



Queensland

Research Involving Human Embryos and Prohibition of Human Cloning Amendment Bill 2007



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2007

A Bill

for

An Act to amend the *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003*

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	The Parliament of Queensland enacts—	1
Clause 1	Short title	2
	This Act may be cited as the <i>Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007</i> .	3 4 5
Clause 2	Act amended	6
	This Act amends the <i>Research Involving Human Embryos and Prohibition of Human Cloning Act 2003</i> .	7 8
Clause 3	Amendment of long title	9
	Long title, after ‘human cloning’—	10
	<i>insert—</i>	11
	‘for reproduction’.	12
Clause 4	Amendment of s 1 (Short title)	13
	Section 1, after ‘ <i>Cloning</i> ’—	14
	<i>insert—</i>	15
	‘ <i>for Reproduction</i> ’.	16
Clause 5	Amendment of s 3 (Object of Act)	17
	Section 3(b), after ‘technology’—	18
	<i>insert—</i>	19
	‘or by other means’.	20
Clause 6	Amendment of s 5 (Definitions)	21
	(1) Section 5—	22
	<i>insert—</i>	23

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‘(4A)	A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.	1 2
(4B)	A reference in this Act to a human egg is a reference to a human oocyte.	3 4
(4C)	A reference in this Act to a human embryo does not include a reference to—	5 6
	(a) a hybrid embryo; or	7
	(b) a human embryonic stem cell line.’.	8
(2)	Section 5(4A) to (5)— <i>renumber</i> as section 5(5) to (8).	9 10
Clause 7	Replacement of pt 2 (Prohibited practices)	11
	Part 2—	12
	<i>omit, insert—</i>	13
‘Part 2	Prohibited practices	14
‘Division 1	Practices that are completely prohibited	15 16
‘7	Offence—placing a human embryo clone in the human body or the body of an animal	17 18
‘(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.	19 20 21
	Maximum penalty—15 years imprisonment.	22
‘(2)	It is not a defence to an offence under subsection (1) that the human embryo clone did not survive or could not have survived.	23 24 25
	<i>Note—</i>	26
	The development of a human embryo (including a human embryo clone) outside the body of a woman for more than 14 days is prohibited by section 10.	27 28 29

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'8	Offence—creating a human embryo for a purpose other than achieving pregnancy in a woman	1 2
	‘(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.	3 4 5 6 7
	Maximum penalty—15 years imprisonment.	8
	‘(2) A defendant does not bear the burden of proving any matter in subsection (1).	9 10
'9	Offence—creating or developing a human embryo by fertilisation that contains genetic material provided by more than 2 persons	11 12 13
	‘A person commits an offence if—	14
	(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	15 16 17
	(b) the human embryo contains genetic material provided by more than 2 persons.	18 19
	Maximum penalty—15 years imprisonment.	20
'10	Offence—developing a human embryo outside the body of a woman for more than 14 days	21 22
	‘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.	23 24 25 26
	Maximum penalty—15 years imprisonment.	27
'11	Offence—heritable alterations to genome	28
	‘(1) A person commits an offence if—	29

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(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	1 2 3
(b)	in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.	4 5 6
	Maximum penalty—15 years imprisonment.	7
‘(2)	In this section—	8
	<i>human cell</i> includes a human embryonal cell, a human fetal cell, human sperm and a human egg.	9 10
‘12	Offence—collecting a viable human embryo from the body of a woman	11 12
	‘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.	13 14 15
	Maximum penalty—15 years imprisonment.	16
‘13	Offence—creating a chimeric embryo	17
	‘A person commits an offence if the person intentionally creates a chimeric embryo.	18 19
	Maximum penalty—15 years imprisonment.	20
‘14	Offence—developing a hybrid embryo	21
	‘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.	22 23 24
	Maximum penalty—15 years imprisonment.	25
‘15	Offence—placing of an embryo	26
‘(1)	A person commits an offence if the person intentionally places a human embryo in an animal.	27 28
	Maximum penalty—15 years imprisonment.	29

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‘(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.	1 2 3
	Maximum penalty—15 years imprisonment.	4
‘(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.	5 6 7
	Maximum penalty—15 years imprisonment.	8
‘16	Offence—placing a prohibited embryo	9
‘(1)	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.	10 11 12
	Maximum penalty—15 years imprisonment.	13
‘(2)	In this section—	14
	<i>prohibited embryo</i> means—	15
	(a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or	16 17
	(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	18 19 20 21
	(c) a human embryo that contains genetic material provided by more than 2 persons; or	22 23
	(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	24 25 26 27
	(e) a human embryo created using precursor cells taken from a human embryo or a human fetus; or	28 29
	(f) a human embryo that contains a human cell (within the meaning of section 11) 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	30 31 32 33

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(g)	a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or	1 2 3
(h)	a chimeric embryo or a hybrid embryo.	4
‘17	Offence—commercial trading in human eggs, human sperm or human embryos	5 6
‘(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.	7 8 9
	Maximum penalty—15 years imprisonment.	10
‘(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.	11 12 13 14
	Maximum penalty—15 years imprisonment.	15
‘(3)	In this section:	16
	<i>reasonable expenses</i> —	17
(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	18 19 20 21
(b)	in relation to the supply of a human embryo—	22
(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 section 22; and	23 24 25
(ii)	includes, but is not limited to, expenses relating to the storage or transport of the embryo.	26 27
	<i>valuable consideration</i> , 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.	28 29 30 31 32 33

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‘Division 2	Practices that are prohibited unless authorised by a licence	1 2
‘18	Offence—creating a human embryo other than by fertilisation, or developing such an embryo	3 4
	‘A person commits an offence if—	5
	(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	6 7 8 9
	(b) the creation or development of the human embryo by the person is not authorised by a licence.	10 11
	Maximum penalty—10 years imprisonment.	12
	<i>Notes—</i>	13
	1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 10.	14 15
	2 The placement in the body of a woman of a human embryo clone, or any other human embryo created other than by the fertilisation of a human egg by a human sperm, is prohibited by sections 7 and 16.	16 17 18
‘19	Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons	19 20 21
	‘A person commits an offence if—	22
	(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	23 24 25
	(b) the human embryo contains genetic material provided by more than 2 persons; and	26 27
	(c) the creation or development of the human embryo by the person is not authorised by a licence.	28 29
	Maximum penalty—10 years imprisonment.	30
	<i>Notes—</i>	31
	1 The development of a human embryo outside the body of a woman for more than 14 days is prohibited by section 10.	32 33

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- 2 The placement in the body of a woman of a human embryo created
other than by the fertilisation of a human egg by a human sperm, is
prohibited by section 16. 1
2
3

‘20 Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo 4
5
6

- ‘A person commits an offence if— 7
- (a) the person uses precursor cells taken from a human 8
embryo or a human fetus, intending to create a human 9
embryo, or intentionally develops an embryo so created; 10
and 11
- (b) the person engages in activities mentioned in paragraph 12
(a) without being authorised by a licence, and the person 13
knows or is reckless as to that fact. 14

Maximum penalty—10 years imprisonment. 15

‘20A Offence—creating a hybrid embryo 16

- ‘(1) A person commits an offence if the person intentionally 17
creates a hybrid embryo. 18

Maximum penalty—10 years imprisonment. 19

- ‘(2) A person commits an offence if the person intentionally 20
develops a hybrid embryo. 21

Maximum penalty—10 years imprisonment. 22

- ‘(3) A person does not commit an offence against subsection (1) or 23
(2) if the creation or development of the hybrid embryo by the 24
person is authorised by a licence. 25

Note— 26

A licence to create or use a hybrid embryo can only be issued under 27
section 29 for the purposes of testing sperm quality in an accredited 28
ART centre up to, but not including, the first mitotic division.’. 29

Clause 8 Replacement of pt 3 hdg 30

Part 3, heading— 31

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	(iv) any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or	1 2 3
	(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	4 5 6 7
	(c) in relation to a human egg—the woman who was the biological donor of the egg.’.	8 9
Clause 10	Amendment of s 23 (Offence—use of excess ART embryo)	10 11
	Section 23(3), ‘an evidential burden in relation to’—	12
	<i>omit, insert—</i>	13
	‘the burden of proving’.	14
Clause 11	Insertion of new ss 23A and 23B	15
	After section 23—	16
	<i>insert—</i>	17
	‘23A Offence—use of other embryos	18
	‘A person commits an offence if—	19
	(a) the person intentionally uses an embryo; and	20
	(b) the embryo is—	21
	(i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or	22 23 24
	(ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons; or	25 26 27 28
	(iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or	29 30
	(iv) a hybrid embryo; and	31

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(c) the use by the person is not authorised by a licence. 1

Maximum penalty—5 years imprisonment. 2

Note— 3

The creation or development of embryos mentioned in this section is
prohibited under part 2, unless authorised by a licence. 4
5

**‘23B Offence—certain activities involving use of human
eggs** 6
7

‘A person commits an offence if— 8

(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 9
10
11
12
13

(b) the person is not authorised by a licence to undertake the
research or training. 14
15

Maximum penalty—5 years imprisonment.’. 16

**Clause 12 Amendment of s 24 (Offence—use of embryo that is not
an excess ART embryo)** 17
18

Section 24(a), from ‘human’— 19

omit, insert— 20

‘human embryo— 21

(i) that was created by fertilisation of a human egg by
a human sperm; and 22
23

(ii) that is not an excess ART embryo; and’. 24

Clause 13 Insertion of new s 25A 25

Part 3, division 2— 26

insert— 27

‘25A Person not liable for conduct purportedly authorised 28

‘(1) To avoid any doubt, it is declared that a person is not
criminally responsible for an offence against this part, or 29
30

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- section 50(1)¹ to the extent the attempt relates to an offence against this part, in respect of particular conduct if—
- (a) the conduct by the person is purportedly authorised by a provision of a licence; and
 - (b) the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and
 - (c) the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.
- ‘(2) In this section—
licence includes a purported licence.’.

- Clause 14 Amendment of s 28 (Person may apply for licence)**
- Section 28(1)—
omit, insert—
- ‘(1) A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following—
- (a) use of excess ART embryos;
 - (b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
 - (c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;
 - (d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
 - (e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including,

¹ Section 50 (Attempts to commit offences against this Act)

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	the first mitotic division, outside the body of a woman for the purposes of research or training in ART;	1 2
	(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—	3 4 5
	(i) the creation or use is for the purposes of testing sperm quality; and	6 7
	(ii) the creation or use will occur in an accredited ART centre.	8 9
	‘(1A) To avoid any doubt, it is declared that subsection (1)(a), (b), (c) or (d) does 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.’.	10 11 12 13 14 15
Clause 15	Amendment of s 29 (Determination of application by committee)	16 17
	(1) Section 29(3)(a)(i), ‘is used’— <i>omit, insert—</i> ‘or human egg is used, or other embryo is created or used,’.	18 19 20
	(2) Section 29(4)(a), after ‘excess ART embryos’— <i>insert—</i> ‘, other embryos or human eggs,’.	21 22 23
	(3) Section 29(4)(b), after ‘excess ART embryos’— <i>insert—</i> ‘or human eggs, or the creation or use of other embryos,’.	24 25 26
Clause 16	Amendment of s 32 (Licence is subject to conditions)	27
	(1) Section 32(1)— <i>omit, insert—</i>	28 29

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‘(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—	1 2 3
(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	4 5 6
(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.’.	7 8 9 10
(2) Section 32(2), after ‘excess ART embryo’—	11
<i>insert—</i>	12
‘or human egg, or the creation or use of any other embryo,’.	13
(3) Section 32(5)(a), after ‘excess ART embryos’—	14
<i>insert—</i>	15
‘or human eggs, or create or use other embryos’.	16
(4) Section 32(5)(b)—	17
<i>omit, insert—</i>	18
‘(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;’.	19 20 21 22
(5) Section 32(5)(e) and (6), after ‘excess ART embryos’—	23
<i>insert—</i>	24
‘or human eggs, or to create or use other embryos’.	25
(6) Section 32(7)(b), after ‘excess ART embryos’—	26
<i>insert—</i>	27
‘or human eggs, or to create or use other embryos,’.	28
(7) Section 32—	29
<i>insert—</i>	30
‘(8) For the purposes of applying the condition referred to in subsection (1)(a)—	31 32

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- (a) a licence may provide that the guidelines referred to in the definition *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 the use, under the licence, of the excess ART embryos.
- Note—*
- For example, the guidelines could apply to a particular licence in a modified form, to alter the cooling-off period required in relation to the use of excess ART embryos that are unsuitable for implantation.’.

- Clause 17 Amendment of s 37 (NHMRC Licensing Committee to make certain information publicly available)**
- (1) Section 37(1)(b), after ‘excess ART embryos’—
insert—
‘or human eggs, or creation or uses of other embryos,’.
- (2) Section 37(1)(d)—
omit, insert—
‘(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;’.
- Clause 18 Amendment of s 39 (Meaning of terms)**
- (1) Section 39, heading—
omit, insert—
- ‘39 Definitions for div 6’.**
- (2) Section 39, definition *eligible person*—
insert—

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‘(ca) in relation to a decision to modify guidelines under section 32(8) in respect of a licence—the licence holder; or’.

1
2
3

Clause 19 Amendment of s 40 (Review of decisions) 4

Section 40(1)— 5

insert— 6

‘(ca) a decision to modify guidelines under section 32(8) in respect of a licence;’.

7
8

Clause 20 Amendment of s 43 (Powers available to inspectors for monitoring compliance) 9
10

Section 43(2)— 11

insert— 12

‘(c) the entry is made under a warrant under section 45A.’.

13

Clause 21 Amendment of s 44 (Monitoring powers) 14

(1) Section 44(1)(b), after ‘human embryo’— 15

insert— 16

‘, other embryo, human egg’.

17

(2) Section 44(1)— 18

insert— 19

‘(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 45A—to require any person in or on the premises to— 20
21
22
23

(i) answer any questions put by the inspector; and 24

(ii) produce any book, record or document requested by the inspector.’.

25
26

Clause 22 Amendment of s 45 (Power to secure) 27

(1) Section 45, after ‘human embryo’— 28

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<i>insert—</i>	1
‘, another embryo, a human egg’.	2
(2) Section 45, ‘the embryo or thing’—	3
<i>omit, insert—</i>	4
‘the embryo, the egg or the thing’.	5

Clause 23	Insertion of new ss 45A to 45D	6
	After section 45—	7
	<i>insert—</i>	8
‘45A	Monitoring warrants	9
	‘(1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.	10 11
	‘(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied by information on oath or affirmation that it is reasonably necessary that one or more inspectors should have access to the premises for the purpose of finding out whether this Act has been complied with.	12 13 14 15 16
	‘(3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.	17 18 19 20 21
	‘(4) The warrant must—	22
	(a) authorise one or more inspectors (whether or not named in the warrant) with such assistance and by such force as is necessary and reasonable—	23 24 25
	(i) to enter the premises; and	26
	(ii) to exercise the powers set out in section 44 in relation to the premises; and	27 28
	(b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night; and	29 30 31

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(c)	specify the day (not more than 15 days after the issue of the warrant) on which the warrant ceases to have effect; and	1 2 3
(d)	state the purpose for which the warrant is issued.	4
‘45B	Details of warrant to be given to occupier etc.	5
‘(1)	If a warrant under section 45A 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.	6 7 8 9 10
‘(2)	The inspector must identify himself or herself to that person.	11
‘(3)	The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.	12 13 14
‘45C	Announcement before entry	15
	‘An inspector must, before entering premises under a warrant—	16 17
(a)	announce that he or she is authorised to enter the premises; and	18 19
(b)	give any person at the premises an opportunity to allow entry to the premises.	20 21
‘45D	Occupier entitled to be present during search	22
‘(1)	If a warrant under section 45A 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.	23 24 25 26
‘(2)	The right to observe the search being conducted ceases if the person impedes the search.	27 28
(3)	This section does not prevent 2 or more areas of the premises being searched at the same time.’.	29 30

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Clause 24	Replacement of s 49 (Review of operation of Act)	1
	Section 49—	2
	<i>omit, insert—</i>	3
‘49	Further review of operation of Act	4
	‘(1) The Minister must cause a review of the operation of this Act as amended by the <i>Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007</i> to be undertaken as soon as possible after the third anniversary of the day on which that Act commenced.	5 6 7 8 9
	‘(2) The review must cover the scope and operation of parts 2 and 3 taking into account the following—	10 11
	(a) developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;	12 13 14 15
	(b) developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;	16 17 18 19
	(c) community standards;	20
	(d) a brief analysis of international developments and legislation relating to the use of human embryos and related research;	21 22 23
	(e) an analysis of research resulting from the licenses granted;	24 25
	(f) an analysis of any research or clinical practice that has been prevented as a result of legislative restrictions.	26 27
	‘(3) The review may be undertaken as part of the reviews under the Commonwealth Act, section 47A and the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> (Cwlth), section 25A.’.	28 29 30 31
Clause 25	Insertion of new pt 6	32
	After part 5—	33

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insert—

	Part 6	1
	Saving provisions	2
54	Saving provision	3
	‘(1) If—	4
	(a) at any time before the commencement of this section, a person made an application under subsection 28(1) for a licence; and	5 6 7
	(b) immediately before that commencement, the NHMRC Licensing Committee had not decided the application;	8 9
	then the person is taken, on and from that commencement, to have applied for the licence under subsection 28(1) of the amended Act.	10 11 12
	‘(2) To avoid any doubt, it is declared that a licence issued under section 29 that was in force immediately before the commencement of this section continues in force after that commencement.	13 14 15 16
	‘(3) In this section—	17
	<i>amended Act</i> means this Act as amended by the <i>Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007</i> .’.	18 19 20
Clause 26	Amendment of schedule (Dictionary)	21
	(1) Schedule, definitions <i>human embryo</i> and <i>licence—</i>	22
	<i>omit.</i>	23
	(2) Schedule—	24
	<i>insert—</i>	25
	‘ <i>ART</i> means assisted reproductive technology.	26
	<i>human embryo</i> means a discrete entity that has arisen from either—	27 28
	(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or	29 30

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- (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.
- licence* see section 21.
- unsuitable for implantation*, in relation to a human embryo, means a human embryo that—
- (a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the CEO of the NHMRC; or
- (b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* (Cwlth) and prescribed under a regulation for the purposes of this paragraph.
- use* includes develop, or development, as the case requires.’.