

Human Reproductive Technology Amendment Bill 2003

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Western Australia

LEGISLATIVE ASSEMBLY

(As divided by the Legislative Assembly)

(As amended during consideration in detail)

**Human Reproductive Technology Amendment
Bill 2003**

A Bill for

An Act to amend the *Human Reproductive Technology Act 1991*.

The Parliament of Western Australia enacts as follows:

1. Short title

This Act may be cited as the *Human Reproductive Technology Amendment Act 2003*.

s. 2

2. Commencement

This Act comes into operation on a day fixed by proclamation.

3. The Act amended

5 The amendments in this Act are to the *Human Reproductive Technology Act 1991**.

[*Act No. 22 of 1991.

For subsequent amendments see *Western Australian*

Legislation Information Tables for 2002, Table 1, p. 177.]

4. Preamble amended

10 (1) Paragraph B of the Preamble is amended as follows:

(a) by deleting “egg in the process of fertilisation or” in the first place where it occurs;

(b) by inserting before “disease” —
“ a ”;

15 (c) by deleting “by giving an egg in the process of fertilisation or an embryo all reasonable opportunities for implanting”.

(2) Paragraph C of the Preamble is amended as follows:

20 (a) by deleting “non harmful research and diagnostic procedures upon an egg in the process of fertilisation or an embryo” and inserting instead —

“

research procedures and other uses upon a human embryo

25

”;

(b) by deleting “egg in the process of fertilisation or an” in the second place where it occurs.

(3) Paragraph D of the Preamble is deleted.

5. Section 3 amended

- (1) Section 3(1) is amended in the definition of “authorised officer” as follows:

(a) after paragraph (b) by deleting “and”;

5 (b) after paragraph (c) by inserting —

“

and

10 (d) in relation to the powers referred to in section 54, a person on whom the powers are conferred by the Commissioner of Health under section 53ZQ(4);

”.

- (2) Section 3(1) is amended in the definition of “biological parent” as follows:

15 (a) in paragraph (a) by deleting “an egg or sperm” and inserting instead —

“ a human egg or human sperm ”;

(b) in paragraph (b) by deleting “an embryo” and inserting instead —

20 “ a human embryo ”.

- (3) Section 3(1) is amended in the definition of “fertilisation” by deleting “with the appearance of a two-cell zygote;” and inserting instead —

“ when an embryo is formed; ”.

- 25 (4) Section 3(1) is amended in the definition of “in vitro fertilisation procedure” as follows:

(a) in paragraph (a) by deleting “an egg” in the first place where it occurs and inserting instead —

“ a human egg ”;

s. 5

- (b) in paragraph (a)(ii) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —

“

a human egg undergoing fertilisation or
a human embryo

”;

- (c) in paragraph (a)(iii) by deleting “egg in the process of fertilisation or embryo” and inserting instead —

“

human egg undergoing fertilisation or
human embryo

”;

- (d) by deleting paragraph (b)(i) and inserting instead the following subparagraph —

“

- (i) a human egg;

”;

- (e) in paragraph (b)(ii) by deleting “an egg in the process of fertilisation or an embryo, whether produced by that woman or by another woman and” and inserting instead —

“

a human egg undergoing fertilisation or
a human embryo,

”.

- (5) Section 3(1) is amended in the definition of “Institutional Ethics Committee” by deleting paragraph (b) and inserting instead —

“

- (b) functions, and a composition, complying with requirements of the NHMRC relating to ethical oversight of research involving humans;

”.

(6) Section 3(1) is amended in the definition of “licensee” as follows:

(a) by deleting “this Act” and inserting instead —
“ Part 4 ”;

(b) by inserting before paragraph (a) the following paragraph —

“

(aa) a person who holds an exemption under section 28A;

”;

(c) in paragraph (b) by deleting “person responsible,” and inserting instead —

“ licence supervisor, ”.

(7) Section 3(1) is amended in paragraph (a)(ii) of the definition of “participant” by deleting “gametes, of an egg in the process of fertilisation, or of an embryo” and inserting instead —

“

human gametes, of a human egg
undergoing fertilisation or of a human
embryo

”.

(8) Section 3(1) is amended in paragraph (b) of the definition of “reproductive technology” as follows:

(a) by deleting “gametes” and inserting instead —
“ human gametes ”;

(b) by deleting “eggs in the process of fertilisation or embryos;” and inserting instead —

“

human eggs undergoing fertilisation or
human embryos;

”.

s. 5

- (9) Section 3(1) is amended by deleting the definitions of “chimaera”, “cloning”, “embryo”, “embryo flushing”, “exemption”, “parthenogenesis” and “person responsible”.
- 5 (10) Section 3(1) is amended by deleting the full stop at the end of the definition of “treatment” and inserting instead a semicolon.
- (11) Section 3(1) is amended by inserting in the appropriate alphabetical positions the following definitions —
- “
- 10 **“Commonwealth Human Embryo Act”** means the *Research Involving Human Embryos Act 2002* of the Commonwealth;
- “excess ART embryo”** has the meaning given to that term in section 53T;
- “exemption”** means —
- 15 (a) an exemption that is applied for and is not refused, or is specifically issued, under section 28; or
- (b) an exemption under section 28A;
- “human egg”** means a live human egg;
- 20 **“human embryo”** has the meaning given to that term in section 3A;
- “human gamete”** means a human egg or a human sperm;
- “human sperm”** means live human sperm or spermatids;
- 25 **“licence supervisor”**, in relation to a licence or exemption, means the individual under whose supervision the storage or practice authorised is, or is to be, carried on;
- 30 **“NHMRC”** means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992* of the Commonwealth;

“**NHMRC licence**” means a licence granted under —

- (a) section 53ZB; or
- (b) section 21 of the Commonwealth Human Embryo Act;

5 “**summary conviction penalty**”, in relation to a crime,
has the same meaning as that term has in section 5
of *The Criminal Code*;

“**woman**” means any female human.

”.

10 (12) Section 3(2) is amended as follows:

- (a) by inserting after “This Act” —
“ , other than Part 4B ”;
- (b) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —

15 “
a human egg undergoing fertilisation or a human embryo
”;

- (c) by deleting paragraph (b) and inserting instead —

20 “
(b) only if the egg or the embryo has been or is
developed in consequence of an in vitro
fertilisation procedure.
”.

25 (13) Section 3(3) is amended as follows:

- (a) by deleting paragraph (a);
- (b) in paragraph (b) —
 - (i) by deleting “an egg,” and inserting instead —
“ a human egg, ”; and
 - (ii) by deleting “an egg in the process of fertilisation;” and inserting instead —
“ a human egg undergoing fertilisation; ”;

30

s. 6

(c) in paragraph (d) by deleting “sperm” and inserting instead —

“ human sperm ”.

(14) Section 3(4) is amended as follows:

5 (a) by deleting “gametes, an egg in the process of fertilisation or any embryo,” and inserting instead —

“

human gametes, a human egg undergoing fertilisation or a human embryo

10

”;

(b) in paragraph (b) by deleting “gametes which are, or egg, egg in the process of fertilisation or embryo” and inserting instead —

“

15

human gametes which are or a human egg or embryo

”.

(15) Section 3(5) is amended by deleting “person responsible” in each place where it occurs and inserting instead —

20

“ licence supervisor ”.

6. Section 3A inserted

After section 3 the following section is inserted —

“

3A. Meaning of “human embryo”

25

(1) In this Act —

“**human embryo**” means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

30

- (2) For the purposes of the definition of “human embryo” in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

”.

7. Section 4 amended

- (1) Section 4 is amended as follows:

- (a) by inserting before “The” the subsection designation “(1)”;
(b) by deleting “The” and inserting instead —
“ Generally, the ”.

- (2) At the end of section 4 the following subsection is inserted —
“

- (2) The particular objects of Part 4B are set out in section 53S.

”.

8. Section 5A inserted

After section 5 the following section is inserted into Part 1 Division 2 —

“

5A. Application

This Division does not apply in relation to an excess ART embryo except in relation to a use of such an embryo that is an exempt use as defined in section 53W(2).

”.

s. 9

9. Section 6 amended

(1) Section 6(1) is amended as follows:

(a) in paragraph (a)(i) by deleting “an egg” and inserting instead —

5 “ a human egg ”;

(b) in paragraph (a)(ii) by deleting “an egg in the process of” and inserting instead —

“ a human egg undergoing ”;

10 (c) in paragraph (a)(iii) by deleting “an embryo;” and inserting instead —

“ a human embryo; ”;

(d) in paragraph (b) by deleting “sperm,” and inserting instead —

“ human sperm, ”;

15 (e) by deleting “or” after paragraph (b);

(f) by deleting the comma at the end of paragraph (c) and inserting instead —

“

; or

20 (d) any other use, outside the body of a woman, of a human embryo, if the use is not for a purpose relating to the reproductive technology treatment of the woman,

”.

25 (2) Section 6(2) and (3) are repealed and the following subsection is inserted instead —

“

(2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.

30 Summary conviction penalty: Imprisonment for one year.

”.

10. Section 7 amended

(1) Section 7(1) is amended as follows:

(a) by deleting “who causes or permits —” and inserting instead —

5 “ must not cause or permit — ”;

(b) in paragraph (a) by deleting “an egg in the process of fertilisation, or any embryo,” and inserting instead —

10 “
a human egg undergoing fertilisation, or any embryo,
”;

(c) after paragraph (a) by inserting “or”;

(d) in paragraph (b) by deleting “an egg in the process of fertilisation, or any embryo,” and inserting instead —

15 “
a human egg undergoing fertilisation, or any embryo,
”;

20 (e) by deleting the semicolon at the end of paragraph (b) and inserting instead a full stop;

(f) by deleting paragraphs (c) to (j);

(g) by deleting “commits an offence.”.

(2) Section 7(2), (3) and (4) are repealed and the following subsection is inserted instead —

25 “
(2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.
Summary conviction penalty: Imprisonment for
30 one year.

”.

s. 11

(3) Section 7(5) is amended as follows:

- (a) in paragraph (a) by deleting “any gametes, or any egg in the process of fertilisation or embryo” and inserting instead —

5

“

human gametes, a human egg undergoing
fertilisation or a human embryo

”;

- (b) by deleting “\$10 000 or”.

10 **11. Section 14 amended**

(1) Section 14(1) is amended as follows:

- (a) in paragraph (c) by deleting “person responsible” and inserting instead —

“ licence supervisor ”;

15

- (b) in paragraph (e)(i) by deleting “egg” and inserting instead —

“ human egg ”;

- (c) in paragraph (e)(ii) by deleting “gametes” and inserting instead —

20

“ human gametes ”;

- (d) in paragraph (e)(iii) by deleting “egg in the process of” and inserting instead —

“ human egg undergoing ”;

- (e) in paragraph (e)(iv) by deleting “embryo” and inserting instead —

25

“ human embryo ”.

(2) Section 14(2) is repealed and the following subsections are inserted instead —

“

30

- (2) Subsection (1)(e)(iv) does not apply in relation to an excess ART embryo except in relation to the use of

such an embryo that is an exempt use as defined in section 53W(2).

(2a) The Council must not grant approval to any research being conducted upon or with a human embryo unless —

- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman; or
- (b) the research consists of a use referred to in section 53W(2)(b) or (f).

(2b) The Council must not grant approval to any diagnostic procedure to be carried out upon or with a human embryo unless —

- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that —
 - (i) the diagnostic procedure is unlikely to leave the embryo unfit to be implanted in the body of a woman; and
 - (ii) where the diagnostic procedure is for the genetic testing of the embryo, there is a significant risk of a serious genetic abnormality or disease being present in the embryo;

or

- (b) the diagnostic procedure consists of a use referred to in section 53W(2)(d) or (f).

”.

s. 12

(3) Section 14(3)(b) is amended as follows:

- (a) in subparagraph (i) by deleting “National Health and Medical Research Council,” and inserting instead —
“ NHMRC, ”;
- 5 (b) in subparagraph (ii) by deleting “the Reproductive Technology Accreditation Committee for the Fertility Society of Australia” and inserting instead —
“ a body referred to in section 29(5)(a)(i) or (ii) ”;
- 10 (c) in subparagraph (iii) by deleting “principal” and inserting instead —
“ principle ”.

12. Section 17 amended

Section 17 is amended as follows:

- (a) by inserting after “prohibit” —
15 “
the mixing in the same artificial fertilisation procedure
of multiple sources of
”;
- 20 (b) by deleting paragraphs (a) and (b) and “or” between those paragraphs and inserting instead —
“
(a) human gametes;
(b) human eggs undergoing fertilisation; or
(c) human embryos,
25 in such a manner as may create confusion as to the biological parentage of any child born as a result of the procedure.
”.

13. Section 18 amended

(1) Section 18(1) is amended as follows:

- (a) in paragraph (c) by inserting before “gametes” —
“ human ”;
- 5 (b) in paragraph (c) by deleting “, including their genetic modification”;
- (c) in paragraph (d) by deleting “an embryo” and inserting instead —
“ a human embryo ”;
- 10 (d) in paragraph (d) by deleting “any gametes, egg in the process of fertilisation or embryo” and inserting instead —
“
human gametes, a human egg undergoing
15 fertilisation or a human embryo
”;
- (e) in paragraph (f) by deleting “gametes, eggs in the process of fertilisation or embryos” and inserting instead —
“
20 human gametes, human eggs undergoing fertilisation or human embryos
”.
- (2) Section 18(2)(a)(ii) is amended by deleting “any gametes, egg
25 in the process of fertilisation or embryo;” and inserting instead —
“
human gametes, a human egg
30 undergoing fertilisation or a human embryo;
”.

s. 14

14. Section 20 amended

(1) Section 20(2)(a) is amended as follows:

(a) in subparagraph (i) by deleting “gametes” and inserting instead —

5 “ human gametes ”;

(b) in subparagraph (ii) by deleting “an egg in the process of fertilisation, or any embryo” and inserting instead —

10 “
a human egg undergoing fertilisation or
a human embryo
”.

(2) After section 20(2) the following subsection is inserted —

15 “
(2a) Subsection (2)(a)(ii) does not apply in relation to an
excess ART embryo except in relation to a use of such
an embryo that is an exempt use as defined in
section 53W(2).
”.

15. Section 21 amended

20 Section 21 is amended as follows:

(a) in paragraph (c) by deleting “gametes, eggs in the process of fertilisation or embryos” and inserting instead —

25 “
human gametes, human eggs undergoing
fertilisation or human embryos
”;

(b) in paragraph (d) by deleting “gametes, eggs in the process of fertilisation or embryos,” and inserting instead —

30 “
human gametes, human eggs undergoing
fertilisation or human embryos,
”.

- (c) in paragraph (f) by deleting “gametes, eggs in the process of fertilisation or embryos;” and inserting instead —

“

5 human gametes, human eggs undergoing fertilisation or human embryos;

”;

- (d) in paragraph (g) by deleting “gametes, eggs in the process of fertilisation or embryos;” and inserting instead —

“

10 human gametes, human eggs undergoing fertilisation or human embryos;

”;

- (e) in paragraph (h) by deleting “gametes, eggs in the process of fertilisation or embryos” and inserting instead —

“

15 human gametes, human eggs undergoing fertilisation or human embryos

”;

- (f) in paragraph (i) by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —

“

25 human gametes, human eggs undergoing fertilisation or human embryos

”;

- (g) in paragraph (j) by deleting “egg in the process of fertilisation or embryo” and inserting instead —

“

30 human egg undergoing fertilisation or human embryo

”;

s. 16

- (h) in paragraph (k) by deleting “egg in the process of fertilisation or an embryo” and inserting instead —

“

human egg undergoing fertilisation or human embryo

”.

16. Section 22 amended

- (1) Section 22(1) is amended as follows:

- (a) by deleting “Where by or under this Act consent is required to be given in relation to the use or keeping of any gametes, egg in the process of fertilisation or embryo —” and inserting instead —

“

For the purposes of the licence condition referred to in section 33(2)(e) —

”;

- (b) in paragraph (c) by deleting “egg in the process of fertilisation or embryo” and inserting instead —

“

human egg undergoing fertilisation or human embryo

”;

- (c) in paragraph (d) by deleting “in the process of fertilisation or an embryo” and inserting instead —

“ undergoing fertilisation or a human embryo ”;

- (d) in paragraph (e) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —

“

a human egg undergoing fertilisation or a human embryo

”;

- (e) after paragraph (e)(i) by inserting the following subparagraphs —

“

(ia) in the case of a use outside the body of a woman, there is an effective consent to the use for that purpose by the woman on whose behalf it is being developed and her spouse or defacto partner, if any;

(ib) in the case of implantation in the body of a woman, there is an effective consent to the implantation by the woman and her spouse or defacto partner, if any;

”.

- (2) Section 22(2) is amended as follows:

- (a) by deleting “gametes” in each place where it occurs and inserting instead —

“ human gametes ”;

- (b) by deleting “whether eggs” and inserting instead —

“ whether human eggs ”;

- (c) by deleting “sperm” in both places where it occurs and inserting instead —

“ human sperm ”;

- (d) by deleting “egg in the process of fertilisation or embryo” and inserting instead —

“

human egg undergoing fertilisation or human embryo

”;

- (e) in paragraph (b) by deleting “an egg in the process of fertilisation, or an embryo,” and inserting instead —

“

a human egg undergoing fertilisation or a human embryo,

”;

s. 16

- (f) in paragraph (b) by deleting “any egg” and inserting instead —
“ any human egg ”;
- 5 (g) by deleting “where an egg in the process of fertilisation, or an embryo,” and inserting instead —
“
where a human egg in the process of fertilisation, or a human embryo,
”;
- 10 (h) by deleting “particular egg in the process of” and inserting instead —
“ particular egg undergoing ”.
- (3) Section 22(3) is amended by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —
15 “
human gametes, human eggs undergoing fertilisation or human embryos
”.
- 20 (4) Section 22(4) is amended by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —
“
human gametes, a human egg undergoing fertilisation or a human embryo
”.
- 25 (5) Section 22(5) is repealed and the following subsection is inserted instead —
“
30 (5) A consent to the use of a human egg undergoing fertilisation or a human embryo must specify the purposes for which the egg or embryo may be used and may specify conditions subject to which the egg or embryo shall or shall not be used.
”.

- (6) Section 22(6) is amended by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —

“

human gametes, a human egg undergoing fertilisation
or a human embryo

”.

- (7) Section 22(8) is amended by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —

“

human gametes, a human egg undergoing fertilisation
or a human embryo

”.

17. Section 23 amended

Section 23(a)(ii) is amended by inserting before “disease” —

“ a ”.

18. Section 24 amended

- (1) Section 24(1) is amended as follows:

- (a) by deleting “any eggs, sperm, egg in the process of fertilisation or embryo —” and inserting instead —

“

any human gametes, human egg undergoing
fertilisation or human embryo —

”;

- (b) in paragraph (a) by deleting “an egg in the process of fertilisation or any embryo” and inserting instead —

“ a human embryo ”;

- (c) in paragraph (a) by deleting “egg or embryo” and inserting instead —

“

embryo or its probable future use under an
NHMRC licence

”;

s. 18

- (d) in paragraph (b) by deleting subparagraphs (i), (ii) and (iii) and the “or” between subparagraphs (ii) and (iii) and inserting instead —

“

- 5 (i) human gametes;
 (ii) a human egg undergoing fertilisation; or
 (iii) a human embryo,
- ”;

- (e) by deleting “no egg in the process of fertilisation or embryo” and inserting instead —

“

no human egg undergoing fertilisation or
human embryo

”;

- (f) by deleting “the permitted storage period” and inserting instead —

“ 10 years ”.

- (2) Section 24(1a) is amended as follows:

- (a) by inserting after “may” —

20 “ , on an application by an eligible person, ”;

- (b) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —

“

25 a human egg undergoing fertilisation or a human
embryo

”.

- (3) Section 24(1c) is amended by deleting “the permitted storage period” and inserting instead —

“ 10 years ”.

- (4) Section 24(2), (3) and (4) are repealed and the following subsections are inserted instead —

“

- (2) In subsection (1a) —

“eligible person”, in relation to a human egg undergoing fertilisation or a human embryo, means —

- (a) a person who is or is to be a participant in an artificial fertilisation procedure in which the egg or embryo is to be used;
- (b) a person for whom the egg or embryo was developed; or
- (c) in the case of an excess ART embryo, except in relation to the use of such an embryo referred to in section 10(2)(e) of the Commonwealth Human Embryo Act, the licensee.

- (3) Three months before the end of a period of storage permitted under this section the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored.

- (4) If a period of storage permitted under this section comes to an end and no application has been made for the extension of the storage period, the licensee may, if the licensee has complied with subsection (3), allow the human egg undergoing fertilisation or the human embryo to succumb and will not be liable to anyone for so doing.

”.

19. Section 25 amended

Section 25 is amended as follows:

- (a) by deleting “gametes —” and inserting instead —
“ human gametes — ”;

s. 20

- (b) in paragraph (a) by deleting “eggs and sperm,” and inserting instead —
“ human eggs and human sperm, ”;
- 5 (c) in paragraph (b) by deleting “where gametes” and inserting instead —
“ where human gametes ”;
- (d) in paragraph (b)(i) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —
“
10 a human egg undergoing fertilisation or
a human embryo
”,
- (e) in paragraph (c) by deleting “gametes” and inserting instead —
15 “ human gametes ”.

20. Section 26 amended

- (1) Before section 26(1) the following subsection is inserted into section 26 —
“
20 (1a) This section does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).
”.
- 25 (2) Section 26(1) is amended as follows:
(a) by deleting “In” and inserting instead —
“ Subject to section 24(4), in ”;

- (b) by deleting “egg in the process of fertilisation or embryo” and inserting instead —

“

human egg undergoing fertilisation or human embryo

”;

- (c) in paragraph (a) by deleting “for implantation”;
(d) in paragraph (a) by deleting “an egg in the process of fertilisation or embryo” and inserting instead —

“

a human egg undergoing fertilisation or a human embryo

”;

- (e) in paragraph (c) by deleting “gametes an egg in the process of fertilisation or embryo” and inserting instead —

“

human gametes, a human egg undergoing fertilisation or a human embryo

”;

- (f) in paragraph (c) by deleting “gamete” and inserting instead —

“ human gamete ”;

- (g) in paragraph (c) by deleting “gametes” and inserting instead —

“ human gametes ”;

- (h) in paragraph (d) by deleting “an egg in the process of” and inserting instead —

“ a human egg undergoing ”;

- (i) in paragraph (d) by deleting “an embryo” and inserting instead —

“ a human embryo ”;

s. 21

- (j) in paragraph (d) by inserting after “that purpose,” —
“ the egg may be used ”;
- (k) in paragraph (d) by deleting “it may be donated for the
purpose of providing treatment for a specific recipient”;
- 5 (l) in paragraph (e) by deleting “an egg in the process of
fertilisation or in an embryo” and inserting instead —
“
a human egg undergoing fertilisation or a
human embryo
10 ”.
- (3) Section 26(2) is amended by deleting “an egg in the process of
fertilisation or an embryo” and inserting instead —
“
a human egg undergoing fertilisation or a human
15 embryo
”.

21. Section 27 amended

- (1) Section 27(1)(d) is amended by inserting after “section 28” —
“ or 28A ”.
- 20 (2) Section 27(2) is amended as follows:
- (a) in paragraph (a)(i) by deleting “egg” and inserting
instead —
“ human egg ”;
- 25 (b) in paragraph (a) by deleting subparagraphs (ii) and (iii) and
the “or” between those paragraphs and inserting instead —
“
(ii) any human embryo; or
(iii) any human egg undergoing fertilisation;
”;

- (c) in paragraph (b) by deleting “sperm” and inserting instead —
“ human sperm ”.

- (3) Section 27(4)(a)(v) is amended by deleting “person responsible” and inserting instead —
“ licence supervisor ”.

22. Section 28 amended

- (1) Section 28(1) is amended by deleting “Act” and inserting instead —
“ Part ”.

- (2) Section 28(2) is amended as follows:

- (a) in paragraph (a) by deleting “Act” and inserting instead —
“ Part ”;

- (b) in paragraph (b) by deleting “person responsible” and inserting instead —
“ licence supervisor ”.

- (3) Section 28(3) is amended by deleting “Act” and inserting instead —
“ Part ”.

23. Section 28A inserted

After section 28 the following section is inserted —

“

28A. Exemptions relating to storage of certain embryos

- (1) The Commissioner of Health may, on an application by a person who holds an NHMRC licence grant an exemption from the requirement to hold a licence under this Part to store excess ART embryos to which the NHMRC licence applies.

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(2) A person who holds an exemption under subsection (1) is not required to hold a licence under this Part to store the excess ART embryos.

5 (3) A person who holds an exemption under subsection (1) is subject to the disciplinary procedures in relation to that exemption as if the exemption were a licence under this Part and the person were the licence supervisor in relation to that licence.

”.

10 **24. Section 29 amended**

(1) After section 29(5)(a) the following paragraph is inserted —

“

(aa) that the applicant is accredited to carry out reproductive technology by —

15 (i) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or

20 (ii) 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;

”.

25 (2) Section 29(6)(b)(i) is amended by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

25. Section 30 amended

Section 30(4) is amended as follows:

30 (a) by deleting “person responsible” and inserting instead —

“ licence supervisor ”;

- (b) in paragraph (a) by deleting “gametes, egg in the process of fertilisation, embryo” and inserting instead —

“

human gametes, a human egg undergoing
fertilisation or a human embryo

”.

26. Section 32 amended

Section 32(3) is amended by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

27. Section 33 amended

- (1) Section 33(2) is amended as follows:

- (a) by deleting “Act” in the first place where it occurs and inserting instead —

“ Part ”;

- (b) in paragraph (a)(i) by deleting “person responsible” and inserting instead —

“ licence supervisor ”;

- (c) in paragraph (b) by deleting “gametes, eggs in the process of fertilisation or embryos,” and inserting instead —

“

human gametes, a human egg undergoing
fertilisation or a human embryo,

”;

- (d) by deleting paragraph (e) and inserting instead —

“

(e) that section 22(1) is complied with;

(ea) that the licensee maintains the accreditation
required by section 29(5)(a);

”;

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- (e) in paragraph (g) by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —

“

5 human gametes, a human egg undergoing fertilisation or a human embryo

”.

- (2) Section 33(3) is amended as follows:

- (a) in paragraph (a) by deleting “gametes of a person or an egg in the process of fertilisation or an embryo” and inserting instead —

“

human gametes, a human egg undergoing fertilisation or a human embryo

”;

- (b) in paragraph (b) by deleting “an egg in the process of fertilisation or an embryo” and inserting instead —

“

a human egg undergoing fertilisation or a human embryo

”;

- (c) in paragraph (c) by deleting “gametes, eggs in the process of fertilisation or embryos” and inserting instead —

“

human gametes, human eggs undergoing fertilisation or human embryos

”;

- (d) in paragraph (d) by deleting “gametes, egg in the process of fertilisation or embryo” and inserting instead —

“

human gametes, human egg undergoing fertilisation or human embryo

”.

28. Section 40 amended

Section 40(1)(f) is amended by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

5 **29. Section 41 amended**

(1) Section 41(2) is amended by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

(2) Section 41(3) is amended as follows:

10 (a) by deleting “egg in the process of fertilisation or any embryo” and inserting instead —

“
human egg undergoing fertilisation or human embryo”,

15 (b) by deleting “gametes” and inserting instead —

“ human gametes ”.

30. Section 44 amended

(1) Section 44(1) is amended as follows:

20 (a) in paragraph (a) by deleting “gametes, eggs in the process of fertilisation and embryos” and inserting instead —

“
human gametes, human eggs undergoing
fertilisation or human embryos”,

25 (b) in paragraph (a)(i) by deleting “gametes,” and inserting instead —

“ human gametes, ”;

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- (c) by deleting paragraph (a)(ii) and inserting instead the following subparagraph —

“

- (ii) if human eggs undergoing fertilisation or human embryos, their biological parentage and the date fertilisation commenced;

”;

- (d) in paragraph (a)(iv) by deleting “gametes, an egg in the process of fertilisation or an embryo was” and inserting instead —

“

human gametes, human eggs undergoing fertilisation or human embryos were

”;

- (e) in paragraph (a)(iv) by deleting “were, or an egg in the process of fertilisation or an embryo was,” and inserting instead —

“

, eggs undergoing fertilisation or embryos were

”;

- (f) in paragraph (b)(v)(B) by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

- (2) Section 44(2) is amended by inserting after “section 28” —

“ or 28A ”.

- (3) Section 44(4)(b) is amended by deleting “gametes, egg in the process of fertilisation or an embryo;” and inserting instead —

“

human gametes, a human egg undergoing
fertilisation or a human embryo;

”.

31. Section 45 amended

Section 45(1) is amended as follows:

- (a) in paragraph (a)(ii) by deleting “gametes, egg in the process of fertilisation or embryo used;” and inserting instead —

“

human gametes, human egg undergoing
fertilisation or human embryo used;

”;

- (b) after paragraph (d) by deleting the “and” and inserting instead —

“

- (da) any information obtained from the NHMRC
Licensing Committee established under
section 13 of the Commonwealth Human
Embryo Act in relation to any NHMRC
licences held or applied for in this State; and

”.

32. Section 48 amended

Section 48 is amended by deleting “gametes or an embryo” and inserting instead —

“ human gametes or a human embryo ”.

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33. Section 49 amended

- (1) Section 49(1)(a) is amended by deleting “gametes, an egg in the process of fertilisation or an embryo;” and inserting instead —

“

5 human gametes, a human egg undergoing
fertilisation or a human embryo;

”.

- (2) Section 49(3)(a) is amended by deleting “gametes, an egg in the process of fertilisation or an embryo;” and inserting instead —

“

10 human gametes, a human egg undergoing
fertilisation or a human embryo;

”.

34. Section 51 amended

- 15 (1) Section 51(1)(a) is amended by deleting “person responsible”
and inserting instead —

“ licence supervisor ”.

- (2) Section 51(2) is amended by deleting “person responsible” and
inserting instead —

20 “ licence supervisor ”.

- (3) Section 51(2)(c) is amended as follows:

- (a) by deleting “gametes, eggs in the process of fertilisation
and embryos” and inserting instead —

“

25 human gametes, human eggs undergoing
fertilisation and human embryos

”;

- (b) by deleting “gametes or any such eggs” and inserting
instead —

30 “ any such gametes, eggs ”.

- (4) Section 51(3) is amended by deleting “person responsible” and inserting instead —
“ licence supervisor ”.
- 5 (5) Section 51(5) is amended by deleting “person responsible” in both places where it occurs and inserting instead —
“ licence supervisor ”.
- (6) Section 51(6) is amended by deleting “person responsible” in both places where it occurs and inserting instead —
“ licence supervisor ”.
- 10 (7) Section 51(7) is amended by deleting “person responsible” and inserting instead —
“ licence supervisor ”.
- (8) Section 51(8) is amended by deleting “person responsible” and inserting instead —
15 “ licence supervisor ”.

35. Section 53 amended

Section 53(1)(b) is amended by deleting “person responsible” and inserting instead —
“ licence supervisor ”.

36. **Part 4B inserted**

Before Part 5 the following Part is inserted —

“

**Part 4B — Regulation of certain uses involving
excess ART embryos**

Division 1 — General

53S. Object of this Part

(1) The object of this Part is —

(a) to address concerns, including ethical concerns,
about scientific developments in relation to
human reproduction and the utilisation of
human embryos by regulating activities that
involve the use of certain human embryos
created by assisted reproductive technology;
and

(b) to adopt in this State a uniform Australian
approach to the regulation of activities that
involve the use of certain human embryos
created by assisted reproductive technology.

(2) For that purpose, this Part contains a number of
provisions that are similar to provisions in the
Commonwealth Human Embryo Act.

53T. Definitions

(1) In this Part, unless the contrary intention appears —

“**AHEC**” means the Australian Health Ethics
Committee established by the *National Health and
Medical Research Council Act 1992* of the
Commonwealth;

“Commonwealth Human Embryo regulations”

means the regulations in force under the
Commonwealth Human Embryo Act;

“confer” includes to impose;

“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;

“corresponding law” means —

- (a) the Commonwealth Human Embryo Act; or
- (b) an Act of another State that is a
corresponding State law as defined in the
Commonwealth Human Embryo Act;

“disclose”, in relation to information, means give or
communicate in any way;

“excess ART embryo” means a human embryo that —

- (a) was created, by assisted reproductive
technology, for use in the assisted
reproductive technology treatment of a
woman; and
- (b) is excess to the needs of —
 - (i) the woman for whom it was created;
and
 - (ii) her spouse or de facto partner (if any) at
the time the embryo was created;

“HREC” means a Human Research Ethics Committee;

“inspector” means a person appointed as an inspector
under section 53ZN(1);

“licence” means a licence issued under section 53ZB;

“licensed ART centre” means a person licensed under
Part 4;

“NHMRC Licensing Committee” means the Committee of that name established under section 13 of the Commonwealth Human Embryo Act;

5 **“proper consent”**, in relation to the use of an excess ART embryo, means —

 (a) consent obtained in accordance with the *Ethical Guidelines on Assisted Reproductive Technology* (1996) issued by the NHMRC;

10 or

 (b) if other guidelines are issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of paragraph (b) of the definition of “proper consent” in section 8 of the Commonwealth Human Embryo Act —

15 consent obtained in accordance with those other guidelines, rather than the guidelines mentioned in paragraph (a);

20

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

 (a) each person who provided the egg or sperm from which the embryo was created;

25

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

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

30

 (d) any person who was the spouse or de facto partner of the woman mentioned in paragraph (b) at the time the embryo was created;

35

“State” includes the Australian Capital Territory and the Northern Territory.

- 5 (2) For the purposes of paragraph (b) of the definition of “excess ART embryo”, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if —
- 10 (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
- (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.
- 15 (3) A reference in this Part to a number of penalty units is a reference to the amount calculated in accordance with the following formula —
- A × B**
- where —
- 20 **A** is that number of penalty units; and
- B** is the amount (in dollars) that is for the time being a penalty unit under section 4AA of the *Crimes Act 1914* of the Commonwealth.
- 25 (4) In this Part, a reference to a Commonwealth Act includes a reference to —
- (a) that Commonwealth Act, as amended and in force for the time being; and
- (b) an Act enacted in substitution for that Act and, if it is amended, as amended and in force for
- 30 the time being.

Division 2 — Performance of functions

53U. Functions not affected by State laws

5 The NHMRC Licensing Committee or an officer of the Commonwealth is not precluded by any law of the State from performing a function conferred by this Part.

53V. Extent to which functions are conferred

- 10 (1) This Part does not purport to impose any duty on the NHMRC Licensing Committee or an officer of the Commonwealth to perform a function if the imposition of the duty would be beyond the legislative power of the Parliament of the State.
- (2) This section does not limit the operation of section 7 of the *Interpretation Act 1984*.

Division 3 — Offences

15 53W. Offence — use of excess ART embryo

- (1) A person commits a crime if the person uses an excess ART embryo, unless —
- 20 (a) the use by the person is authorised by a licence; or
- (b) the use by the person is an exempt use as defined in subsection (2).

Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.

25 Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.

- (2) A use of an excess ART embryo by a person is an “**exempt use**” for the purposes of subsection (1) if —
- (a) the use consists only of —
- (i) storage of the excess ART embryo;

-
- (ii) removal of the excess ART embryo
from storage; or
- (iii) transport of the excess ART embryo;
or
- 5 (b) the use consists only of observation of the
excess ART embryo;
- (c) the use consists only of allowing the excess
ART embryo to succumb;
- 10 (d) the use is carried out by a licensed ART centre,
and —
- (i) the excess ART embryo is not suitable
to be placed in the body of the woman
for whom it was created where the
15 suitability of the embryo is determined
only on the basis of its biological fitness
for implantation; and
- (ii) the use forms part of diagnostic
investigations conducted in connection
with the assisted reproductive
20 technology treatment of the woman for
whom the excess ART embryo was
created;
- (e) the use is carried out by a licensed ART centre
and is for the purposes of achieving pregnancy
25 in a woman other than the woman for whom the
excess ART embryo was created; or
- (f) the use is of a kind prescribed by the
Commonwealth Human Embryo regulations for
the purposes of section 10(2)(f) of the
30 Commonwealth Human Embryo Act.
- (3) A defendant does not bear an evidential burden in
relation to any matter in subsection (1).

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(4) In subsection (2) —

“diagnostic investigation”, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created;

“observation”, in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

53X. Offence — breaching a licence condition

(1) A person commits a crime if the person engages in conduct that contravenes a condition of a licence that applies to the person.

Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.

Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.

(2) In this section —

“engage in conduct” means —

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

Division 4 — Embryo Research Licensing Committee of the NHMRC

53Y. Functions of Committee

The functions of the NHMRC Licensing Committee are —

- (a) to perform functions in relation to licences under Division 5;

- (b) to perform functions in relation to databases under Division 6; and
- (c) to perform such other functions as are conferred on it by this Part or any other law.

5 **53Z. Powers of Committee**

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

Division 5 — Licensing system

10 **53ZA. Person may apply for licence**

- (1) A person may apply to the NHMRC Licensing Committee for a licence authorising use of excess ART embryos.
- (2) An application under subsection (1) —
 - 15 (a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and
 - (b) must be accompanied by a fee that is equal to the fee (if any) prescribed by the
20 Commonwealth Human Embryo regulations for the purposes of section 20(2)(b) of the Commonwealth Human Embryo Act.

53ZB. Determination of application by Committee

- 25 (1) This section applies if a person has made an application under section 53ZA for a licence.
- (2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.

- (3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following —
- (a) that appropriate protocols are in place —
 - (i) to enable proper consent to be obtained before an excess ART embryo is used under the licence (see section 53ZE(1)(a)); and
 - (ii) to enable compliance with any restrictions on such consent;
 - (b) if the use of an excess ART embryo proposed in the application may damage or destroy the embryo — that appropriate protocols are in place to enable compliance with the condition that such use is authorised only in respect of an embryo created before 5 April 2002 (see section 53ZE(3));
 - (c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999), as in force from time to time;
 - (d) that there is no possibility that an excess ART embryo proposed in the application could be used for technical or commercial purposes in the testing, creation or manufacture of cosmetic products such as lipstick, mascara, face moisturising creams and other like beauty products.

-
- (4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following —
- (a) restricting the number of excess ART embryos to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
 - (b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means;
 - (c) any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of section 21(4)(c) of the Commonwealth Human Embryo Act;
 - (d) the HREC assessment of the application mentioned in subsection (3)(c);
 - (e) such additional matters (if any) as are prescribed by the Commonwealth Human Embryo regulations for the purposes of section 21(4)(e) of the Commonwealth Human Embryo Act.
- (5) The NHRMC Licensing Committee must not issue a licence if the use of an excess ART embryo proposed in the application is, or could be, for technical or commercial purposes in the testing, creation or manufacture of cosmetic products such as lipstick, mascara, face moisturising creams and other like beauty products.

53ZC. Notification of decision

- (1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 53ZA 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 53ZB(3)(c);
 - (c) the Commissioner as defined in section 3(1) of the *Health Act 1911*.
- (2) If the NHMRC Licensing Committee decides to issue the licence, it must, in addition to issuing the licence to the applicant, give a copy of the licence to the bodies mentioned in subsection (1)(b) and (c).

53ZD. Period of licence

- (1) A licence —
- (a) comes into force on the day specified in the licence, or if no day is specified, on the day on which it is issued; and
 - (b) remains in force until the day specified in the licence, unless it is suspended, revoked or surrendered before that day.
- (2) A licence is not in force throughout any period of suspension.

53ZE. Licence is subject to conditions

- (1) A licence is subject to the condition that before an excess ART embryo is used as authorised by the licence —
- (a) each responsible person in relation to the excess ART embryo must have given proper consent to that use;

- (b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject; and
- 5 (c) if the licence authorises use of an excess ART embryo that may damage or destroy the embryo — the licence holder must have reported in writing to the NHMRC Licensing Committee that the embryo was created before
- 10 5 April 2002.
- (2) A licence is subject to the condition that the use of an excess ART embryo must be in accordance with any restrictions to which the proper consent under subsection (1) is subject.
- 15 (3) If a licence authorises the use of an excess ART embryo that may damage or destroy the embryo, the licence is subject to the condition that such use is authorised only in respect of an embryo created before
- 20 5 April 2002.
- (4) A licence is subject to a condition that an excess ART embryo may only be used for purposes permitted by the licence and a condition that prohibits the use of an excess ART embryo for any other purpose including
- 25 technical or commercial purposes for the testing, creation or manufacture of cosmetic products such as lipstick, mascara, face moisturising creams and other like beauty products.
- (5) A licence is subject to such other conditions as are specified in the licence.
- 30 (6) The conditions specified in the licence may include, but are not limited to, conditions relating to the following —
- (a) the persons authorised by the licence to use excess ART embryos;

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- 5 (b) the number of excess ART embryos in respect
 of which use is authorised by the licence;
- (c) reporting;
- (d) monitoring;
- (e) information to be given by the licence holder to
 persons authorised by the licence to use excess
 ART embryos.
- 10 (7) The licence conditions set out in subsections (1), (2)
 and (3) apply to all persons who are authorised by the
 licence to use excess ART embryos.
- (8) Licence conditions specified in the licence apply to —
- (a) the licence holder; and
- (b) such other persons authorised by the licence to
 use excess ART embryos as are specified in the
15 licence.

53ZF. Variation of licence

- 20 (1) The NHMRC Licensing Committee may, by notice in
 writing given to the licence holder, vary a licence if the
 Committee believes on reasonable grounds that it is
 necessary or desirable to do so.
- (2) The NHMRC Licensing Committee may vary a licence
 under subsection (1) on its own initiative or on
 application by the licence holder.
- 25 (3) Without limiting subsection (1), the NHMRC
 Licensing Committee may vary the licence by
 specifying additional conditions or varying existing
 conditions.
- 30 (4) The NHMRC Licensing Committee must not vary a
 licence in such a way that, had a person applied under
 section 53ZA for the licence as varied, the Committee

would not have been permitted by this Part to issue the licence.

53ZG. Suspension or revocation of licence

- 5 (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a licence if the Committee believes on reasonable grounds that a condition of the licence has been breached.
- 10 (2) If a licence holder is convicted of an offence under this Division, a corresponding law or the *Prohibition of Human Cloning Act 2002* of the Commonwealth, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

15 **53ZH. Surrender of licence**

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

53ZI. Notification of variation, suspension, revocation or surrender of licence

- 20 If the NHMRC Licensing Committee varies, suspends or revokes a licence, or a licence is surrendered, the Committee must notify —
- (a) the licence holder;
- 25 (b) the HREC to which the NHMRC Licensing Committee notified its decision on the application for the licence under section 53ZC; and
- (c) the Commissioner as defined in section 3(1) of the *Health Act 1911*.

Division 6 — Reporting and confidentiality

53ZJ. NHMRC Licensing Committee to make certain information publicly available

- 5 (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;
- 10 (b) a short statement about the nature of the uses of excess ART embryos that are authorised by the licence;
- (c) any conditions to which the licence is subject;
- (d) the number of excess ART embryos in respect of which use is authorised by the licence;
- 15 (e) the date on which the licence was issued;
- (f) the period throughout which the licence is to remain in force.
- (2) The database is to be made publicly available.
- 20 (3) The database may be kept and made publicly available in electronic form.
- (4) Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.

53ZK. Confidential commercial information may only be disclosed in certain circumstances

- 25 (1) A person commits an offence if —
- (a) the person discloses confidential commercial information that the person has only because of performing duties or functions under this Part
- 30 or under a corresponding law;

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

(c) the disclosure is not —

(i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Part or under a corresponding law;

(ii) by order of a court; or

(iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

(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;

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

(c) the disclosure is not —

(i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Part or under a corresponding law;

(ii) by order of a court; or

(iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

(3) In this section —

“Commonwealth authority” means —

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

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

“State agency” means —

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

Division 7 — Review provisions

53ZKA. Annual Reports

- 5 (1) The NHMRC Licensing Committee must furnish to the Minister a copy of any report prepared under section 19(3) of the *Research Involving Human Embryos Act 2002* of the Commonwealth (insofar as the report is relevant to the operation of this Act).
- 10 (2) The Minister must, within 12 sitting days after receipt of a report under subsection (1), cause copies of the report to be laid before each House of Parliament.

53ZL. Meaning of terms

In this Division —

15 “**decision**” has the same meaning as in the *Administrative Appeals Tribunal Act 1975* of the Commonwealth;

“**eligible person**”, in relation to a decision of the NHMRC Licensing Committee, means —

- 20 (a) in relation to a decision under section 53ZB not to issue a licence — the applicant for the licence;
- (b) in relation to a decision in respect of the period throughout which the licence is to be in force under section 53ZD — the licence holder;
- 25 (c) in relation to a decision to specify a licence condition under section 53ZE(5) — the licence holder;
- (d) in relation to a decision to vary or refuse to vary a licence under section 53ZF — the licence holder; or
- 30 (e) in relation to a decision to suspend or revoke a licence under section 53ZG — the person

who was the licence holder immediately
before the suspension or revocation.

53ZM. Review of decisions

- 5 (1) An eligible person may apply to the Administrative
Appeals Tribunal for review of the following decisions
of the NHMRC Licensing Committee —
- (a) a decision under section 53ZB not to issue a
licence;
- 10 (b) a decision in respect of the period throughout
which the licence is to be in force under
section 53ZD;
- (c) a decision to specify a licence condition under
section 53ZE(5);
- 15 (d) a decision to vary or refuse to vary a licence
under section 53ZF;
- (e) a decision to suspend or revoke a licence under
section 53ZG.
- 20 (2) This section has effect subject to the *Administrative
Appeals Tribunal Act 1975* of the Commonwealth and
section 43 of the Commonwealth Human Embryo Act.

Division 8 — Monitoring powers

53ZN. Appointment of inspectors

- 25 (1) The Chairperson of the NHMRC Licensing Committee
may, by instrument in writing, appoint any of the
following persons as inspectors —
- (a) an officer of the Commonwealth;
- (b) a person who is appointed or employed by the
State.
- 30 (2) In exercising powers or performing functions as an
inspector, an inspector must comply with any

directions of the Chairperson of the NHMRC Licensing Committee.

- (3) The Chairperson of the NHMRC Licensing Committee must not appoint a person as an inspector under subsection (1) unless he or she is satisfied that the person has appropriate skills and experience.

53ZO. Identity card

- (1) The Chairperson of the NHMRC Licensing Committee must issue an identity card to an inspector.

- (2) The identity card —

- (a) must be in the form prescribed by the Commonwealth Human Embryo regulations for the purposes of section 34(2)(a) of the Commonwealth Human Embryo Act; 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.

Penalty: One penalty unit.

- (4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.

53ZP. Powers available to inspectors for monitoring compliance

- (1) For the purpose of finding out whether this Part has been complied with, an inspector may —
- (a) enter any premises; and
- (b) exercise the monitoring powers set out in section 53ZQ.

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(2) An inspector is not authorised to enter premises under subsection (1) unless —

(a) the occupier of the premises has consented to the entry; or

(b) the premises are premises at which the occupier of the premises is carrying out activities authorised by a licence issued under section 53ZB, and the entry is at a reasonable time.

53ZQ. Monitoring powers

(1) The monitoring powers that an inspector may exercise under section 53ZP(1)(b) are as follows —

(a) to search the premises and any thing on the premises;

(b) to inspect, examine, take measurements of, conduct tests on, or take samples of, any human embryo or thing on the premises that relates to this Part;

(c) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises;

(d) to inspect any book, record or document on the premises;

(e) to take extracts from or make copies of any such book, record or document;

(f) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.

(2) For the purposes of this Division, 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,
- 5 contains information that is relevant to determining whether there has been compliance with this Part.
- (3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains
- 10 information mentioned in subsection (2), the inspector may —
- (a) operate equipment or facilities at the premises to put the information in documentary form and copy the document so produced; or
 - 15 (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
- 20 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.
- (4) In addition, the Commissioner of Health may confer on
- 25 an inspector the powers set out in section 54.

53ZR. Power to secure

- If an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a
- 30 human embryo or a thing that may afford evidence of the commission of an offence against this Part, the monitoring powers include securing the embryo or

thing pending the obtaining of a warrant (whether by the inspector or by another person) to seize it.

53ZS. Inspector must produce identity card on request

An inspector is not entitled to exercise any powers under this Division 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.

53ZT. Consent

- (1) Before obtaining the consent of a person for the purposes of section 53ZP(2)(a), the inspector must inform the person that he or she may refuse consent.
- (2) An entry of an inspector by virtue of the consent of a person is not lawful unless the person voluntarily consented to the entry.

53ZU. Compensation for damage

- (1) The owner of equipment or other facilities is entitled to compensation for damage to the equipment or other facilities if —
 - (a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this Division; and
 - (b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.
- (2) An application for compensation is to be made to the NHMRC Licensing Committee.

- 5 (3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment or other facilities that was appropriate in the circumstances.

Division 9 — Expiry

53ZV. Expiry of certain provisions

- 10 Sections 53ZB(3)(b) and 53ZE(1)(c) and (3) expire on 5 April 2005.

Division 10 — Conscientious objection to use of excess ART embryos

53ZVA. Conscientious objection to use of excess ART embryos

15 Despite any requirement under a contract or a written law, a person is not required to use, or assist another person in using, an excess ART embryo under this Part if the person has a conscientious objection to doing so.

Division 11 — Review of Part

53ZW. Review of Part

- 20 (1) The Minister must cause a review of the operation of this Part to be undertaken as soon as possible after 19 December 2004.
- 25 (2) The review must take into account —
- (a) developments in technology in relation to assisted reproductive technology;

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- (b) developments in medical research and scientific research and the potential therapeutic applications of such research;
- (c) community standards; and
- 5 (d) the applicability of establishing a National Stem Cell Bank.

- (3) The review of this Part may be undertaken as part of the review of the Commonwealth Human Embryo Act mentioned in section 47 of that Act.

10 ”.

37. Section 54 amended

Section 54(1) is amended as follows:

- (a) in paragraph (a)(i) by deleting “egg in the process of fertilisation or any embryo” and inserting instead —

15 “
human egg undergoing fertilisation or
human embryo
”;

- (b) in paragraph (a)(ii) by deleting “gametes” and inserting instead —

20 “ human gametes ”;

- (c) in paragraph (a)(iv) by deleting “gametes or participants or any egg in the process of fertilisation or embryo;” and inserting instead —

25 “
human gametes or participants or any
human egg undergoing fertilisation or
human embryo;
”;

- (d) in paragraph (a) by deleting “gametes, egg in the process of fertilisation or embryo,” and inserting instead —

“

human gametes, human egg undergoing
fertilisation or human embryo,

”;

- (e) in paragraph (c) by deleting “gametes, an egg in the process of fertilisation or an embryo,” and inserting instead —

“

human gametes, a human egg undergoing
fertilisation or a human embryo,

”.

38. Section 56 amended

Section 56(1) is amended by deleting “an offence” and inserting instead —

“ a simple offence ”.

39. Section 57 amended

Section 57(1) is amended as follows:

- (a) in paragraph (a) by deleting “gametes, an egg in the process of fertilisation or an embryo” and inserting instead —

“

human gametes, a human egg undergoing
fertilisation or a human embryo

”;

- (b) in paragraph (b)(iii) by deleting “person responsible” and inserting instead —

“ licence supervisor ”.

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40. Section 59 amended

Section 59(2) is amended as follows:

- (a) after paragraph (b) by deleting “or”;
- (b) at the end of paragraph (c) by deleting the comma and inserting instead —

“

; or

- (d) a person on whom a power is conferred under section 53ZQ(4),

”.

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