16 January 2003
3. Sections 10 to 12	At the end of the period of 6 months beginning on the day on which this Act receives the Royal Assent	19 June 2003
4. Sections 13 to 48	The 28th day after the day on which this Act receives the Royal Assent	16 January 2003

Note: This table relates only to the provisions of this Act as originally passed by the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

- (2) Column 3 of the table is for additional information that is not part of this Act. This information may be included in any published version of this Act.

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

4 Operation of Act

- (1) This Act applies as follows:
- (a) to things done, or omitted to be done, by constitutional corporations;
 - (b) to things done, or omitted to be done, in the course of constitutional trade or commerce;
 - (c) to matters within the legislative power of the Commonwealth under paragraph 51(xxix) of the Constitution;
 - (d) to the Commonwealth and Commonwealth authorities;
 - (e) for purposes relating to the collection, compilation, analysis and dissemination of statistics;
 - (f) to matters within the legislative power of the Commonwealth under paragraph 51(xxxix) of the Constitution, so far as it relates to the matters mentioned in paragraphs (a) to (e) of this subsection.

- (2) In this section:

constitutional corporation means a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution.

constitutional trade or commerce means trade or commerce:

- (a) between Australia and places outside Australia; or
- (b) among the States; or
- (c) by way of the supply of services to the Commonwealth or to a Commonwealth authority.

5 Act to bind the Crown

- (1) This Act binds the Crown in each of its capacities.

- (2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.

6 External Territories

This Act extends to every external Territory.

7 Definitions

- (1) In this Act:

Commonwealth authority means the following:

- (a) a body corporate established for a public purpose by or under an Act;
- (b) a company in which a controlling interest is held by any one 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 either of the above subparagraphs.

corresponding State law, in relation to a State, means a law of that State declared by the Minister, by notice in the *Gazette*, to be a corresponding State law for the purposes of this Act.

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.

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

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- (d) an animal egg into which the nucleus of a human cell has been introduced; or
- (e) a thing declared by the regulations to be a hybrid embryo.

inspector means a person appointed as an inspector under subsection 33(1).

NHMRC Licensing Committee means the Committee established by section 13.

spouse, in relation to a person, includes a de facto partner of the person within the meaning of the *Acts Interpretation Act 1901*.

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*.

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* and prescribed by the regulations for the purposes of this paragraph.

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

woman means a female human.

- (2) For the purposes of the definition of **human embryo** in subsection (1), 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.

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- (3) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.
- (4) A reference in this Act to a human egg is a reference to a human oocyte.
- (5) 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.

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

Division 1—Interpretation

8 Definitions [see Note 2]

In this Part:

accredited ART centre means a person or body accredited to carry out assisted reproductive technology by:

- (a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
- (b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires.

AHEC means the Australian Health Ethics Committee established by the *National Health and Medical Research Council Act 1992*.

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 9.

HREC means a Human Research Ethics Committee.

licence means a licence issued under section 21.

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* and prescribed by the regulations for the purposes of this definition.

relevant State body means a person or body notified by a State to the Chairperson of the NHMRC Licensing Committee for the purposes of this Part.

responsible person means: [see Note 2]

- (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.

9 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 of **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

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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

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
 - (b) the use by the person is an exempt use within the meaning of subsection (2).

Maximum penalty: Imprisonment for 5 years.

- (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 by the regulations for the purposes of this paragraph.

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(3) Despite subsection 13.3(3) of the *Criminal Code*, a defendant does not bear an evidential burden in relation to any matter in subsection (1) or (2) of this section.

(4) In subsection (2):

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.

10A Offence—use of other embryos

A person commits an offence if:

- (a) the person intentionally uses an embryo; and
- (b) the embryo is:
 - (i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or
 - (ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons; or
 - (iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or
 - (iv) a hybrid embryo; and
- (c) the use by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 5 years.

Note: The creation or development of embryos mentioned in this section is prohibited under Part 2 of the *Prohibition of Human Cloning for Reproduction Act 2002*, unless authorised by a licence under this Act.

10B Offence—certain activities involving use of human eggs

A person commits an offence if:

- (a) the person undertakes research or training involving the fertilisation of a human egg by a human sperm up to, but not

- including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART; and
- (b) the person is not authorised by a licence to undertake the research or training.

Maximum penalty: Imprisonment for 5 years.

11 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: Imprisonment for 5 years.

12 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: Imprisonment for 5 years.

- (2) In this section:

engage in conduct means:

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

12A Person not liable for conduct purportedly authorised

- (1) To avoid doubt, a person is not criminally responsible for an offence against this Act in respect of particular conduct if:

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- (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

13 Establishment of Committee

- (1) The Embryo Research Licensing Committee of the NHMRC (the *NHMRC Licensing Committee*) is established by this section.
- (2) The NHMRC Licensing Committee is taken to be a Principal Committee within the meaning of the *National Health and Medical Research Council Act 1992*, other than for the purposes of the following provisions of that Act:
 - (a) sections 5D and 5E;
 - (b) section 35;
 - (c) section 41;
 - (d) section 80;
 - (e) subsections 82(1C) and (2).
- (3) This section has effect despite the definition of *Principal Committee* in section 4 of the *National Health and Medical Research Council Act 1992*.
- (4) The regulations may make provision for and in relation to the disclosure of members' interests in matters being considered by the NHMRC Licensing Committee.
- (5) Section 42A of the *National Health and Medical Research Council Act 1992* does not have effect in relation to the NHMRC Licensing Committee at any time when regulations under subsection (4) are in force.

14 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.

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15 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.

16 Membership of Committee

- (1) The NHMRC Licensing Committee consists of the following members:
 - (a) a member of AHEC;
 - (b) a person with expertise in research ethics;
 - (c) a person with expertise in a relevant area of research;
 - (d) a person with expertise in assisted reproductive technology;
 - (e) a person with expertise in a relevant area of law;
 - (f) a person with expertise in consumer health issues relating to disability and disease;
 - (g) a person with expertise in consumer issues relating to assisted reproductive technology;
 - (h) a person with expertise in the regulation of assisted reproductive technology;
 - (i) a person with expertise in embryology.
- (2) The Minister must appoint the members of the NHMRC Licensing Committee.
- (3) Before appointing a member, the Minister must:
 - (a) seek nominations from the States and from such bodies as are prescribed by the regulations for the purpose;
 - (b) consult, and have regard to the views expressed by, the States on the proposed appointment; and
 - (c) be satisfied upon receipt of a written declaration by the member proposed to be appointed that the member proposed does not have a direct or indirect pecuniary interest in a body that undertakes uses of excess ART embryos or human eggs, or creation or uses of other embryos, being an interest of a kind that could conflict with the proper performance of the member's functions.

- (4) The Minister must appoint one of the members, other than the member mentioned in paragraph (1)(a), as the Chairperson of the NHMRC Licensing Committee.
- (5) The Minister must not appoint a person:
 - (a) as the Chairperson under subsection (4); or
 - (b) as the member mentioned in paragraph (1)(h);unless a majority of the States agree with that appointment.
- (6) In appointing the members of the NHMRC Licensing Committee, the Minister must have regard to the desirability of ensuring that the Committee as a whole comprises members from different States.
- (7) It is the intention of the Parliament that any vacancy on the NHMRC Licensing Committee be filled as soon as possible.
- (8) If there is a vacancy in the membership of the NHMRC Licensing Committee for a period of 3 months the Minister must, within 3 sitting days of the expiration of that 3 months, table in each House of the Parliament a written statement of reasons for the failure to fill the vacancy.

17 Terms of appointment

- (1) A member of the NHMRC Licensing Committee holds office on a part-time basis.
- (2) A member holds office for a period not exceeding 3 years that is specified in the instrument of appointment, but is eligible for reappointment.

18 Annual report

- (1) A report under section 83 of the *National Health and Medical Research Council Act 1992* must, in addition to the matters set out in that section, include details relating to the operations of the NHMRC Licensing Committee.
- (2) The NHMRC Licensing Committee must give written details relating to its operations to the CEO of the NHMRC for the purposes of subsection (1).

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19 Reports to Parliament

- (1) The NHMRC Licensing Committee may at any time cause a report about matters relating to the Committee's functions to be tabled in either House of the Parliament.
- (2) The NHMRC Licensing Committee must give a copy of the report to the Minister and to each State.
- (3) The NHMRC Licensing Committee must cause a report to be tabled in either House of Parliament on or before:
 - (a) 30 June of each year; and
 - (b) 31 December of each year; and
 - (c) any other time required by either House of Parliament;that must include information about:
 - (d) the operation of this Act; and
 - (e) the licences issued under this Act.

Division 4—Licensing system

20 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 doubt, paragraphs (1)(a), (b), (c) and (d) do not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.
- (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 by the regulations.

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21 Determination of application by Committee [see Note 1]

- (1) This section applies if a person has made an application under section 20 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 paragraph 24(1)(a)); and
 - (ii) to enable compliance with any restrictions on such consent;
 - (b) if the use of an excess ART embryo proposed in the application may damage or destroy the embryo—that appropriate protocols are in place to enable compliance with the condition that such use is authorised only in respect of an embryo created before 5 April 2002 (see subsection 24(3));
 - (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 CEO of the NHMRC under the *National Health and*

Medical Research Council Act 1992 and prescribed by the regulations for the purposes of this paragraph;

- (d) the HREC assessment of the application mentioned in paragraph (3)(c);
- (e) such additional matters (if any) as are prescribed by the regulations.

22 Notification of decision

- (1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 20 to the following:
 - (a) the applicant;
 - (b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in paragraph 21(3)(c);
 - (c) the relevant State body in relation to the State in which the use is to occur.
- (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 paragraphs (1)(b) and (c).

23 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.

24 Licence is subject to conditions [see Note 1]

- (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

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- (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.
 - (3) If a licence authorises the use of an excess ART embryo that may damage or destroy the embryo, the licence is subject to the condition that such use is authorised only in respect of an embryo created before 5 April 2002.
 - (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), (2) and (3) 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 paragraph (1)(a):
-

- (a) a licence may provide that the guidelines referred to in the definition of *proper consent* apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation; and
- (b) if a licence so provides, the guidelines as modified by the licence have effect in relation to the giving of consent for such creation or use.

Note: For example, the guidelines could apply to a particular licence in a modified form, to alter the cooling-off period required in relation to the use of excess ART embryos that are unsuitable for implantation.

25 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 20 for the licence as varied, the Committee would not have been permitted by this Part to issue the licence.

26 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 or the *Prohibition of Human Cloning Act 2002*, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

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27 Surrender of licence

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

28 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 to which the NHMRC Licensing Committee notified its decision on the application for the licence under section 22.
- (2) The NHMRC Licensing Committee must also notify the bodies mentioned in paragraph (1)(b) if a licence is surrendered.

Division 5—Reporting and confidentiality

29 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, and creations 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.

30 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 Act or under a corresponding State law; and
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not:
 - (i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or

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functions under this Act or under a corresponding State law; 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: Imprisonment for 2 years.

- (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:
 - (i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Act or under a corresponding State law; 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: Imprisonment for 2 years.

- (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) the Crown in right of a State;
- (b) a Minister of a State;
- (c) a State Government department;
- (d) an instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State;
- (e) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:
 - (i) the Crown in right of a State;
 - (ii) a person or body covered by paragraph (b) or (d);

(iii) a person or body covered by either of the above subparagraphs.

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

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Division 6—Review provisions

31 Meaning of terms

In this Division:

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

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

- (a) in relation to a decision under section 21 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 23—the licence holder; or
- (c) in relation to a decision to specify a licence condition under subsection 24(4)—the licence holder; or
- (ca) in relation to a decision to modify guidelines under subsection 24(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 25—the licence holder; or
- (e) in relation to a decision to suspend or revoke a licence under section 26—the person who was the licence holder immediately before the suspension or revocation.

32 Review of decisions

- (1) An eligible person may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee:
 - (a) a decision under section 21 not to issue a licence;
 - (b) a decision in respect of the period throughout which the licence is to be in force under section 23;
 - (c) a decision to specify a licence condition under subsection 24(4);
 - (ca) a decision to modify guidelines under subsection 24(8) in respect of a licence;

- (d) a decision to vary or refuse to vary a licence under section 25;
 - (e) a decision to suspend or revoke a licence under section 26.
- (2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975*.

Part 3—Monitoring powers

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

34 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; 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.

35 Powers available to inspectors for monitoring compliance

- (1) For the purpose of finding out whether this Act or the regulations have been complied with, an inspector may:
 - (a) enter any premises; and
 - (b) exercise the monitoring powers set out in section 36.
- (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 21, and the entry is at a reasonable time; or
 - (c) the entry is made under a warrant under section 37A.

36 Monitoring powers

- (1) The monitoring powers that an inspector may exercise under paragraph 35(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 37A—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.

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- (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 the Act or the regulations.
- (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.

37 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 (whether by the inspector or by another person) to seize it.

37A 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 purposes of finding out whether this Act or the regulations have been complied with.
- (3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.
- (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 36 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.

37B Details of warrant to be given to occupier etc.

- (1) If a warrant under section 37A 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.

37C Announcement before entry

An inspector must, before entering premises under a warrant:

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- (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.

37D Occupier entitled to be present during search

- (1) If a warrant under section 37A 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.

38 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.

39 Consent

- (1) Before obtaining the consent of a person for the purposes of paragraph 35(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.

40 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
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- (b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.
- (2) Compensation is payable out of money appropriated by the Parliament.
- (3) 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.

41 Extended operation of Part

A reference in this Part to this Act includes a reference to the *Prohibition of Human Cloning Act 2002*, and a reference in this Part to the regulations includes a reference to regulations made under the *Prohibition of Human Cloning Act 2002*.

Part 4—Commonwealth/State arrangements

42 Operation of State laws

This Act is not intended to exclude the operation of any law of a State, to the extent that the law of the State is capable of operating concurrently with this Act.

43 Conferral of functions on Commonwealth officers and bodies

- (1) A corresponding State law may confer functions, powers and duties on the following:
 - (a) the NHMRC Licensing Committee;
 - (b) a Commonwealth authority;
 - (c) an officer of the Commonwealth or a Commonwealth authority.
- (2) If a function, power or duty is conferred on a person or body under subsection (1), the person or body may perform the function or duty or exercise the power, as the case requires.
- (3) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:
 - (a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority; or
 - (b) the authorisation would otherwise exceed the legislative power of the Commonwealth.
- (4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on the NHMRC Licensing Committee, a Commonwealth officer or a Commonwealth authority to the extent to which that law:
 - (a) is consistent with subsections (1) and (2); and
 - (b) is capable of operating concurrently with this Act.

44 When duty imposed

- (1) This section applies if a corresponding State law purports to impose a duty on the following:
 - (a) the NHMRC Licensing Committee;
 - (b) a Commonwealth authority;
 - (c) an officer of the Commonwealth or a Commonwealth authority.
- (2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:
 - (a) imposing the duty is within the legislative powers of the State concerned; and
 - (b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 43 to the imposition of the duty by the corresponding State law).
- (3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.
- (4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.
- (5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:
 - (a) is within the legislative power of the Commonwealth; and
 - (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority.
- (6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the NHMRC Licensing

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Committee, a Commonwealth officer or a Commonwealth authority to the extent to which imposing such a duty would:

- (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth body, officer or authority; or
 - (b) otherwise exceed the legislative power of the Commonwealth.
- (7) Subsections (1) to (6) do not limit section 43.

45 Review of certain decisions

- (1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.
- (2) A decision made by the NHMRC Licensing Committee in the performance of a function or the exercise of a power conferred by a corresponding State law is a reviewable State decision for the purposes of this section if:
 - (a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and
 - (b) the decision is declared by the regulations to be a reviewable State decision for the purposes of this section.
- (3) For the purposes of this section, the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

Part 5—Sunset clause, review provision and regulations

Division 1—Repeal

46 Repeal of paragraphs 21(3)(b) and 24(1)(c) and subsection 24(3) [see Note 1]

Paragraphs 21(3)(b) and 24(1)(c) and subsection 24(3) are repealed 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.

Division 2—Review of Act

47 Review of operation of Act

- (1) The CEO of the NHMRC must cause an independent review of the operation of this Act to be undertaken as soon as possible after the second anniversary of the day on which this Act received the Royal Assent.
- (2) The review must be:
 - (a) undertaken by the persons who undertake the Prohibition of Human Cloning Act review; and
 - (b) undertaken concurrently with the Prohibition of Human Cloning Act review.
- (3) The persons undertaking the review must give to the Council of Australian Governments and both Houses of the Parliament a written report of the review. The report must accompany the report of the Prohibition of Human Cloning Act review.
- (4) The persons undertaking the review must consider and report on the scope and operation of this Act 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.
- (5) The report must contain recommendations about amendments (if any) that should be made to this Act, having regard to the matters mentioned in subsection (4).
- (6) The persons undertaking the review must consult:
 - (a) the Commonwealth and the States; and
 - (b) a broad range of persons with expertise in or experience of relevant disciplines;

and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

(7) In this section:

Prohibition of Human Cloning Act review means the review mentioned in section 25 of the *Prohibition of Human Cloning Act 2002*.

47A Further review of operation of Act

- (1) The Minister must cause an independent review of the operation of this Act as amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the **amending Act**) to be undertaken as soon as possible after the third anniversary of the day on which the amending Act received the Royal Assent.
- (2) The review must be:
 - (a) undertaken by the persons who undertake the Prohibition of Human Cloning for Reproduction Act further review; and
 - (b) undertaken concurrently with that Prohibition of Human Cloning for Reproduction Act further review.
- (3) The persons undertaking the review must give the Council of Australian Governments and both Houses of the Parliament a written report of the review before the fourth anniversary of the day on which the amending Act received the Royal Assent.
- (4) The persons undertaking the review must consider and report on the scope and operation of this Act as amended by the amending Act, 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;

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- (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) any National Stem Cell Centre and any national register of donated excess ART embryos;
 - (g) an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;
 - (h) an evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;
 - (i) an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;
 - (j) the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings;
 - (k) the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.
- (5) The report must contain recommendations about amendments that should be made to this Act, having regard to the matters mentioned in subsection (4).
- (6) The persons undertaking the review must consult:
- (a) the Commonwealth and the States; and
 - (b) a broad range of persons with expertise in or experience of relevant disciplines;
- and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.
- (7) In this section:

Prohibition of Human Cloning for Reproduction Act further review means the review mentioned in section 25A of the *Prohibition of Human Cloning for Reproduction Act 2002*.

47B Minister to report to Parliament

- (1) The Minister must prepare a report on the following matters:
 - (a) the establishment of a National Stem Cell Centre and a national register of donated excess ART embryos; and
 - (b) the making of guidelines referred to in this Act, to the extent that those guidelines were not in force on the day on which this Act commenced.
- (2) The report must be completed not later than 6 months after the day on which *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* commenced.
- (3) The Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of that House after the day on which the report was completed.

47C Study of non-blood human tissue based therapies

- (1) The Minister must cause to be prepared a report on the feasibility of establishing a national legislative or regulatory approach for effective governance of non-blood human tissue based therapies.
- (2) The review must be undertaken by persons chosen by the Minister with the agreement of each State.
- (3) The report of the review must contain recommendations for a national legislative or regulatory framework.
- (4) The persons undertaking the review must give to the Council of Australian Governments and both Houses of the Parliament a written report of the review.
- (5) The report must be completed not later than 18 months after the day on which the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* receives the Royal Assent.
- (6) The Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of that House after the day on which the report was completed.

Division 3—Regulations

48 Regulations

- (1) The Governor-General may make regulations prescribing matters:
 - (a) required or permitted by this Act to be prescribed; or
 - (b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.
- (2) Before the Governor-General makes regulations under this Act, the Minister must be satisfied that:
 - (a) the States have been consulted in relation to the proposed regulations; and
 - (b) the proposed regulations have been prepared having regard to views expressed by the States in those consultations.

Table of Acts**Notes to the *Research Involving Human Embryos Act 2002*****Note 1**

The *Research Involving Human Embryos Act 2002* as shown in this compilation comprises Act No. 145, 2002 amended as indicated in the Tables below.

For repealed details of paragraphs 21(3)(b), 24(1)(c) and subsection 24(3), *see* section 46.

For all relevant information pertaining to application, saving or transitional provisions *see* Table A.

Table of Acts

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Research Involving Human Embryos Act 2002</i>	145, 2002	19 Dec 2002	Ss. 3–9 and 13–48: 16 Jan 2003 Ss. 10–12: 19 June 2003 Remainder: Royal Assent	
<i>National Health and Medical Research Council Amendment Act 2006</i>	50, 2006	9 June 2006	Schedule 1: 1 July 2006 Remainder: Royal Assent	—
<i>Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006</i>	172, 2006	12 Dec 2006	Schedules 1–4: 12 June 2007 Remainder: Royal Assent	Sch. 3 (Item 1)
<i>Same-Sex Relationships (Equal Treatment in Commonwealth Laws—General Law Reform) Act 2008</i>	144, 2008	9 Dec 2008	Schedule 9 (item 2): 10 Dec 2008	—

Table of Amendments**Table of Amendments**

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Part 1	
S. 3.....	am. No. 172, 2006
S. 7.....	am. No. 172, 2006; No. 144, 2008
Part 2	
Heading to Part 2.....	rs. No. 172, 2006
Division 1	
S. 8.....	am. Nos. 50 and 172, 2006
Division 2	
Ss. 10A, 10B.....	ad. No. 172, 2006
S. 11.....	am. No. 172, 2006
S. 12A.....	ad. No. 172, 2006
Division 3	
S. 13.....	am. No. 50, 2006
S. 16.....	am. No. 172, 2006
S. 18.....	am. No. 50, 2006
Division 4	
S. 20.....	am. No. 172, 2006
S. 21.....	am. Nos. 50 and 172, 2006
S. 24.....	am. No. 172, 2006
Division 5	
S. 29.....	am. No. 172, 2006
Division 6	
Ss. 31, 32.....	am. No. 172, 2006
Part 3	
Ss. 35–37.....	am. No. 172, 2006
Ss. 37A–37D.....	ad. No. 172, 2006
Part 5	
Division 2	
S. 47.....	am. No. 50, 2006
Ss. 47A–47C.....	ad. No. 172, 2006

Note 2

Note 2

The amendment made by Schedule 2 (item 9) of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (No. 172, 2006) was misdescribed. However, the intention of the amendment was clear and it has been incorporated in this compilation.

Table A

Application, saving or transitional provisions

Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (No. 172, 2006)

Schedule 3

1 Saving provision

(1) If:

- (a) at any time before the commencement of this item, a person made an application under subsection 20(1) of the *Research Involving Human Embryos Act 2002* for a licence; and
- (b) immediately before the commencement of this item, the NHMRC Licensing Committee had not decided the application;

then the person is taken, on and from the commencement of this item, to have applied for the licence under subsection 20(1) of the amended Act.

(2) To avoid doubt, a licence issued under section 21 of the *Research Involving Human Embryos Act 2002* that was in force immediately before the commencement of this item continues in force after that commencement.

(3) In this item:

amended Act means the *Research Involving Human Embryos Act 2002* as amended by this Act.