

Human Cloning and Embryo Research Act 2004

A2004-22

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About this republication

The republished law

This is a republication of the *Human Cloning and Embryo Research Act 2004* (including any amendment made under the *Legislation Act 2001*, part 11.3 (Editorial changes)) as in force on 14 November 2019. It also includes any commencement, amendment, repeal or expiry affecting this republished law to 14 November 2019.

The legislation history and amendment history of the republished law are set out in endnotes 3 and 4.

Kinds of republications

The Parliamentary Counsel's Office prepares 2 kinds of republications of ACT laws (see the ACT legislation register at www.legislation.act.gov.au):

- authorised republications to which the Legislation Act 2001 applies
- unauthorised republications.

The status of this republication appears on the bottom of each page.

Editorial changes

The *Legislation Act 2001*, part 11.3 authorises the Parliamentary Counsel to make editorial amendments and other changes of a formal nature when preparing a law for republication. Editorial changes do not change the effect of the law, but have effect as if they had been made by an Act commencing on the republication date (see *Legislation Act 2001*, s 115 and s 117). The changes are made if the Parliamentary Counsel considers they are desirable to bring the law into line, or more closely into line, with current legislative drafting practice.

This republication includes amendments made under part 11.3 (see endnote 1).

Uncommenced provisions and amendments

If a provision of the republished law has not commenced, the symbol $\boxed{\textbf{U}}$ appears immediately before the provision heading. Any uncommenced amendments that affect this republished law are accessible on the ACT legislation register (www.legislation.act.gov.au). For more information, see the home page for this law on the register.

Modifications

If a provision of the republished law is affected by a current modification, the symbol **M** appears immediately before the provision heading. The text of the modifying provision appears in the endnotes. For the legal status of modifications, see the *Legislation Act 2001*, section 95.

Penalties

At the republication date, the value of a penalty unit for an offence against this law is \$160 for an individual and \$810 for a corporation (see *Legislation Act 2001*, s 133).



Human Cloning and Embryo Research Act 2004

Contents

		Page
Part 1	Preliminary	
1	Name of Act	2
2	Dictionary	2
3	Notes	2
4	Offences against Act—application of Criminal Code etc	2
5	Object of Act	3
6	Meaning of human embryo—Act	3
7	Meaning of human embryo clone	4

R5 14/11/19 Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21 contents 1

		Page
Part 2	Prohibited practices	
Division	2.1 Practices that are completely prohibited	
8	Offence—placing human embryo clone in human body or body of an animal	5
9	No defence that human embryo clone could not survive	5
10	Offence—creating human embryo for purpose other than achieving pregnancy in woman	5
11	Offence—creating or developing human embryo by fertilisation that contains genetic material provided by more than 2 people	6
12	Offence—developing human embryo outside body of woman for more than 14 days	6
13	Offence—heritable alterations to genome	6
14	Offence—collecting viable human embryo from body of woman	7
15	Offence—creating chimeric embryo	7
16	Offence—developing hybrid embryo	7
17	Offence—placing of embryo	7
18	Offence—importing, exporting or placing prohibited embryo	8
19	Offence—commercial trading in human eggs, human sperm or human embryos	9
Division	2.2 Practices that are prohibited unless authorised by licence	
20	Offence—creating human embryo other than by fertilisation, or developing embryo	10
21	Offence—creating or developing human embryo containing genetic material provided by more than 2 people	10
22	Offence—using precursor cells from human embryo or human fetus to create human embryo, or developing such an embryo	11
22A	Offence—creating hybrid embryo	11
Part 3	Regulation of the use of excess ART embryos, other embryos and human eggs	
Division	3.1 Interpretation for pt 3	
23	Definitions for pt 3	13
24	Meaning of excess ART embryo	15
contents	2 Human Cloning and Embryo Research Act 2004	R5

Effective: 14/11/19-22/06/21

14/11/19

		Page
Division :	3.2 Offences	
25	Offence—use of excess ART embryo	16
25A	Offence—use of other embryos	18
25B	Offence—certain activities involving use of human eggs	18
26	Offence—use of embryo that is not excess ART embryo	19
27	Offence—breaching licence condition	19
27A	Person not liable for conduct purportedly authorised	19
Division 3	3.3 Embryo research licensing committee of NHMRC	
28	Functions of committee	20
Division :	3.4 Licensing system	
29	Person may apply for licence	20
30	Committee decision on application	21
31	Notification of decision	23
32	Period of licence	23
33	Licence is subject to conditions	23
34	Variation of licence	25
35	Suspension or revocation of licence	26
36	Surrender of licence	26
37	Notice of variation, suspension or revocation of licence	26
Division 3	3.5 Reporting and confidentiality	
38	NHMRC licensing committee to make certain information publicly available	26
39	Confidential commercial information may only be disclosed in cert circumstances	ain 27
Division :	3.6 Review provisions	
40	Definitions for div 3.6	30
41	Review of decisions	31
Part 4	Monitoring powers	
42	Appointment of inspectors	32
43	Identity card	32
44	Powers available to inspectors for monitoring compliance	33
45	Monitoring powers	34
46	Power to secure	35
R5 14/11/19	Human Cloning and Embryo Research Act 2004	contents 3

Contents

		Page
46A	Monitoring warrants	36
46B	Details of warrant to be given to occupier etc	37
46C	Announcement before entry	37
46D	Occupier entitled to be present during search	37
47	Inspector must produce identity card on request	38
48	Consent	38
49	Compensation for damage	38
Part 5	Miscellaneous	
50	Reports to Legislative Assembly	39
51	Report on operation of Act	39
52	Determination of fees	39
53	Approved forms	40
54	Regulation-making power	40
Dictionary		41
Endnote	es	
1	About the endnotes	44
2	Abbreviation key	44
3	Legislation history	45
4	Amendment history	46
5	Earlier republications	55



Human Cloning and Embryo Research Act 2004

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

Part 1 Preliminary

1 Name of Act

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

2 Dictionary

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

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

For example, the signpost definition 'human embryo—see section 6.' means that the term 'human embryo' is defined that section.

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

3 Notes

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

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

4 Offences against Act—application of Criminal Code etc

Other legislation applies in relation to offences against this Act.

Note 1 Criminal Code

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

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

Note 2 Penalty units

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

5 Object of Act

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

- (a) by prohibiting certain practices; and
- (b) by regulating activities that involve the use of certain human embryos created by assisted reproductive technology or by other means.

6 Meaning of human embryo—Act

(1) In 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.

- (2) However, *human embryo* does not include a—
 - (a) hybrid embryo; or
 - (b) human embryonic stem cell line.
- (3) 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.

7 Meaning of human embryo clone

(1) In this Act:

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.

- (2) To establish 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) 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.

Part 2 Prohibited practices

Division 2.1 Practices that are completely prohibited

8 Offence—placing human embryo clone in human body or 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 s 12.

9 No defence that human embryo clone could not survive

It is not a defence to an offence against section 8 that the human embryo clone did not survive or could not have survived.

10 Offence—creating human embryo for purpose other than achieving pregnancy in 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 the Criminal Code, section 58 (3), a defendant does not bear an evidential burden in relation to anything mentioned in subsection (1).

11 Offence—creating or developing human embryo by fertilisation that contains genetic material provided by more than 2 people

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 people.

Maximum penalty: imprisonment for 15 years.

12 Offence—developing human embryo outside body of 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.

13 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.

(2) In this section:

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

14 Offence—collecting viable human embryo from body of 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.

15 Offence—creating chimeric embryo

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

Maximum penalty: imprisonment for 15 years.

16 Offence—developing 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.

17 Offence—placing of 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.

18 Offence—importing, exporting or placing prohibited embryo

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

Maximum penalty: imprisonment for 15 years.

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

Maximum penalty: imprisonment for 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 about 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 people; 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 13) 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.

19 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 embryo became an excess ART embryo; and
 - (ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo.

Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21 page 9

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 2.2 Practices that are prohibited unless authorised by licence

20 Offence—creating human embryo other than by fertilisation, or developing 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 s 12.
- 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 s 8 and s 18.

21 Offence—creating or developing human embryo containing genetic material provided by more than 2 people

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 people; 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 s 12.
- 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 s 18.

Offence—using precursor cells from human embryo or human fetus to create 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 about that fact.

Maximum penalty: imprisonment for 10 years.

22A Offence—creating 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.

Part 3 Regulation of the use of excess ART embryos, other embryos and human eggs

Division 3.1 Interpretation for pt 3

23 Definitions for pt 3

In this part:

accredited ART centre means an entity 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.

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 information means give or communicate the information in any way.

HREC means a human research ethics committee.

Section 23

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—

- (a) the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research issued by the CEO of the NHMRC in 2007, and existing on 24 August 2007; or
 - Note These guidelines are available on the internet—see http://www.nhmrc.gov.au
- (b) if other guidelines are issued by the CEO of the NHMRC and prescribed by the *Research Involving Human Embryos Regulations* 2003 (Cwlth)—those guidelines, rather than the guidelines mentioned in paragraph (a).

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

responsible person means—

- (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) anyone who was the domestic partner of a person mentioned in subparagraph (i) when the egg or sperm mentioned in that subparagraph was provided; and
 - (iv) anyone who was the domestic partner of the woman mentioned in subparagraph (ii) when the embryo was created; or

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

- (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.

unsuitable for implantation—a human embryo is unsuitable for implantation if it—

(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* issued by the CEO of the NHMRC in 2007, and existing on 24 August 2007; or

Note These guidelines are available on the internet—see http://www.nhmrc.gov.au

(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 and prescribed by the *Research Involving Human Embryos Regulations* 2003 (Cwlth).

use includes develop.

Note If an Act defines a term, other parts of speech and grammatical forms of the term have a corresponding meaning (see Legislation Act, s 157).

24 Meaning of excess ART embryo

(1) In this Act:

excess ART embryo means a human embryo that—

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21 page 15

Section 25

- (b) is excess to the needs of—
 - (i) the woman for whom it was created; and
 - (ii) her domestic partner (if any) when the embryo was created.

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

- (2) For subsection (1) (b), a human embryo is excess to the needs of the people mentioned in that paragraph at a particular time if—
 - (a) each of the people has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
 - (b) each of the people has declared in writing that the embryo is excess to their needs, and the declaration is in force at that time.

Division 3.2 Offences

25 Offence—use of excess ART embryo

- (1) A person commits an offence if the person intentionally uses an excess ART embryo, unless—
 - (a) the use by the person is authorised by a licence; or
 - (b) the use by the person is an exempt use.

Maximum penalty: imprisonment for 5 years.

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

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.

exempt use—a use of an excess ART embryo by a person is an exempt use 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
 - (iv) observation of the excess ART embryo; or
 - (v) allowing the excess ART embryo to succumb; or
- (b) the use is carried out by an accredited ART centre, and—
 - (i) the excess ART embryo is not suitable (based only on its biological fitness for implantation) to be placed in the body of the woman for whom it was created; 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
- (c) the use is carried out by an accredited ART centre and is for the purpose of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
- (d) the use is prescribed under the regulations.

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.

Division 3.2

Offences

Section 25A

25A 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 people; 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 pt 2, unless authorised by a licence.

25B 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.

26 Offence—use of embryo that is not 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 about that fact.

Maximum penalty: imprisonment for 5 years.

27 Offence—breaching 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 about 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.

27A Person not liable for conduct purportedly authorised

- (1) To remove any doubt, a person is not criminally responsible for an offence against this part in relation to particular conduct if—
 - (a) the conduct by the person is purportedly authorised by a provision of a licence; and

Section 28

- (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 3.3 Embryo research licensing committee of NHMRC

28 Functions of committee

The functions of the NHMRC licensing committee are—

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

Division 3.4 Licensing system

29 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 people, 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.
- (2) To remove any doubt, subsection (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.
- (3) An application under subsection (1) must be made in accordance with the written requirements (if any) of the NHMRC licensing committee.

Note A fee may be determined under s 52 for this section.

30 Committee decision on application

- (1) This section applies if a person has made an application under section 29 for a licence.
- (2) The NHMRC licensing committee must decide, in accordance with this section, whether or not to issue the licence.

Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21 page 21

- (3) The NHMRC licensing committee must not issue the licence unless it is satisfied of the following:
 - (a) that appropriate protocols are in place—

Licensing system

- (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 section 33 (1) (a)); and
- (ii) to enable compliance with any restrictions on the consent;
- (b) 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, that 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 (Cwlth) and prescribed by the Research Involving Human Embryos Regulations 2003 (Cwlth) for this paragraph;
 - (d) the HREC assessment of the application mentioned in subsection (3) (b);

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

31 Notification of decision

- (1) The NHMRC licensing committee must notify its decision on an application for a licence 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 30 (3) (b);
 - (c) the relevant Territory entity.
- (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 entities mentioned in subsection (1) (b) and (c).

32 Period of licence

- (1) A licence—
 - (a) comes into force on the day stated in the licence or, if no day is stated, on the day it is issued; and
 - (b) remains in force until the day stated 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.

33 Licence is subject to conditions

- (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

Section 33

- (b) the licence holder must have reported in writing to the NHMRC licensing committee that the 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) A licence is subject to the other conditions (if any) stated in the licence.
- (4) The conditions stated in the licence may include, for example, conditions relating to the following:
 - (a) the people 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 people authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (5) The licence conditions mentioned in subsections (1) and (2) apply to all people who are authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (6) Licence conditions stated in the licence apply to—
 - (a) the licence holder; and
 - (b) such other people authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos as are stated in the licence.

- (7) For the purposes of applying the condition mentioned in subsection (1) (a)—
 - (a) a licence may provide that the guidelines mentioned 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.

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.

34 Variation of licence

- (1) The NHMRC licensing committee may, by written notice 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 stating 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 29 for the licence as varied, the committee would not have been permitted under this part to issue the licence.

Part 3 Regulation of the use of excess ART embryos, other embryos and

human eggs

Division 3.5 Reporting and confidentiality

Section 35

35 Suspension or revocation of licence

- (1) The NHMRC licensing committee may, by written notice 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 against this Act, the NHMRC licensing committee must, by written notice given to the licence holder, revoke each licence held by the licence holder.

36 Surrender of licence

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

37 Notice of variation, suspension or revocation of licence

- (1) If the NHMRC licensing committee varies, suspends or revokes a licence, the committee must tell—
 - (a) the licence holder; and
 - (b) the HREC and the relevant Territory entity.
- (2) The NHMRC licensing committee must also tell the entities mentioned in subsection (1) (b) if a licence is surrendered.

Division 3.5 Reporting and confidentiality

38 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 the licence was issued;
- (f) the period throughout which the licence is to remain in force.
- (2) The database must 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 disclose confidential commercial information.

39 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 exercising functions under this Act or under the Commonwealth Act; and
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not—
 - to the Territory, a Territory agency, the Commonwealth, a Commonwealth authority, a State, or a State agency for this Act, a corresponding State law or the Commonwealth Act; or
 - (ii) by order of a court; or

Section 39

(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—
 - to the Territory, a Territory agency, the Commonwealth, a Commonwealth authority, a State, or a State agency for this Act, a corresponding State law 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.

Maximum penalty: imprisonment for 2 years.

(3) In this section:

Commonwealth authority means—

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

corresponding State law—see the Commonwealth Act, section 7 (1).

court includes a tribunal, authority or person having power to require the production of documents or the answering of questions.

State agency means—

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

Territory agency means—

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

Note For the definition of *confidential commercial information*, see s 23.

human eggs

Division 3.6 Review provisions

Section 40

Division 3.6 Review provisions

40 Definitions for div 3.6

In this division:

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

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

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

- (a) in relation to a decision under section 30 not to issue a licence—the applicant for the licence; or
- (b) in relation to a decision about the period throughout which the licence is to be in force under section 32—the licence holder; or
- (c) in relation to a decision to state a licence condition under section 33 (3)—the licence holder; or
- (d) in relation to a decision to modify guidelines under section 33 (7) in relation to a licence—the licence holder; or
- (e) in relation to a decision to vary or refuse to vary a licence under section 34—the licence holder; or
- (f) in relation to a decision to suspend or revoke a licence under section 35—the person who was the licence holder immediately before the suspension or revocation.

41 Review of decisions

- (1) An eligible person may apply to the Commonwealth administrative appeals tribunal for review of the following decisions of the NHMRC licensing committee:
 - (a) a decision under section 30 not to issue a licence;
 - (b) a decision about the period throughout which the licence is to be in force under section 32;
 - (c) a decision to state a licence condition under section 33 (3);
 - (d) a decision to modify guidelines under section 33 (7) in relation to a licence;
 - (e) a decision to vary or refuse to vary a licence under section 34;
 - (f) a decision to suspend or revoke a licence under section 35.
- (2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975* (Cwlth).

Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21

R5 14/11/19

Part 4 Monitoring powers

42 Appointment of inspectors

- (1) The chairperson of the NHMRC licensing committee may, by instrument in writing, appoint any of the following as inspectors:
 - (a) a person who is appointed or employed by the Territory;
 - (b) a person who is appointed or employed by a State;
 - (c) a person who is appointed or employed by the Commonwealth.
- (2) The Legislation Act, part 19.3 (Appointments) does not apply to appointments under this section.
- (3) In exercising functions as an inspector, an inspector must comply with any directions of the chairperson of the NHMRC licensing committee.
- (4) The chairperson of the NHMRC licensing committee must not appoint a person as an inspector under subsection (1) unless the chairperson is satisfied that the person has appropriate skills and experience.

43 Identity card

- (1) The chairperson of the NHMRC licensing committee must issue an identity card to an inspector.
- (2) The identity card—
 - (a) must be in the approved form; and
 - (b) must contain a recent photograph of the inspector.

- (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 functions as an inspector.

44 Powers available to inspectors for monitoring compliance

- (1) To find out whether this Act has been complied with, an inspector may—
 - (a) enter any premises; and
 - (b) exercise the monitoring powers set out in section 45.

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

- (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 where the occupier of the premises is carrying out activities authorised by a licence issued under section 30, and the entry is at a reasonable time; or
 - (c) the entry is made under a warrant under section 46A.

45 Monitoring powers

- (1) The monitoring powers that an inspector may exercise under section 44 (1) (b) are as follows:
 - (a) to search the premises and anything 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 anything 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 the equipment and materials that the inspector requires to exercise 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 46A—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.

Note The Legislation Act, s 170 and s 171 deal with the application of the privilege against self-incrimination and client legal privilege.

- (2) For 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 deciding whether there has been compliance with this Act.

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

- (3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a disk, tape 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 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.

46 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 provide evidence of the commission of an offence against this Act, the monitoring powers include securing the embryo, the egg or the thing while a warrant to seize it is obtained (whether by the inspector or by another person).

46A 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 that it is reasonably necessary that 1 or more inspectors should have access to the premises for the purposes of finding out whether this Act has been complied with.
 - Note 1 Oath includes affirmation, and take an oath includes make an affirmation (see Legislation Act, dict, pt 1).
 - Note 2 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).
- (3) The magistrate must not issue the warrant unless the inspector or someone else has given to the magistrate, either orally or by affidavit, any further information the magistrate requires about the grounds on which the issue of the warrant is being sought.
- (4) The warrant must—
 - (a) authorise 1 or more inspectors (whether or not named in the warrant) with the assistance and force that is necessary and reasonable—
 - (i) to enter the premises; and
 - (ii) to exercise the powers set out in section 45 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 stated hours of the day or night; and
 - (c) state 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.

46B Details of warrant to be given to occupier etc

- (1) If a warrant under section 46A 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 mentioned in subsection (1) need not include the signature of the magistrate who issued the warrant.

46C Announcement before entry

An inspector must, before entering premises under a warrant—

- (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.

46D Occupier entitled to be present during search

- (1) If a warrant under section 46A 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.

47 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.

48 Consent

- (1) Before obtaining the consent of a person for section 44 (2) (a), the inspector must tell the person that he or she may refuse consent.
- (2) An entry of an inspector with the consent of a person is not lawful unless the person voluntarily consented to the entry.

49 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 because of it being operated by an inspector as mentioned in this part; and
 - (b) the damage was caused because insufficient care was exercised by the inspector operating the equipment or other facilities.
- (2) In deciding 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.

Part 5 Miscellaneous

50 Reports to Legislative Assembly

As soon as practicable (but within 6 sitting days) after receiving a copy of a report from the NHMRC licensing committee under the Commonwealth Act, section 19, the Minister must present a copy of the report to the Legislative Assembly.

51 Report on operation of Act

- (1) This section applies to—
 - (a) a report of the review mentioned in the *Prohibition of Human Cloning for Reproduction Act 2002* (Cwlth), section 25A; and
 - (b) a report of the review mentioned in the *Research Involving Human Embryos Act 2002* (Cwlth), section 47A.
- (2) The Minister must present a copy of the report to the Legislative Assembly as soon as practicable after it is tabled in a house of the Commonwealth Parliament.

52 Determination of fees

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

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

(2) A determination is a disallowable instrument.

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

53 Approved forms

- (1) The Minister may, in writing, approve forms for this Act.
 - *Note* For other provisions about forms, see Legislation Act, s 255.
- (2) If the Minister approves a form for a particular purpose, the approved form must be used for that purpose.
- (3) An approved form is a notifiable instrument.

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

54 Regulation-making power

The Executive may make regulations for this Act.

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

Dictionary

(see s 3)

- Note 1 The Legislation Act contains definitions and other provisions relevant to this Act.
- Note 2 For example, the Legislation Act, dict, pt 1, defines the following terms:
 - corporation
 - entity
 - exercise
 - functions
 - State
 - under.

accredited ART centre—see section 23.

animal does not include a human.

chimeric embryo means—

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

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

 $\textbf{\textit{Commonwealth administrative appeals tribunal}} - see \ section \ 40.$

confidential commercial information—see section 23.

decision, for division 3.6 (Review provisions)—see section 40.

disclose information, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

eligible person, for division 3.6 (Review provisions)—see section 40.

embryo means a living embryo, and includes a human embryo.

excess ART embryo—see section 24.

R5 14/11/19

HREC—see section 23.

human egg means a human oocyte.

human embryo—see section 6.

human embryo clone—see section 7.

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 under the regulations to be a hybrid embryo.

inspector means a person appointed as an inspector under section 42 (1).

licence means a licence issued under section 30 (Committee decision on application).

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

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

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

proper consent, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

relevant Territory entity, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

responsible person, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

unsuitable for implantation, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

use, for part 3 (Regulation of the use of excess ART embryos, other embryos and human eggs)—see section 23.

woman means a female human.

Endnotes

1 About the endnotes

Amending and modifying laws are annotated in the legislation history and the amendment history. Current modifications are not included in the republished law but are set out in the endnotes.

Not all editorial amendments made under the *Legislation Act 2001*, part 11.3 are annotated in the amendment history. Full details of any amendments can be obtained from the Parliamentary Counsel's Office.

Uncommenced amending laws are not included in the republished law. The details of these laws are underlined in the legislation history. Uncommenced expiries are underlined in the legislation history and amendment history.

If all the provisions of the law have been renumbered, a table of renumbered provisions gives details of previous and current numbering.

The endnotes also include a table of earlier republications.

2 Abbreviation key

page 44

A = Act NI = Notifiable instrument

 $\begin{array}{ll} \mathsf{AF} = \mathsf{Approved} \; \mathsf{form} & \mathsf{o} = \mathsf{order} \\ \mathsf{am} = \mathsf{amended} & \mathsf{om} = \mathsf{omitted/repealed} \end{array}$

amdt = amendment ord = ordinance
AR = Assembly resolution orig = original

ch = chapter par = paragraph/subparagraph

CN = Commencement notice pres = present

def = definition prev = previous
DI = Disallowable instrument (prev...) = previously

 $\begin{array}{ll} \mbox{dict = dictionary} & \mbox{pt = part} \\ \mbox{disallowed = disallowed by the Legislative} & \mbox{r = rule/subrule} \\ \end{array}$

Assembly reloc = relocated div = division renum = renumbered

 \exp = expires/expired R[X] = Republication No Gaz = gazette R[X] = Republication No R[X] = reissue R[X] = reissue

IA = Interpretation Act 1967 sch = schedule
ins = inserted/added sdiv = subdivision
LA = Legislation Act 2001 SL = Subordinate law
LR = legislation register sub = substituted

LRA = Legislation (Republication) Act 1996 <u>underlining</u> = whole or part not commenced

R5

mod = modified/modification or to be expired

3 Legislation history

This Act was made as the *Human Embryo (Research) Act 2004* A2004-22. It was renamed by sch 1, amdt 1.2 as the *Human Cloning and Embryo Research Act 2004* on the commencement of the *Human Cloning (Prohibition) Act 2004* (see A2004-22 s 41).

Human Cloning and Embryo Research Act 2004 A2004-22

notified LR 7 April 2004 s 1, s 2 commenced 7 April 2004 (LA s 75 (1)) remainder commenced 8 April 2004 (s 2)

as amended by

Human Cloning and Embryo Research Amendment Act 2008 A2008-8

notified LR 17 April 2008 s 1, s 2 commenced 17 April 2008 (LA s 75 (1)) remainder commenced 18 April 2008 (s 2)

Statute Law Amendment Act 2019 A2019-42 sch 3 pt 3.14

notified LR 31 October 2019 s 1, s 2 commenced 31 October 2019 (LA s 75 (1)) sch 3 pt 3.14 commenced 14 November 2019 (s 2 (1))

4 Amendment history

Long title

title sub A2004-22 amdt 1.1; A2008-8 s 4

Name of Act

s 1 sub A2004-22 amdt 1.2

Dictionary

s 2 orig s 2 om LA s 89 (4)

(prev s 3) renum R1 LA (see A2004-22 amdt 1.10)

Notes

s 3 orig s 3 renum as s 2

(prev s 4) renum R1 LA (see A2004-22 amdt 1.10)

Offences against Act—application of Criminal Code etc

s 4 orig s 4 renum as s 3

(prev s 5) renum R1 LA (see A2004-22 amdt 1.10)

Object of Act

s 5 orig s 5 renum as s 4

(prev s 6) sub A2004-22 amdt 1.3 renum R1 LA (see A2004-22 amdt 1.10)

am A2008-8 s 5

Meaning of human embryo-Act

s 6 orig s 6 renum as s 5

(prev s 7) renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 6

Meaning of human embryo clone

s 7 orig s 7 renum as s 6

(prev s 7A) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 8 by A2004-22 amdt 1.11 renum R1 LA (see A2004-22 amdt 1.10)

Meaning of *human embryo clone* s 7A renum as s 7

Prohibited practices

pt 1A hdg renum as pt 2 hdg

Human cloning

page 46

div 1A.1 hdg renum as div 2.1 hdg

Other prohibited practices

div 1A.2 hdg renum as div 2.2 hdg

Human Cloning and Embryo Research Act 2004

14/11/19

Prohibited practices

pt 2 hdg orig pt 2 hdg renum as pt 3 hdg

(prev pt 1A hdg) reloc from Human Cloning (Prohibition) Act

2004 A2004-21 pt 2 hdg by A2004-22 amdt 1.12

renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Practices that are completely prohibited

div 2.1 hdg orig div 2.1 hdg renum as div 3.1 hdg

(prev div 1A.1 hdg) reloc from Human Cloning (Prohibition) Act

2004 A2004-21 div 2.1 hdg by A2004-22 amdt 1.12

renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

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

s 8 orig s 8 renum as s 23

(prev s 9) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 9 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

No defence that human embryo clone could not survive

s 9 orig s 9 renum as s 24

prev s 9 (as reloc from A2004-21 s 9) renum as s 8

(prev s 10) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 10 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

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

s 10 orig s 10 renum as s 25

prev s 10 (as reloc from A2004-21 s 10) renum as s 9 (prev s 11) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 11 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

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

s 11 orig s 11 renum as s 26

> prev s 11 (as reloc from A2004-21 s 11) renum as s 10 (prev s 12) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 12 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Human Cloning and Embryo Research Act 2004 14/11/19 Effective: 14/11/19-22/06/21

page 48

Amendment history

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

s 12 orig s 12 renum as s 27

prev s 12 (as reloc from A2004-21 s 12) renum as s 11 (prev s 13) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 13 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

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

s 13 orig s 13 renum as s 28

prev s 13 (as reloc from A2004-21 s 13) renum as s 12 (prev s 14) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 14 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7 am A2019-42 amdt 3.21

Offence—collecting viable human embryo from body of woman

orig s 14 renum as s 29 s 14

prev s 14 (as reloc from A2004-21 s 14) renum as s 13 (prev s 15) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 15 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10) sub A2008-8 s 7

Offence—creating chimeric embryo

orig s 15 renum as s 30

prev s 15 (as reloc from A2004-21 s 15) renum as s 14 (prev s 16) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 16 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10) sub A2008-8 s 7

Offence—developing hybrid embryo

s 16 orig s 16 renum as s 31

> prev s 16 (as reloc from A2004-21 s 16) renum as s 15 (prev s 17) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 17 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Human Cloning and Embryo Research Act 2004

Effective: 14/11/19-22/06/21

Offence—placing of embryo

s 17 orig s 17 renum as s 32

prev s 17 (as reloc from A2004-21 s 17) renum as s 16 (prev s 18) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 18 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Offence—importing, exporting or placing prohibited embryo

orig s 18 renum as s 33 s 18

> prev s 18 (as reloc from A2004-21 s 18) renum as s 17 (prev s 19) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 19 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7 am A2019-42 amdt 3.22

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

s 19 orig s 19 renum as s 34

> prev s 19 (as reloc from A2004-21 s 19) renum as s 18 (prev s 20) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 20 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10) sub A2008-8 s 7

Practices that are prohibited unless authorised by licence

orig div 2.2 hdg renum as div 3.2 hdg div 2.2 hdg

(prev div 1A.2 hdg) reloc from Human Cloning (Prohibition) Act

2004 A2004-21 div 2.2 hdg by A2004-22 amdt 1.12

renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Offence—creating human embryo other than by fertilisation, or developing embryo

s 20 orig s 20 renum as s 35

prev s 20 (as reloc from A2004-21 s 20) renum as s 19 (prev s 21) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 21 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

Human Cloning and Embryo Research Act 2004 14/11/19 Effective: 14/11/19-22/06/21

4 Amendment history

Offence—creating or developing human embryo containing genetic material provided by more than 2 people

s 21 orig s 21 renum as s 36

prev s 21 (as reloc from A2004-21 s 21) renum as s 20 (prev s 22) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 22 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7

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

s 22 hdg am A2019-42 amdt 3.22 s 22 orig s 22 renum as s 37

prev s 22 (as reloc from A2004-21 s 22) renum as s 21 (prev s 23) reloc from Human Cloning (Prohibition) Act 2004

A2004-21 s 23 by A2004-22 amdt 1.12 renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 7 am A2019-42 amdt 3.22

Offence—creating hybrid embryo

s 22A ins A2008-8 s 7

Regulation of the use of excess ART embryos, other embryos and human

eggs pt 3 hdg

orig pt 3 hdg renum as pt 4 hdg

(prev pt 2 hdg) renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 8

Interpretation for pt 3

div 3.1 hdg (prev div 2.1 hdg) renum R1 LA (see A2004-22 amdt 1.10)

Definitions for pt 3

s 23 orig s 23 renum as s 38

prev s 23 (as reloc from A2004-21 s 23) renum as s 22 (prev s 8) renum R1 LA (see A2004-22 amdt 1.10)

def *licence* om A2008-8 s 9

def *proper consent* sub A2008-8 s 10 def *responsible person* sub A2008-8 s 11 def *unsuitable for implantation* ins A2008-8 s 12

def use ins A2008-8 s 12

Meaning of excess ART embryo

s 24 orig s 24 renum as s 39

(prev s 9) renum R1 LA (see A2004-22 amdt 1.10)

Interpretation for pt 3

page 50

div 3.2 hdg (prev div 2.2 hdg) renum R1 LA (see A2004-22 amdt 1.10)

Human Cloning and Embryo Research Act 2004

R5

Effective: 14/11/19-22/06/21

Offence—use of excess ART embryo

orig s 25 renum as s 40

(prev s 10) renum R1 LA (see A2004-22 amdt 1.10)

Offence—use of other embryos

ins A2008-8 s 13 s 25A

am A2019-42 amdt 3.22

Offence—certain activities involving use of human eggs

ins A2008-8 s 13 s 25B

Offence—use of embryo that is not excess ART embryo

orig s 26 renum as s 41 s 26

(prev s 11) renum R1 LA (see A2004-22 amdt 1.10)

äm A2008-8 s 14

Offence—breaching licence condition

s 27 orig s 27 renum as s 42

(prev s 12) renum R1 LA (see A2004-22 amdt 1.10)

Person not liable for conduct purportedly authorised

ins A2008-8 s 15

Embryo research licensing committee of NHMRC

(prev div 2.3 hdg) renum R1 LA (see A2004-22 amdt 1.10) div 3.3 hdg

Functions of committee

s 28 orig s 28 renum as s 43

(prev s 13) renum R1 LA (see A2004-22 amdt 1.10)

Licensing system

div 3.4 hdg (prev div 2.4 hdg) renum R1 LA (see A2004-22 amdt 1.10)

Person may apply for licence

orig s 29 renum as s 44 s 29

> (prev s 14) renum R1 LA (see A2004-22 amdt 1.10) am A2008-8 s 16; ss renum R3 LA; A2019-42 amdt 3.22

Committee decision on application

orig s 30 renum as s 45 s 30

(prev s 15) renum R1 LA (see A2004-22 amdt 1.10)

(3) (b) exp 5 April 2005 (s 55)

par renum R2 LA am A2008-8 ss 17-20

Notification of decision

s 31 orig s 31 renum as s 46

(prev s 16) renum R1 LA (see A2004-22 amdt 1.10)

Period of licence

s 32 orig s 32 renum as s 47

(prev s 17) renum R1 LA (see A2004-22 amdt 1.10)

R5 Human Cloning and Embryo Research Act 2004

14/11/19 Effective: 14/11/19-22/06/21

4 Amendment history

Licence is subject to conditions

s 33 orig s 33 renum as s 48

(prev s 18) renum R1 LA (see A2004-22 amdt 1.10)

(1) (c), (3) exp 5 April 2005 (s 55)

ss renum R2 LA am A2008-8 ss 21-26

Variation of licence

s 34 orig s 34 renum as s 49

(prev s 19) renum R1 LA (see A2004-22 amdt 1.10)

Suspension or revocation of licence

s 35 orig s 35 renum as s 50

(prev s 20) renum R1 LA (see A2004-22 amdt 1.10)

Surrender of licence

s 36 orig s 36 renum as s 51

(prev s 21) renum R1 LA (see A2004-22 amdt 1.10)

Notice of variation, suspension or revocation of licence

s 37 orig s 37 renum as s 52

(prev s 22) renum R1 LA (see A2004-22 amdt 1.10)

Reporting and confidentiality

div 3.5 hdg (prev div 2.5 hdg) renum R1 LA (see A2004-22 amdt 1.10)

NHMRC licensing committee to make certain information publicly available

s 38 orig s 38 renum as s 53

(prev s 23) renum R1 LA (see A2004-22 amdt 1.10)

am A2008-8 s 27, s 28

Confidential commercial information may only be disclosed in certain circumstances

s 39 orig s 39 renum as s 54

(prev s 24) renum R1 LA (see A2004-22 amdt 1.10)

Review provisions

div 3.6 hdg (prev div 2.6 hdg) renum R1 LA (see A2004-22 amdt 1.10)

Definitions for div 3.6

s 40 orig s 40 renum as s 55

(prev s 25) renum R1 LA (see A2004-22 amdt 1.10) def *eligible person* am A2008-8 s 29; pars renum R3 LA

Review of decisions

s 41 orig s 41 om LA s 89 (3)

(prev s 26) renum R1 LA (see A2004-22 amdt 1.10)

am A2008-8 s 30; pars renum R3 LA

Monitoring powers

pt 4 hdg orig pt 4 hdg renum as pt 5 hdg

(prev pt 3 hdg) renum R1 LA (see A2004-22 amdt 1.10)

page 52 Human Cloning and Embryo Research Act 2004

R5

Effective: 14/11/19-22/06/21

14/11/19

Appointment of inspectors

s 42 (prev s 27) renum R1 LA (see A2004-22 amdt 1.10)

Identity card

s 43 (prev s 28) renum R1 LA (see A2004-22 amdt 1.10)

Powers available to inspectors for monitoring compliance

s 44 (prev s 29) am A2004-22 amdt 1.4

renum R1 LA (see A2004-22 amdt 1.10)

am A2008-8 s 31

Monitoring powers

s 45 (prev s 30) am A2004-22 amdt 1.5, amdt 1.6

renum R1 LA (see A2004-22 amdt 1.10)

am A2008-8 s 32, s 33

Power to secure

s 46 (prev s 31) am A2004-22 amdt 1.7

renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 34

Monitoring warrants

s 46A ins A2008-8 s 35

Details of warrant to be given to occupier etc

s 46B ins A2008-8 s 35

Announcement before entry

s 46C ins A2008-8 s 35

Occupier entitled to be present during search

s 46D ins A2008-8 s 35

Inspector must produce identity card on request

s 47 (prev s 32) renum R1 LA (see A2004-22 amdt 1.10)

Consent

s 48 (prev s 33) renum R1 LA (see A2004-22 amdt 1.10)

Compensation for damage

s 49 (prev s 34) renum R1 LA (see A2004-22 amdt 1.10)

Miscellaneous

pt 5 hdg (prev pt 4 hdg) renum R1 LA (see A2004-22 amdt 1.10)

Reports to Legislative Assembly

s 50 (prev s 35) renum R1 LA (see A2004-22 amdt 1.10)

Report on operation of Act

s 51 (prev s 36) am A2004-22 amdt 1.8, amdt 1.9

renum R1 LA (see A2004-22 amdt 1.10)

sub A2008-8 s 36

R5 Human Cloning and Embryo Research Act 2004

page 53

14/11/19 Effective: 14/11/19-22/06/21

Determination of fees

s 52 (prev s 37) renum R1 LA (see A2004-22 amdt 1.10)

Approved forms

s 53 (prev s 38) renum R1 LA (see A2004-22 amdt 1.10)

Regulation-making power

s 54 (prev s 39) renum R1 LA (see A2004-22 amdt 1.10)

Expiry of certain provisions

s 55 (prev s 40) renum R1 LA (see A2004-22 amdt 1.10)

exp 5 April 2005 (s 55)

Transitional

pt 10 hdg ins A2008-8 s 37

exp 18 April 2009 (s 101)

Existing applications for licences

s 100 ins A2008-8 s 37

exp 18 April 2009 (s 101)

Expiry—pt 10

s 101 ins A2008-8 s 37

exp 18 April 2009 (s 101)

Amendments

sch 1 om LA s 89 (3)

Dictionary

dict def *animal* reloc from Human Cloning (Prohibition) Act 2004

A2004-21 dict by A2004-22 amdt 1.13

def *chimeric embryo* reloc from Human Cloning (Prohibition)

Act 2004 A2004-21 dict by A2004-22 amdt 1.13

def *disclose* sub A2008-8 s 38 def *embryo* ins A2008-8 s 39

def *human egg* ins A2008-8 s 40

def human embryo clone reloc from Human Cloning

(Prohibition) Act 2004 A2004-21 dict by A2004-22 amdt 1.13 def *human sperm* reloc from Human Cloning (Prohibition) Act

2004 A2004-21 dict by A2004-22 amdt 1.13

def *hybrid embryo* reloc from Human Cloning (Prohibition)

Act 2004 A2004-21 dict by A2004-22 amdt 1.13

def licence sub A2008-8 s 41

def precursor cell reloc from Human Cloning (Prohibition) Act

2004 A2004-21 dict by A2004-22 amdt 1.13

def *proper consent* sub A2008-8 s 42

def relevant Territory entity sub A2008-8 s 42

def *responsible person* sub A2008-8 s 42

def *unsuitable for implantation* ins A2008-8 s 43

def use ins A2008-8 s 43

Human Cloning and Embryo Research Act 2004

R5

Effective: 14/11/19-22/06/21 14/11/19

5 Earlier republications

Some earlier republications were not numbered. The number in column 1 refers to the publication order.

Since 12 September 2001 every authorised republication has been published in electronic pdf format on the ACT legislation register. A selection of authorised republications have also been published in printed format. These republications are marked with an asterisk (*) in column 1. Electronic and printed versions of an authorised republication are identical.

Republication No and date	Effective	Last amendment made by	Republication for
R1 8 Apr 2004	8 Apr 2004– 5 Apr 2005	not amended	new Act and commencement of Human Cloning (Prohibition) Act 2004 A2004-21
R2 6 Apr 2005	6 Apr 2005– 17 Apr 2008	not amended	commenced expiry
R3 18 Apr 2008	18 Apr 2008– 18 Apr 2009	A2008-8	amendments by A2008-8
R4 19 Apr 2009	19 Apr 2009– 13 Nov 2019	A2008-8	commenced expiry

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Human Cloning and Embryo Research Act 2004 Effective: 14/11/19-22/06/21 page 55