# Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003

Act No. 11/2003

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The Parliament of Victoria enacts as follows:

PART 1—PRELIMINARY

1. Purpose

The purpose of this Act is to amend the Infertility Treatment Act 1995 so as to make fresh provision for—

(a) the regulation of certain activities involving the use of human embryos; and
Part 1—Preliminary

(b) the prohibition of human cloning and certain other practices associated with reproductive technology.

2. Commencement

This Act comes into operation on a day or days to be proclaimed.

3. Principal Act

In this Act, the Infertility Treatment Act 1995 is called the Principal Act.

4. Purposes of Principal Act

In section 1 of the Principal Act—

(a) after paragraph (b) insert—

"(ba) to regulate certain activities involving the use of human embryos;

(bb) to prohibit human cloning and certain other practices associated with reproductive technology;";

(b) in paragraph (c) omit ", zygotes";
(c) after paragraph (f) insert—

"(fa) to confer functions on the Embryo Research Licensing Committee of the National Health and Medical Research Council;".

5. **Definitions and interpretation**

(1) In section 3(1) of the Principal Act, **insert** the following definitions—

"**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 declares by the regulations to be a chimeric embryo;

"**Commonwealth Act**" means the Research Involving Human Embryos Act 2002 of the Commonwealth;

"**Commonwealth authority**" means the following—

(a) a body corporate established for a public purpose by or under a Commonwealth 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 sub-paragraph (i) or (ii);
"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;

"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;

"inspector" means a person appointed as an inspector under section 33(1) of the Commonwealth Act;

"NHMRC Licensing Committee" means the Committee established by section 13 of the Commonwealth Act;

"oocyte in the process of fertilisation" means an oocyte at any stage of human development from the commencement of penetration of the oocyte by human sperm up to but not including the appearance of 2 pro-nuclei;
"precursor cell" means a cell that has the potential to develop into a human egg or human sperm;

"the NHMRC" means the National Health and Medical Research Council established by the National Health and Medical Research Council Act 1992 of the Commonwealth;

"woman" means a female human.'.

(2) In section 3(1) of the Principal Act—

(a) the definitions of "clone", "donor zygote", "embryo", "parthenogenesis", "parthenogenetic oocyte", "syngamy" and "zygote" are repealed;

(b) in the definition of "donor treatment procedure" omit "or a donor zygote";

(c) in the definition of "fertilisation procedure", paragraph (a) is repealed;

(d) in the definition of "oocyte", omit "but does not include a parthenogenetic oocyte";

(e) in the definition of "research"—

(i) at the end of paragraph (a) omit "and";

(ii) paragraph (b) is repealed;

(f) in the definition of "store", omit "zygote," (where twice occurring).

(3) In section 3 of the Principal Act, after sub-section (1) insert—

'(1A) 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.

(1B) For the purposes of the definition of "human embryo" in sub-section (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.

(1C) For the purposes of the definition of "human embryo clone" in sub-section (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.

(1D) In this Act, a reference to an embryo is a reference to a human embryo, unless the contrary intention appears.

(4) In section 4(1) of the Principal Act—

(a) in paragraph (f), for "a zygote or" substitute "an";

(b) in paragraph (g), omit ", zygote" (where twice occurring).

6. New section 5A inserted

After section 5 of the Principal Act insert—

"5A. Act to bind the Crown

(1) This Act binds the Crown, not only in right of the State of Victoria, but also, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

(2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.".
PART 2—EXCESS EMBRYOS

7. New Part 2A inserted

After Part 2 of the Principal Act insert—

'PART 2A—REGULATION OF CERTAIN USES INVOLVING EXCESS ART EMBRYOS

Division 1—Interpretation

21A. Definitions

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 of the Commonwealth;

"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 21B;

"HREC" means a Human Research Ethics Committee;

"licence" means a licence issued under section 21I;

"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 of the Commonwealth and prescribed by the regulations under the Commonwealth Act for the purposes of paragraph (b) of the definition of "proper consent" in section 8 of that Act—consent obtained in accordance with those other guidelines, rather than the guidelines mentioned in paragraph (a);

"responsible person", in relation to an excess ART embryo, means—

(a) each person who provided the egg or sperm from which the embryo was created; and
Part 2—Excess Embryos

(b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and

c) any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and

d) any person who was the spouse of the woman mentioned in paragraph (b) at the time the embryo was created.

21B. 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 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

21C. 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 sub-section (3).

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.

(3) A use of an excess ART embryo by a person is an exempt use for the purposes of sub-section (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.

(4) Despite section 130(1) of the Magistrates' Court Act 1989, a defendant does not bear a burden of presenting or pointing to evidence in accordance with that section in relation to any matter in sub-section (1) or (3) of this section.

(5) In sub-section (3)—

"diagnostic investigation", in relation to an excess ART embryo, means any procedure undertaken on embryos for
Part 2—Excess Embryos

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.

21D. Offence—use of embryo that is not an excess ART embryo

(1) A person commits an offence if—

(a) the person intentionally uses, outside the body of a woman, a human embryo 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.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.

21E. 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.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.
(3) In this section—

"engage in conduct" means—

(a) do an act; or

(b) omit to perform an act.

Division 3—Embryo Research Licensing Committee of the NHMRC

21F. Functions of Committee

The functions of the NHMRC Licensing Committee under this Part 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 Part or any other law.

21G. Powers of Committee

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

Division 4—Licensing System

21H. Person may apply for licence

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

(2) An application under sub-section (1)—

(a) must be made in accordance with the requirements (if any) specified in
Part 2—Excess Embryos

writing by the NHMRC Licensing Committee; and

(b) must be accompanied by the fee (if any) prescribed by the regulations.

21I. Determination of application by Committee

(1) This section applies if a person has made an application under section 21H 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 is used under the licence; 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;

(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
Part 2—Excess Embryos

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 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 proposed in the application, which could not reasonably be achieved by other means;

(c) any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC under the National Health and Medical Research Council Act 1992 of the Commonwealth and prescribed by the regulations under the Commonwealth Act for the purposes of section 21(4)(c) of that Act;

(d) the HREC assessment of the application mentioned in sub-section (3)(c);

(e) such additional matters (if any) as are prescribed by the regulations.

21J. Notification of decision

(1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 21H to the following—

(a) the applicant;
(b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in section 21I(3)(c);

(c) the Authority.

(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 sub-section (1)(b) and (c).

21K. **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.

21L. **Licence is subject to conditions**

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

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

(b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject; and
(c) if the licence authorises use of an excess ART embryo that may damage or destroy the embryo—the licence holder must have reported in writing to the NHMRC Licensing Committee that the embryo was created before 5 April 2002.

(2) A licence is subject to the condition that the use of an excess ART embryo must be in accordance with any restrictions to which the proper consent under sub-section (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;

(b) the number of excess ART embryos in respect of which use is authorised by 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.
(6) The licence conditions set out in sub-sections (1), (2) and (3) apply to all persons who are authorised by the licence to use excess ART 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 as are specified in the licence.

21M. 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 sub-section (1) on its own initiative or on application by the licence holder.

(3) Without limiting sub-section (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 21H for the licence as varied, the Committee would not have been permitted by this Part to issue the licence.

21N. 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 Part or Part 4A or under the Commonwealth Act or the Prohibition of Human Cloning Act 2002 of the Commonwealth, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

21O. Surrender of licence

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

21P. 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

(c) the Authority.

(2) The NHMRC Licensing Committee must also notify the HREC and the Authority if a licence is surrendered.

Division 5—Reporting and Confidentiality

21Q. 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)—
Part 2—Excess Embryos

(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 that are authorised by the licence;

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

(d) the number of excess ART embryos in respect of which use is authorised by 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 sub-section (1) must not be such as to disclose confidential commercial information.

21R. **Confidential commercial information may only be disclosed in certain circumstances**

(1) A person commits an offence if—

(a) the person discloses confidential commercial information that the person has only because of performing duties or functions under this Part or the Commonwealth Act; and

(b) the person knows that the information is confidential commercial information; and
(c) the disclosure is not—
   
   (i) to a State agency, the Commonwealth or a Commonwealth authority in the course of carrying out duties or functions under this Part or the Commonwealth Act; 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.

(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 sub-section (1) or this sub-section; and

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

   (c) the disclosure is not—

   (i) to a State agency, the Commonwealth or a Commonwealth authority in the course of carrying out duties or functions under this Part or the Commonwealth Act; 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.
(3) An offence against sub-section (1) or (2) is punishable by imprisonment for a term not exceeding 2 years.

(4) 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 the State;
(b) a Minister of the State;
(c) a State Government department;
(d) the Authority or any other instrumentality of the State, including a body corporate established for a public purpose by or under a law of the 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 the State;
(ii) a person or body covered by paragraph (b) or (d);
(iii) a person or body covered by either sub-paragraph (i) or (ii).

Note: For the definition of confidential commercial information, see section 21A.
Division 6—Review provisions

21S. Meaning of terms

In this Division—

"Administrative Appeals Tribunal" means the Administrative Appeals Tribunal established by the Administrative Appeals Tribunal Act 1975 of the Commonwealth;

"decision" has the same meaning as in the Administrative Appeals Tribunal Act 1975 of the Commonwealth;

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

(a) in relation to a decision under section 21I 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 21K—the licence holder; or

(c) in relation to a decision to specify a licence condition under section 21L(4)—the licence holder; or

(d) in relation to a decision to vary or refuse to vary a licence under section 21M—the licence holder; or

(e) in relation to a decision to suspend or revoke a licence under section 21N—the person who was the licence holder immediately
21T. 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 21I not to issue a licence;

(b) a decision in respect of the period throughout which the licence is to be in force under section 21K;

(c) a decision to specify a licence condition under section 21L(4);

(d) a decision to vary or refuse to vary a licence under section 21M;

(e) a decision to suspend or revoke a licence under section 21N.

(2) This section has effect subject to the Administrative Appeals Tribunal Act 1975 of the Commonwealth.

Division 7—Monitoring Powers

21U. Powers available to inspectors for monitoring compliance

(1) For the purpose of finding out whether this Part or the regulations made for the purposes of this Part have been complied with, an inspector may—

(a) enter any premises; and

(b) exercise the monitoring powers set out in section 21V.
(2) An inspector is not authorised to enter premises under sub-section (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 21I, and the entry is at a reasonable time.

21V. Monitoring powers

(1) The monitoring powers that an inspector may exercise under section 21U(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 or thing on the premises that relates to this Part;

(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.
(2) For the purposes of this Part, monitoring powers include the power to operate equipment at premises to see whether—

(a) the equipment; or

(b) a disk, tape or other storage device that—

(i) is at the premises; and

(ii) can be used with the equipment or is associated with it—

contains information that is relevant to determining whether there has been compliance with this Part or the regulations made for the purposes of this Part.

(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 sub-section (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.

21W. **Power to secure**

If an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a human embryo or a thing that may afford evidence of the commission of an offence against this Part, the monitoring powers include securing the embryo or thing pending the obtaining of a warrant (whether by the inspector or by another person) to seize it.

21X. **Inspector must produce identity card on request**

(1) 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.

(2) In this section "identity card" means identity card issued under section 34(1) of the Commonwealth Act.

21Y. **Consent**

(1) Before obtaining the consent of a person for the purposes of section 21U(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.
21Z. Compensation for damage

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

(a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this Part; and

(b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.

(2) Compensation is payable by the NHMRC Licensing Committee.

(3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and the occupier's 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.'.

8. New Division 5 inserted in Part 3

In Part 3 of the Principal Act, after Division 4 insert—

'Division 5—Application of Part

35A. Meaning of "research" in this Part

(1) In this Part, "research", in relation to an excess ART embryo within the meaning of Part 2A, does not include a use of the embryo for which a licence is required under that Part.
(2) Research comprised of a use of an excess ART embryo within the meaning of Part 2A for which a licence is required under that Part may only be carried out in accordance with that Part.'.
PART 3—OFFENCES

9. New Part 4A inserted

After Part 4 of the Principal Act insert—

"PART 4A—PROHIBITED PRACTICES"

Division 1—Human Cloning

38A. Offence—creating a human embryo clone

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

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 15 years.

38B. Offence—placing a human embryo clone in the human body or the body of an animal

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

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 15 years.

38C. Offence—importing or exporting a human embryo clone

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

(2) A person commits an offence if the person intentionally exports a human embryo clone from Victoria.
(3) An offence against sub-section (1) or (2) is an indictable offence punishable by imprisonment for a term not exceeding 15 years.

38D. **No defence that human embryo clone could not survive**

It is not a defence to an offence under section 38A, 38B or 38C that the human embryo clone did not survive or could not have survived.

**Division 2—Other Prohibited Practices**

38E. **Offence—creating a human embryo other than by fertilisation, or developing such an embryo**

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

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38F. **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 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.
Part 3—Offences

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

(3) Despite section 130(1) of the Magistrates' Court Act 1989, a defendant does not bear a burden of presenting or pointing to evidence in accordance with that section in relation to any matter in sub-section (1) of this section.

38G. Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons

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

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38H. Offence—developing a human embryo outside the body of a woman for more than 14 days

(1) 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.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.
38I. **Offence—using precursor cells from a human embryo or a human foetus to create a human embryo, or developing such an embryo**

(1) A person commits an offence if the person uses precursor cells taken from a human embryo or a human foetus, intending to create a human embryo, or intentionally develops an embryo so created.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38J. **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.

(2) In this section—

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

(3) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.
38K. **Offence—collecting a viable human embryo from the body of a woman**

(1) 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.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38L. **Offence—creating a chimeric or hybrid embryo**

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

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

(3) An offence against sub-section (1) or (2) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38M. **Offence—placing of an embryo**

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

(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.

(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.
(4) An offence against sub-section (1), (2) or (3) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38N. **Offence—importing, exporting or placing a prohibited embryo**

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

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

(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.

(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
Part 3—Offences

(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 using precursor cells taken from a human embryo or a human foetus; or

(f) a human embryo that contains a human cell (within the meaning of section 38J) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or

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

(h) a chimeric embryo or a hybrid embryo.

(5) An offence against sub-section (1), (2) or (3) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.

38O. 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.

(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.

(3) In this section—

"reasonable expenses"—

(a) in relation to the supply of a human egg or human sperm—
includes, but is not limited to,
expenses relating to the collection,
storage or transport of the egg or sperm; and

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

(i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo within the meaning of Part 2A; 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.

(4) An offence against sub-section (1) or (2) is an indictable offence punishable by imprisonment for a term not exceeding 10 years.'.
10. Amendment of Part 5

(1) For the heading to Part 5 of the Principal Act substitute—

"PART 5—OTHER MISCELLANEOUS OFFENCES".

(2) Sections 39, 42, 44, 45, 46(1)(c) and (2), 47, 48, 49 and 57 of the Principal Act are repealed.

11. New section 38P inserted

In Division 1 of Part 5 of the Principal Act, after the heading to the Division insert—

'38P. Application of Division

In this Division—

(a) "embryo" does not include an excess ART embryo within the meaning of Part 2A; and

(b) "research" does not include a use of an excess ART embryo for which a licence is required under that Part."

12. New section 50A inserted

In Division 2 of Part 5 of the Principal Act, before section 51 insert—

'50A. Application of Division

In this Division—

(a) "embryo" does not include an excess ART embryo within the meaning of Part 2A; and

(b) "research" does not include a use of an excess ART embryo for which a licence is required under that Part."
PART 4—MISCELLANEOUS

13. Register to be kept for licensed centre

In section 62(2) of the Principal Act, after paragraph (b) insert—

"(ba) any human embryo that becomes an excess ART embryo within the meaning of Part 2A;".

14. New section 104A inserted

In Division 5 of Part 8 of the Principal Act, before section 105 insert—

'104A. Application of Part

In this Part—

(a) "embryo" does not include an excess ART embryo within the meaning of Part 2A; and

(b) "research" does not include a use of an excess ART embryo for which a licence is required under that Part.'.

15. New section 110A inserted

After section 110 of the Principal Act insert—

"110A. Formation of embryos

(1) A person who is not a doctor or scientist who has been approved under this Part for the purpose of forming embryos outside the body of a woman must not knowingly or recklessly form or attempt to form an embryo outside the body of a woman.

Penalty: 480 penalty units or 4 years imprisonment or both.
(2) A person must not knowingly or recklessly form or attempt to form an embryo outside the body of a woman, except at a place licensed for the purpose under this Part.

Penalty: 480 penalty units or 4 years imprisonment or both.

16. Infertility Treatment Authority

(1) In section 122(1)(b) of the Principal Act—

(a) for "this Act" (where first occurring) substitute "Part 8";

(b) for "this Act" (where secondly occurring) substitute "that Part or section 56".

(2) In section 122(1)(f)(i) of the Principal Act, after "Act" insert ", other than Part 2A".

(3) In section 122(2)(b) of the Principal Act, for "this Act" substitute "Part 8 or section 56".

(4) In section 122 of the Principal Act, after subsection (4) insert—

'(5) In this section "embryos" does not include excess ART embryos within the meaning of Part 2A.'.

(5) In section 137 of the Principal Act, after subsection (1) insert—

'(1A) In sub-section (1)—

(a) "embryos" does not include excess ART embryos within the meaning of Part 2A; and

(b) "research" does not include a use of an excess ART embryo for which a licence is required under that Part.'.
17. **Search warrants**

In section 162(1) and (3)(a) of the Principal Act, for "this Act or the regulations" **substitute** "this Act (other than Part 2A) or the regulations (other than the regulations made for the purposes of Part 2A)".

18. **Indictable offences**

(1) In section 163(1) of the Principal Act—
   
   (a) **omit** "or (2)";
   
   (b) **omit** "39, 45, 47, 49,";
   
   (c) for "or 54" **substitute** ", 54 or 110A".

(2) In section 163 of the Principal Act, after sub-section (2) **insert**—

"(3) Offences that are indictable offences by force of this section are additional to any other offence that is expressed by this Act as being an indictable offence.".

19. **Amendment of heading to Part 14**

In the heading to Part 14 of the Principal Act, for "REPEALS, AMENDMENTS" **substitute** "REVIEW".

20. **New Division 1 substituted in Part 14**

For Division 1 of Part 14 of the Principal Act **substitute**—

"Division 1—Review of Parts 2A and 4A

166. **Review of operation of Parts 2A and 4A**

(1) The NHMRC must cause an independent review of the operation of—

(a) Part 2A to be undertaken as soon as possible after the second anniversary of
the day on which the Commonwealth Act received the Royal Assent; and

(b) Part 4A to be undertaken as soon as possible after the second anniversary of the day on which the Prohibition of Human Cloning Act 2002 of the Commonwealth received the Royal Assent.

(2) The review is to be undertaken by persons chosen by the NHMRC, with the agreement of the Minister.

(3) The persons undertaking the review must give the Minister a written report of the review before the third anniversary of the day on which the relevant Commonwealth Act received the Royal Assent.

(4) The persons undertaking the review must consider and report on the scope and operation of Parts 2A and 4A 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 sub-section (4).
(6) The persons undertaking the review must consult—

(a) the State and the Commonwealth; and

(b) a broad range of persons with expertise in or experience of relevant disciplines—

and the views of the State, the Commonwealth 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) The Minister must cause a copy of the report to be laid before each House of the Parliament as soon as practicable after he or she receives it.

21. New Division 3 inserted in Part 14

After Division 2 of Part 14 of the Principal Act insert—

'Division 3—Savings and Transitional Provisions (2003 Act)

200. Definition

In this Division, "the amending Act" means the Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003.

201. Status of certain licences and approvals

A licence or approval under Part 8, that is in force immediately before the commencement of section 7 of the amending Act, ceases to have effect by force of this sub-section on and from that commencement to the extent to which it relates to a use of an excess ART
embryo within the meaning of Part 2A for which a licence is required under that Part.

202. Regulations

The regulations may contain provisions of a savings or transitional nature consequent to—

(a) the coming into operation of any provision of the amending Act;
(b) the repeal of any provision of this Act by the amending Act;
(c) the coming into operation of a regulation under this Act as amended by any provision of the amending Act.

203. General transitional provision

(1) Subject to sub-section (2), this Division does not affect or take away from the operation of the Interpretation of Legislation Act 1984.

(2) If a provision of this Division, or a regulation made under this Division, is inconsistent with a provision of the Interpretation of Legislation Act 1984, the provision of this Division or the regulation (as the case requires) prevails.'.

22. Consequential amendments

(1) In Part 2 of the Principal Act—

(a) insert the following heading to section 12—
"Donation of gametes or embryos";

(b) in section 12(3) and (4)—

(i) for "A zygote or embryo" substitute "An embryo";
(ii) for "the zygote or embryo" (wherever occurring) substitute "the embryo";
(iii) for "a zygote or embryo" (wherever occurring) substitute "an embryo";

(c) in section 12(5)—

(i) for "A zygote or embryo" substitute "An embryo";

(ii) for "the zygote or embryo" substitute "the embryo";

(d) in section 13(1), omit ", zygote,";

(e) in section 13(4), omit "zygote or";

(f) in section 14(1)(b) and (2), omit ", zygote";

(g) in section 14(4)—

(i) for "a zygote or embryo" substitute "an embryo";

(ii) for "the zygote or embryo" substitute "the embryo";

(h) in section 15(1), (2) and (4), omit ", zygote" (wherever occurring);

(i) in section 17(a), omit ", zygotes";

(j) in section 18(1)—

(i) omit ", a zygote";

(ii) in paragraph (e), omit ", zygotes";

(k) in section 19(1)(b), omit ", zygote";

(l) in section 19(3)—

(i) omit "a zygote or";

(ii) omit "zygote or";

(m) in section 20(1), (2) and (3)—

(i) for "a zygote or embryo" substitute "an embryo";

(ii) omit "a zygote or" (where secondly and thirdly occurring).
(2) In Part 3 of the Principal Act—

(a) for section 22(1)(a) and (b) substitute—

"(a) carry out research, outside the body of a woman, involving the formation or use of an oocyte in the process of fertilisation; or

(b) carry out research, outside the body of a woman, involving an embryo—";

(b) section 22(2) is repealed;

(c) in section 22(3), omit "or (2)";

(d) insert the following heading to section 24—

"Ban on destructive research on non-excess ART embryos";

(e) insert the following heading to section 25—

"Authority must not approve destructive research on non-excess ART embryos";

(f) insert the following heading to section 26—

"Authority must not approve certain research on oocytes in the process of fertilisation";

(g) in section 26—

(i) for "a zygote" substitute "an oocyte in the process of fertilisation";

(ii) for "zygote continue to develop to syngamy" substitute "oocyte continue to develop into a human embryo";

(h) for the heading to Division 2 substitute

"Division 2—Preliminary Requirements for Research Involving Embryos";

(i) insert the following heading to section 27—

"Consent to research involving embryos";
(j) in section 27—
   (i) sub-section (1) is **repealed**;
   (ii) in sub-section (2)—
      (A) **omit "a zygote or"**;
      (B) in paragraph (a), **omit "zygote or"**;
      (C) paragraph (b) is **repealed**;
      (D) in paragraph (c), **omit "zygote or"** (where twice occurring);

(k) in section 28(1), **omit ", zygote"**;

(l) in section 29(1), **omit ", zygote"** (where 
twice occurring);

(m) in section 30, **omit ", zygote"** (wherever 
occuring);

(n) in section 32(1)(a), **omit ", zygotes"**;

(o) Division 3 is **repealed**;

(p) in section 34, **omit "or (2)"**.

(3) In Part 4 of the Principal Act—
   (a) in section 37(3)(b), **omit ", zygote"**;
   (b) in section 38(2), **omit "donor zygote or"**.

(4) In Part 5 of the Principal Act—
   (a) **insert** the following heading to section 40—
       "Transfer of gametes or embryos used for research";
   (b) in section 40(1)—
      (i) in paragraph (a), **omit "or zygote"**;
      (ii) in paragraph (b), **omit "zygote or"**;
      (iii) paragraph (c) is **repealed**;
   (c) in section 41(b), **omit "a zygote or"**;
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Part 4—Miscellaneous

(d) in section 43—
   (i) in paragraph (b), for "dead; or"
       substitute "dead.";
   (ii) paragraphs (d) and (e) are repealed;

(e) insert the following heading to section 46—
   "Ban on certain procedures";

(f) in section 46(1)(b)—
   (i) omit "zygote or" (where twice occurring);
   (ii) for "people; or" substitute "people.";

(g) in section 50(1)(a), omit ", zygote";

(h) insert the following heading to section 52—
   "Storing embryos";

(i) in section 52(1), omit "a zygote or";

(j) for section 52(2)(a) substitute—
    "(a) it is intended to transfer the embryo to
    the body of a woman in a treatment
    procedure in accordance with this Act;
    and";

(k) in section 52(2)(b)—
   (i) omit "zygote or";
   (ii) omit "use or";

(l) in section 52(3)(b), omit "zygote or";

(m) in section 52(4) and (5), for "a zygote or embryo" substitute "an embryo";

(n) insert the following heading to section 53—
    "Removal of embryos from storage";
(o) in section 53(1)—
   (i) **omit** "a zygote or" (where twice occurring);
   (ii) in paragraphs (c) and (d), **omit** "zygote or";

(p) in section 53(2)—
   (i) for "a zygote or embryo" **substitute** "an embryo";
   (ii) for "the zygote or embryo" **substitute** "the embryo";

(q) in section 54—
   (i) in paragraph (a), for "a zygote or embryo" **substitute** "an embryo";
   (ii) in paragraph (c), **omit** "a zygote or";

(r) **insert** the following heading to section 55—
   "Ban on use of gametes or embryos not stored at licensed centre";

(s) in section 55—
   (i) **omit** ", zygote" (wherever occurring);
   (ii) in paragraph (b), for "zygote or gamete; or" **substitute** "gamete.";
   (iii) paragraph (c) is **repealed**;

(t) **insert** the following heading to section 56—
   "Import or export of gametes and embryos";

(u) in section 56—
   (i) in sub-section (1), **omit** ", zygote" (where twice occurring);
   (ii) in sub-section (2), **omit** ", zygote";
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(iii) in sub-sections (4) and (5), omit "zygote" (wherever occurring);

(iv) in sub-section (5), omit "49(1) and (2),".

(5) In Part 7 of the Principal Act—

(a) in section 62(2)—

(i) omit "zygotes" (wherever occurring);

(ii) in paragraph (c), for "a zygote or embryo" substitute "an embryo";

(iii) in paragraph (f), omit "zygote";

(b) in sections 71(1) and 72(1), for "a zygote or embryo" substitute "an embryo";

(c) in section 73(1), omit "or a zygote";

(d) in section 73(5)—

(i) for "a zygote or embryo" substitute "an embryo";

(ii) omit "zygote";

(e) in sections 74(1) and 76(1), omit "a zygote or embryos";

(f) in section 79(1), for "a zygote or embryo" substitute "an embryo".

(6) In Part 7A of the Principal Act, in section 92A, in the definition of "pre-1 July 1988 donor", omit "zygote".

(7) In Part 8 of the Principal Act—

(a) in sections 93(f) and 94(e), omit "zygotes";

(b) section 98(2) is repealed;

(c) in section 106(2)(a), omit "and zygotes";

(d) in section 116(1)(c), omit "zygotes" (where twice occurring);
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(e) in section 116(2)(b), for ",, zygotes, embryos, parthenogenetic oocytes or parthenogenes" substitute "or embryos".

(8) In Part 9 of the Principal Act—
(a) in section 122(1)(d) and (i), omit ",, zygotes";
(b) in section 137(1)—
   (i) in paragraph (a), for ",, gametes and zygotes" substitute "and gametes";
   (ii) in paragraph (b)(v), omit "and zygotes".

(9) In Part 12 of the Principal Act—
(a) in section 152(1), omit ",, zygotes";
(b) in section 154(1), for ",, zygote, embryo, parthenogenetic oocyte or parthenogene" (where twice occurring) substitute "or embryo";
(c) in section 162(2), (3)(b) and (7), for ",,, zygote, embryo, parthenogenetic oocyte or parthenogene" (wherever occurring) substitute "or embryo";
(d) in section 162(7), for ",,, zygote, embryo, parthenogene or parthenogenetic oocyte" substitute "or embryo".

(10) In Part 13 of the Principal Act, in section 165(1)—
(a) in paragraph (l), omit "zygotes or";
(b) in paragraph (p)(i) and (ii), for ",, zygote, embryo, parthenogenetic oocyte or parthenogene" substitute "or embryo";
(c) in paragraph (p)(iv), for "zygote, embryo, parthenogenetic embryo or parthenogene" substitute "or embryo";

(d) paragraph (q) is repealed.

23. Repeal of certain provisions

Sections 21I(3)(b) and 21L(1)(c) and (3) are repealed on the day on which the provisions of the Commonwealth Act referred to in section 46 of that Act are repealed.

Note: The Commonwealth provisions are to be repealed on 5 April 2005 or an earlier date declared by the Council of Australian Governments.


Sections 192B, 192C and 192D of the Gene Technology Act 2001 are repealed.

25. Consequential amendments of other Acts

(1) In sections 38(3) and 39(1A) of the Human Tissue Act 1982, for "an amount to which section 57(3) of the Infertility Treatment Act 1995 applies" substitute "reasonable expenses of a kind referred to in section 38O(3) of the Infertility Treatment Act 1995".

(2) In section 10A(3) of the Status of Children Act 1974, in the definitions of "embryo" and "syngamy", after "1995" insert "," as in force immediately before the commencement of section 5(2)(a) of the Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003".
(3) At the foot of section 10A(3) of the Status of Children Act 1974 insert—

Note: The Infertility Treatment Act 1995 defined "embryo" and "syngamy" as follows—

"embryo" means any stage of human embryonic development at and from syngamy;

"syngamy" means that stage of development of a fertilised oocyte where the chromosomes derived from the male and female pronuclei align on the mitotic spindle.'.
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ENDNOTES

† Minister’s second reading speech—
Legislative Assembly: 27 February 2003
Legislative Council: 27 March 2003

The long title for the Bill for this Act was "to amend the Infertility Treatment Act 1995 so as to make fresh provision for the regulation of certain activities involving the use of human embryos and for the prohibition of human cloning and certain other practices associated with reproductive technology, to make consequential amendments to the Gene Technology Act 2001 and certain other Acts and for other purposes."