



Prohibition of Human Cloning for Reproduction Act 2002

Act No. 144 of 2002 as amended

This compilation was prepared on 12 June 2007
taking into account amendments up to Act No. 172 of 2006

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

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An Act to prohibit human cloning for reproduction and other unacceptable practices associated with reproductive technology, and for related purposes

Part 1—Preliminary

1 Short title [see Note 1]

This Act may be cited as the *Prohibition of Human Cloning for Reproduction 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 26 and Schedule 1	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

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reproduction and the utilisation of human embryos by prohibiting certain practices.

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 Schedule

The *Gene Technology Act 2000* is amended as set out in item 1 of Schedule 1.

8 Definitions

(1) In this Act:

animal does not include a human.

chimeric embryo means:

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

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.

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.

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;

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and has not yet reached 8 weeks of development since the first mitotic division.

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

human sperm includes human spermatids.

hybrid embryo means:

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

licence means a licence issued under section 21 of the *Research Involving Human Embryos Act 2002*.

NHMRC Licensing Committee means the Committee established under section 13 of the *Research Involving Human Embryos Act 2002*.

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

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

State includes the Australian Capital Territory and the Northern Territory.

woman means a female human.

- (2) For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human:
 - (a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and

- (b) it is not necessary to establish that the copy is an identical genetic copy.
- (3) For the purposes of the definition 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.
- (4) For the purposes of the definition of *human embryo clone* in subsection (1), a human embryo that results from the technological process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by human sperm.
- (5) 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 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.
- (6) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.
- (7) A reference in this Act to a human egg is a reference to a human oocyte.
- (8) A reference in this Act to a human embryo does not include a reference to:
- (a) a hybrid embryo; or
 - (b) a human embryonic stem cell line.

Part 2 Prohibited practices

Division 1 Practices that are completely prohibited

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Part 2—Prohibited practices

Division 1—Practices that are completely prohibited

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

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

Maximum penalty: Imprisonment for 15 years.

Note: The development of a human embryo (including a human embryo clone) outside the body of a woman for more than 14 days is prohibited by section 14.

10 Offence—importing or exporting a human embryo clone

- (1) A person commits an offence if the person intentionally imports a human embryo clone into Australia.

Maximum penalty: Imprisonment for 15 years.

- (2) A person commits an offence if the person intentionally exports a human embryo clone from Australia.

Maximum penalty: Imprisonment for 15 years.

11 No defence that human embryo clone could not survive

It is not a defence to an offence under section 9 or 10 that the human embryo clone did not survive or could not have survived.

12 Offence—creating a human embryo for a purpose other than achieving pregnancy in a woman

- (1) A person commits an offence if the person intentionally creates a human embryo by a process of the fertilisation of a human egg by a human sperm outside the body of a woman, unless the person's intention in creating the embryo is to attempt to achieve pregnancy in a particular woman.

Maximum penalty: Imprisonment for 15 years.

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

13 Offence—creating or developing a human embryo by fertilisation that contains genetic material provided by more than 2 persons

A person commits an offence if:

- (a) the person intentionally creates or develops a human embryo by a process of the fertilisation of a human egg by a human sperm outside the body of a woman; and
- (b) the human embryo contains genetic material provided by more than 2 persons.

Maximum penalty: Imprisonment for 15 years.

14 Offence—developing a human embryo outside the body of a woman for more than 14 days

A person commits an offence if the person intentionally develops a human embryo outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended.

Maximum penalty: Imprisonment for 15 years.

15 Offence—heritable alterations to genome

- (1) A person commits an offence if:
- (a) the person alters the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and
 - (b) in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.

Maximum penalty: Imprisonment for 15 years.

Part 2 Prohibited practices

Division 1 Practices that are completely prohibited

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(2) In this section:

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

16 Offence—collecting a viable human embryo from the body of a woman

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

Maximum penalty: Imprisonment for 15 years.

17 Offence—creating a chimeric embryo

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

Maximum penalty: Imprisonment for 15 years.

18 Offence—developing a hybrid embryo

A person commits an offence if the person intentionally develops a hybrid embryo for a period of more than 14 days, excluding any period when development is suspended.

Maximum penalty: Imprisonment for 15 years.

19 Offence—placing of an embryo

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

20 Offence—importing, exporting or placing a prohibited embryo

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

- (4) In this section:

prohibited embryo means:

- (a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or
- (b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman; or
- (c) a human embryo that contains genetic material provided by more than 2 persons; or
- (d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or
- (e) a human embryo created using precursor cells taken from a human embryo or a human fetus; or
- (f) a human embryo that contains a human cell (within the meaning of section 15) whose genome has been altered in

Part 2 Prohibited practices

Division 1 Practices that are completely prohibited

Section 21

such a way that the alteration is heritable by human descendants of the human whose cell was altered; or

- (g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or
- (h) a chimeric embryo or a hybrid embryo.

21 Offence—commercial trading in human eggs, human sperm or human embryos

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

Maximum penalty: Imprisonment for 15 years.

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

Maximum penalty: Imprisonment for 15 years.

- (3) In this section:

reasonable expenses:

- (a) in relation to the supply of a human egg or human sperm—includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and
- (b) in relation to the supply of a human embryo:
 - (i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and
 - (ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo.

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

Division 2—Practices that are prohibited unless authorised by a licence

22 Offence—creating a human embryo other than by fertilisation, or developing such an embryo

A person commits an offence if:

- (a) the person intentionally creates a human embryo by a process other than the fertilisation of a human egg by a human sperm, or develops a human embryo so created; and
- (b) the creation or development of the human embryo by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 10 years.

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

Note 2: The placement in the body of a woman of a human embryo clone, or any other human embryo created other than by the fertilisation of a human egg by a human sperm, is prohibited by sections 9 and 20.

23 Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons

A person commits an offence if:

- (a) the person intentionally creates or develops a human embryo by a process other than the fertilisation of a human egg by a human sperm; and
- (b) the human embryo contains genetic material provided by more than 2 persons; and
- (c) the creation or development of the human embryo by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 10 years.

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

Note 2: The placement in the body of a woman of a human embryo created other than by the fertilisation of a human egg by a human sperm is prohibited by section 20.

Part 2 Prohibited practices

Division 2 Practices that are prohibited unless authorised by a licence

Section 23A

23A Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo

A person commits an offence if:

- (a) the person uses precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or intentionally develops an embryo so created; and
- (b) the person engages in activities mentioned in paragraph (a) without being authorised by a licence, and the person knows or is reckless as to that fact.

Maximum penalty: Imprisonment for 10 years.

23B Offence—creating a hybrid embryo

- (1) A person commits an offence if the person intentionally creates a hybrid embryo.
- (2) A person commits an offence if the person intentionally develops a hybrid embryo.
- (3) A person does not commit an offence against subsection (1) or (2) if the creation or development of the hybrid embryo by the person is authorised by a licence.

Maximum penalty: Imprisonment for 10 years.

Note: A licence to create or develop a hybrid embryo can only be issued under section 21 of the *Research Involving Human Embryos Act 2002*:

- (a) for the purposes of testing sperm quality in an accredited ART centre—up to, but not including, the first mitotic division; or
- (b) in the case of hybrid embryo created by introducing the nucleus of a human cell into an animal egg—for not longer than 14 days.

23C Regulations under Customs Act

The Minister who administers the *Customs Act 1901* must take all reasonable steps to ensure that regulations are made, within 6 months after the commencement of this section, permitting, subject to appropriate conditions or restrictions, the import and export of human embryonic stem cell lines which have been derived from human embryo clones using practices consistent with Australian legislation.

Part 3—Commonwealth/State arrangements

24 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.

Part 4—Review provision and regulations

Division 1—Review of Act

25 Review of operation of Act

- (1) The Minister 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 is to be undertaken by persons chosen by the Minister, with the agreement of each State.
- (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 third anniversary of the day on which this Act received the Royal Assent.
- (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 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.

25A 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 is to be undertaken by persons chosen by the Minister, with the agreement of each State.
- (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;
 - (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;

Part 4 Review provision and regulations

Division 1 Review of Act

Section 25A

- (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.

Division 2—Regulations

26 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.

Schedule 1—Consequential amendment

Gene Technology Act 2000

1 Sections 192B, 192C and 192D

Repeal the sections.

Table of Acts**Notes to the *Prohibition of Human Cloning for Reproduction Act 2002*****Note 1**

The *Prohibition of Human Cloning for Reproduction Act 2002* as shown in this compilation comprises Act No. 144, 2002 amended as indicated in the Tables below.

Table of Acts

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Prohibition of Human Cloning Act 2002</i>	144, 2002	19 Dec 2002	Ss. 3–26 and Schedule 1: 16 Jan 2003 Remainder: Royal Assent	
<i>Statute Law Revision Act 2005</i>	100, 2005	6 July 2005	Schedule 1 (item 39): (a)	—
<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	—

Act Notes

(a) Subsection 2(1) (item 22) of the *Statute Law Revision Act 2005* provides as follows:

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provision(s)	Commencement	Date/Details
22. Schedule 1, item 39	Immediately after the commencement of section 8 of the <i>Prohibition of Human Cloning Act 2002</i> .	16 January 2003

Table of Amendments**Table of Amendments**

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

Provision affected	How affected
Title	am. No. 172, 2006
Part 1	
S. 1	am. No. 172, 2006
S. 8	am. No. 100, 2005; No. 172, 2006
Part 2	
Part 2	rs. No. 172, 2006
Division 1	
Ss. 9–21	rs. No. 172, 2006
Division 2	
Ss. 22, 23	rs. No. 172, 2006
Ss. 23A–23C	ad. No. 172, 2006
Part 4	
Division 1	
S. 25A	ad. No. 172, 2006