HUMAN REPRODUCTIVE TECHNOLOGY AMENDMENT BILL 2003

EXPLANATORY MEMORANDUM
LEGISLATIVE COUNCIL

On 5 April 2002, the Council of Australian Governments (COAG) agreed that the Commonwealth, States and Territories would:

- introduce nationally consistent legislation to ban cloning of whole humans and other related practices;
- legislate to regulate human embryo research through a licensing scheme administered by the National Health and Medical Research Council (NHMRC);
- adopt a nationally consistent approach to the regulation of assisted reproductive technology (ART) clinical practice based on providers of ART services being accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA). Accreditation by the RTAC requires that all relevant guidelines issued by the NHMRC are complied with and that all aspects of practice are monitored by an Institutional Ethics Committee.

To give effect to this agreement the Commonwealth has passed the following legislation (collectively referred to in this explanatory memorandum as the Commonwealth legislation):

- the *Prohibition of Human Cloning Act 2002* (the Commonwealth Cloning Act) is an Act to prohibit human cloning and other unacceptable practices associated with reproductive technology, and for related purposes;
- the *Research Involving Human Embryos Act 2002* (the Commonwealth Human Embryo Act) is an Act to regulate certain activities involved in the use of human embryos, and for related purposes.

Both these Acts were proclaimed on 19 December 2002. The legislation came into effect on 16 January 2003, with the exception of the offence provisions in the Commonwealth Human Embryo Act, which came into force on 19 June 2003.

This Bill, together with the *Human Reproductive Technology Amendment (Prohibition of Human Cloning) Bill 2003* (WA Cloning Bill) seeks to amend the *Human Reproductive Technology Act 1991* (the Act) to give effect to the agreement made by COAG.

The relevant provisions of the Commonwealth Cloning Act are mirrored in a new Part 4A to the Act that is to be inserted by the WA Cloning Bill.

The relevant provisions of the Commonwealth Human Embryo Act are mirrored in a new Part 4B to the Act that is inserted by clause 36.

Other clauses in the Bill contain changes to the Act that are necessary to

accommodate the provisions included in the new Parts 4A and 4B and to provide for national consistency of ART clinical practice.

The amendments include some changes in terminology, which require consequential amendment to multiple sections in the Act. The changes to terminology are required to provide consistency with, or avoid confusion with, terms that have been used in the Commonwealth legislation. The following is a summary of the changes that result from changes in terminology and a reference to where the effect of the change is discussed in the explanatory memorandum:

Current Term	**Replacement Term introduced by this Bill**	**Explanation of the change**
egg	human egg	See sub-clause 5(11) under heading "human egg"
sperm	human sperm	See sub-clause 5(11) under heading "human sperm"
gametes	human gametes	See sub-clause 5(11) under heading "human gametes"
egg in the process of fertilisation	human egg undergoing fertilisation	This change picks up the change from "egg" to "human egg" and includes a grammatical correction because "fertilisation" is itself defined as a process (see sub-clause 5(3))
embryo	human embryo	See Clause 6
person responsible	licence supervisor	See sub-clause 5(9)

A glossary of abbreviations used in this explanatory memorandum is included at attachment 1.

Clause 1 – Short Title

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

Clause 2 – Commencement

This clause provides that the amendments in this Act operate from the date of proclamation.

Clause 3 – The Act amended

This clause specifies that the amendments are to the *Human Reproductive Technology Act 1991* (the Act).

Clause 4 – Preamble amended

Sub-clause 4(1)

The amendments to Preamble B:

- are consequential on the change of terminology for "embryo";
- reflect amendments in the body of the Act that would allow limited circumstances in which a human egg undergoing fertilisation could be created for diagnostic reasons subject to approval by the Reproductive Technology Council (RT Council). An example of such a diagnostic procedure would be to assess the interaction of sperm and eggs (see clause 12 for detailed discussion);
- reflect amendments in the body of the Act that clarify that a disease is not required to be a genetic disease (see clause 17 for detailed discussion);
- reflect amendments in the body of the Act that allow for the limited use of human embryos for purposes other than implantation (see clause 11 for detailed discussion).

Sub-clause 4(2)

The amendments to Preamble C:

- reflect amendments in the body of the Act that will allow some uses of a human embryo that may be destructive, subject to licensing requirements in the Act;
- are consequential on change of terminology for "embryo";
- reflect amendments in the body of the Act that would allow limited circumstances in which a human egg undergoing fertilisation could be created for diagnostic reasons subject to approval by the RT Council. An example of such a diagnostic procedure would be to assess the interaction of sperm and eggs (see clause 12 for detailed discussion).

Sub-clause 4(3)

The deletion of Preamble D reflects amendments in the body of the Act that would allow an embryo to remain in storage when it has been donated for research and is therefore not stored as a step in the process of implantation.

Clause 5 – Section 3 amended

Sub-clause 5(1)

The amendment to the definition of "authorised officer" includes a reference to a person on whom the Commissioner of Health has conferred enforcement powers in accordance with new section 53ZQ(4) inserted by clause 36.

Sub-clause 5(2)

The amendments in this sub-clause reflect the changes in terminology for "sperm", "egg", and "embryo".

Sub-clause 5(3)

The amendment to the definition of "**fertilisation**" is consequential on the changes to the definition of "embryo". The term "embryo" is replaced throughout the Act by the term "human embryo". The definition of human embryo mirrors the definition in the Commonwealth legislation, which designates the appearance of 2 pro-nuclei rather than the appearance of a 2-cell zygote as the point at which an embryo is formed. The appearance of 2 pro-nuclei occurs before a fertilising egg divides to become a 2-cell zygote. If the definition of "fertilisation" is not amended there would be a period of overlap between an "egg undergoing fertilisation" and an "embryo". The effect of this amendment is that an embryo is defined from an earlier point in the development process than under the existing definition.

Sub-clause 5(4)

The amendments in this sub-clause reflect the change in terminology for "egg", "egg in the process of fertilisation" and "embryo".

Sub-clause 5(5)

The amendment to the definition of Institutional Ethics Committee provides a more general description of the NHMRC guidelines that are to be complied with, which recognises that the name of the document may change over time.

Sub-clause 5(6)

The amendments to the definition of a "**licensee**" provide:

- that the term does not apply to a person who is a holder of a licence issued by the NHMRC under Part 4B or the Commonwealth Human Embryo Act. Holders of licences issued by the NHMRC are regulated by Part 4B and the Commonwealth Human Embryo Act;
- that the term does apply to a person who holds an exemption under the new section 28A (which covers storage of embryos that are to be used in connection with an NHMRC licence);
- are consequential on the change of terminology for "person responsible".

Sub-clause 5(7)

The amendments in this sub-clause are consequential on changes in terminology for "gametes", "egg in the process of fertilisation" and "embryo".

Sub-clause 5(8)

The amendments in this sub-clause are consequential on changes in terminology for "gametes", "egg in the process of fertilisation" and "embryo".

Sub-clause 5(9)

The amendments in this sub-clause delete definitions that are inconsistent with terminology used in the Commonwealth legislation and which are no longer required or are replaced or incorporated elsewhere.

"**chimaera**" is replaced by "**chimeric embryo**" (see section 53B inserted by the WA Cloning Bill).

"**cloning**" is no longer required as it has been incorporated within the prohibition on "creating a human embryo clone" (see section 53C inserted by the WA Cloning Bill).

"**embryo**" is replaced by "**human embryo**" (see clause 6).

"**embryo flushing**" is no longer required as it has been incorporated within the prohibition on "collecting a viable human embryo from the body of a woman" (see section 53M inserted by the WA Cloning Bill).

"**exemption**" is replaced by a new definition of "**exemption**" that refers to new exemptions provided for in proposed section 28A (see sub-clause 5(11)).

"**parthenogenisis**" is not required as the concept included in the term is incorporated within the term "human embryo clone" (see section 53B inserted by the WA Cloning Bill).

"**person responsible**" has been renamed "**licence supervisor**" to avoid any confusion with the term "responsible person" used in the Commonwealth Human Embryo Act. The new definition of "licence supervisor" is in the same terms as "person responsible".

Sub-clause 5(10)

The amendments in this sub-clause replace a full stop with a semicolon as an additional definition is added after the definition of "treatment".

Sub-clause 5(11)

The amendments in this sub-clause insert new definitions required to mirror definitions in the Commonwealth legislation or to replace definitions deleted in sub-clauses 5(9) and 5(13).

"**Commonwealth Human Embryo Act**" is defined to mean the *Research Involving Human Embryos Act 2002* of the Commonwealth.

"**excess ART embryo**" has the meaning given to that term in the new section 53T that is inserted by clause 36.

"**exemption**" incorporates the deleted definition of "exemption" and expands it to include a reference to an exemption under the proposed new section 28A to cover storage of excess ART embryos that are to be used in connection with an NHMRC licence.

"**human egg**" – this definition is inserted to ensure consistency with the use of the term "human egg" in the Commonwealth Cloning Act. Previously "egg" was referred to in section 3(3)(a), which provided that except where otherwise

explicitly stated, eggs meant human eggs which are live.

"**human embryo**" is defined as having the meaning given to that term in a new section 3A of the Act (see notes under clause 6 for detailed description).

"**human gamete**" – this definition is inserted to ensure consistency with the use of the term "human gamete" in the Commonwealth Cloning Act. Previously "gametes" were referred to in section 3(3)(a), which provided that except where otherwise explicitly stated, gametes meant human gametes which are live.

"**human sperm**" – this definition is inserted to reflect the use of the term "human sperm" in the Commonwealth Cloning Act. Previously "sperm" was referred to in section 3(3)(a), which provided that except where otherwise explicitly stated, sperm meant human sperm which are live. The meaning given to human sperm incorporates the inclusion of human spermatids (precursors of sperm) from the Commonwealth Cloning Act and the qualification that the sperm or spermatids are live from section 3(3)(a).

"**licence supervisor**" replaces the definition of "**person responsible**" and is in the same terms.

"**NHMRC**" is defined to mean the National Health and Medical Research Council.

"**NHMRC licence**" is defined as a licence issued by the NHMRC under either Part 4B of the Act or the Commonwealth Human Embryo Act.

"**summary conviction penalty**" – this definition has been included to allow prosecution and penalties for offences under the Act to be dealt with in accordance with the general provisions under the Criminal Code.

"**woman**" is defined to mean a female human. This definition mirrors the definition in the Commonwealth Cloning Act.

Sub-clause 5(12)

The amendment in this sub-clause is to section 3(2), which limits the scope of the legislation in relation to human eggs undergoing fertilisation and human embryos to eggs or embryos that are developed in consequence of an in vitro fertilisation procedure, and kept or used outside the body of a woman.

The amendments:

- provide that the limitation on scope applies to all aspects of clinical practice of reproductive technology, but not to Part 4B (research involving human embryos);
- are consequential on changes in terminology for "egg in the process of fertilisation" and "embryo";
- delete section 3(2)(b)(ii). This is consequential on the deletion of the term "embryo flushing" and the inclusion of an offence in the WA Cloning Bill that incorporates embryo flushing as a practice that is prohibited.

Sub-clause 5(13)

The amendments in this sub-clause:

- delete section 3(3)(a) as the contents of section 3(3)(a) have been incorporated in the new definitions of “human egg”, “human gametes” and “human sperm” inserted by clause 5(11).
- are consequential on changes in terminology for “egg” and “sperm” and replace the term “egg in the process of fertilisation” with “human egg undergoing fertilisation” for grammatical reasons as fertilisation is defined as a process.

Sub-clause 5(14)

The amendments in this sub-clause are consequential on changes in terminology for “gametes”, “egg in the process of fertilisation” and “embryo”.

Sub-clause 5(15)

The amendments in this sub-clause are consequential on changes in terminology for “person responsible”.

Clause 6 – Section 3A inserted

This clause includes a new definition of “human embryo” which is in the same terms as the definition in the Commonwealth legislation.

“**human embryo**” is defined to mean a live embryo that has a human genome or an altered human genome, that has been developing for less than 8 weeks since:

- the appearance of 2 pro-nuclei; or
- the initiation of development by other means.

This definition is intended to include:

a) a human embryo created by the fertilisation of a human egg by human sperm.

The definition relies upon the appearance of 2 pro-nuclei to establish the existence of a human embryo that has been created by the fertilisation of a human egg by human sperm. The appearance of the pro-nuclei indicates that the nuclei from the sperm and the egg are aligning prior to possible fusion. For the purposes of this legislation, the 8 weeks of development is taken to start with the appearance of 2 pro-nuclei. The effect of this is that embryo is defined from an earlier stage of development than under the current Act.

b) a human embryo that has had its development initiated by any means other than by the fertilisation of a human egg by human sperm.

It is intended that the definition includes the following types of embryos:

- a human egg that has had its nucleus replaced by the nucleus of a somatic cell (ie a cell from the body) by the process referred to as somatic cell nuclear transfer (SCNT); and

- a parthenogenetic human embryo. It is possible that a human egg could be mechanically or chemically stimulated to undergo spontaneous activation and exhibit some of the characteristics of a fertilised human egg. A parthenogenetic human embryo may have the capacity to continue its development in a similar manner to a human embryo created by fertilisation.

It should be noted that the procedures outlined above are provided as examples only as there may be other ways that the development of an embryo may be initiated. For the purposes of the legislation the 8 weeks of development is taken to start with the initiation of development by other means.

Proposed section 3A(2) clarifies that for the purposes of the definition of "human embryo", in working out the length of period of development of a human embryo, any period when development of the embryo is suspended (for example, while it is frozen) is not included. For example, if an embryo is placed in storage 2 days after fertilisation and is held in storage for 10 weeks, it is still considered to be a 2 day embryo in terms of its development.

Clause 7 – Section 4 amended

Section 4 sets out the objects of the Act. The amendments provide that the new Part 4B, which mirrors the Commonwealth Human Embryo Act, has specific objects. The specific objects of Part 4B are set out in that part.

Clause 8 – Section 5A inserted

This clause inserts a new Section 5A to provide that the Division 2 of Part 1 (which deals with specific offences under the Act) does not apply to excess ART embryos which are subject to the licensing requirements under the Commonwealth Human Embryo Act and Part 4B of the Act. Division 2 of Part 1 will still apply to exempt uses of excess ART embryos (ie those uses that do not require a licence from the NHMRC) so the exempt uses will be subject to licensing and approval requirements under the Act.

Clause 9 – Section 6 amended

Sub-clause 9(1)

Section 6 of the Act deals with clinical practices that require a licence from the RT Council. Amendments in this sub-clause:

- are consequential on changes to the terminology for “egg”, “egg in the process of fertilisation” and “sperm” (sub-clause 10(1)(a) to (d));

- add an additional category of clinical practice that requires a licence. The additional category is to ensure that the Act provides complete coverage of any clinical use that may not be captured by the existing provisions in section 6(1). It is drafted in similar terms to the provisions in section 11(b) of the Commonwealth Human Embryo Act, which provides for offences for use of a human embryo that is not an excess ART embryo (sub-clause 9(1)(e) and (f)).

Sub-clause 9(2)

This sub-clause repeals subsections 6(2) and (3), which deal with levels of penalties and replaces them with a new penalty provision – section 6(2).

The new section 6(2) rephrases the offences so that they become indictable rather than summary offences, which is appropriate in light of the term of imprisonment which may be imposed. The penalty for a contravention by a person of sub-section 1, is 5 years, and the summary conviction penalty is 1 year.

Section 41 of the *Sentencing Act 1995* applies to sentencing of a natural person for an offence that has a statutory penalty only. The effect of Section 41 is that a Court may impose a fine in addition to, or instead of imposing a term of imprisonment. If the matter is dealt with in the Supreme Court a fine of any amount may be imposed. If the offence is dealt with summarily in a court of petty sessions, the maximum fine that could be imposed is $12,000.

If the offender is a body corporate, section 40 of the *Sentencing Act 1995* provides that the maximum sentence that can be imposed is a fine of 5 times the maximum fine that could be imposed on a natural person.

Clause 10 – Section 7 amended

Sub-clause 10(1)

Section 7 of the Act provides for offences relating to reproductive technology. Amendments in this sub-clause:

- are consequential on changes in terminology for “egg in the process of fertilisation” and “embryo” (sub-clauses 11(1)(b) and (c));
- rephrase the offences so that they become indictable rather than summary offences, which is appropriate in light of the term of imprisonment which may be imposed (sub-clauses 11(1)(a) and (f));
- delete offences that are provided for in the Commonwealth Prohibition of Cloning Act and in the new Part 4A to be inserted in the Act by the WA Cloning Bill. In particular:
    - the offence in 7(1)(c) is incorporated in new section 53J;
    - the offences in 7(1)(d) are incorporated in Division 2 of new Part 4A (cloning), new section 53M (embryo flushing) and new section 53N (chimaera);
    - the offence in 7(1)(e) is incorporated in new section 53G and Division 2 of new Part 4A;
    - the offence in 7(1)(f) is incorporated in new section 53L;
    - the offence in 7(1)(g) is incorporated in new section 53O;
    - the offence in 7(1)(h) is incorporated in new section 53O(3) and 53P;
    - the offence in 7(1)(j) is incorporated in new section 53Q.

Sub-clause 10(2)

The amendments in this sub-clause:

- repeal subsection 7(2) which defines "valuable consideration". This is defined in new section 53Q(4) to be inserted by the WA Cloning Bill;
- repeal subsections 7(2) and (3), which deal with levels of penalties and replaces them with a new penalty provision – section 7(2).

The new section 7(2) provides that the penalty for a contravention of sub-section 1 by a person is 5 years and the summary conviction penalty is 1 year.

Section 41 of the *Sentencing Act 1995* applies to sentencing of a natural person for an offence that has a statutory penalty only. The effect of Section 41 is that a Court may impose a fine in addition to, or instead of imposing a term of imprisonment. If the matter is dealt with in the Supreme Court a fine of any amount may be imposed. If the offence is dealt with summarily in a court of petty sessions, the maximum fine that could be imposed is $12,000.

If the offender is a body corporate, section 40 of the *Sentencing Act 1995* provides that the maximum sentence that can be imposed is a fine of 5 times the maximum fine that could be imposed on a natural person.

Sub-clause 10(3)

The amendments in this sub-clause:

- are consequential on changes in terminology for "gametes", "egg in the process of fertilisation" and "embryo";
- removes reference to the financial penalty of $10,000 that may be imposed for an offence under section 7(5). This has the effect that financial penalties will be calculated in accordance with the *Sentencing Act 1995*. The application of sections 41 and 40 of the *Sentencing Act 1995* result in a maximum fine for a natural person of $24,000, and the maximum fine for a body corporate of $120,000.

Clause 11 – Section 14 amended

Sub-clause 11(1)

The amendments in this sub-clause are consequential on the changes of terminology for "person responsible", "egg", "gametes", "egg in the process of fertilisation" and "embryo".

Sub-clause 11(2)

The amendments in this sub-clause delete section 14(2) and replace it with 3 new sections.

New section 14(2) provides that research on excess ART embryos which are subject to the NHMRC licensing requirements is not subject to RT Council approval. Uses of excess ART embryos that are exempt from the NHMRC licensing requirements will require RT Council approval. This amendment clarifies that there is not a dual licensing scheme operating in relation to

excess ART embryos and that approval from the RT Council is not required in addition to a licence from the NHMRC.

New section 14(2a) and (2b) vary the restrictions previously imposed on the RT Council by deleted section 14(2) in relation to approving research or diagnostic procedures on an embryo. This amendment gives effect to standards applying nationally to clinical practice, and to section 10(2)(b) and (d) and (f) of the Commonwealth Human Embryo Act, which allows some non-therapeutic uses of human embryos.

A distinction is made between an embryo that is intended for use in providing treatment for a woman and embryos that are excess ART embryos.

In the case of an embryo that is intended for treatment, the focus is on ensuring that the research or diagnostic procedure does not damage the embryo. Before granting approval for research or a diagnostic procedure, the RT Council must be satisfied that the research or diagnostic procedure is unlikely to affect the fitness for implantation of the embryo. The RT Council must base the decision to approve research or diagnostic procedures on existing scientific and medical knowledge. It is intended the amendments would allow the RT Council to approve therapeutic or non-harmful research on an embryo that is intended for implantation, such as comparing 2 culture media that have been previously approved for use in IVF procedures.

The amendments allow the RT Council to approve genetic testing of an embryo prior to implantation, but only if it is satisfied that there is a significant risk of a serious genetic abnormality or disease being present in the embryo. Genetic testing of embryos prior to implantation is permitted in all other Australian jurisdictions including the 2 States with legislation regulating ART clinical practice. The Code of Practice that applies to all ART clinics accredited by the RTAC indicates that such testing may be part of standard practice in ART clinics where there is relevant expertise and equipment. As part of the COAG agreement, accreditation by the RTAC is the basis for a nationally consistent approach to the regulation of ART clinical practice.

The RT Council may approve research or diagnostic procedures on an excess ART embryo, which has not been donated for use in the treatment of another person, if:

- it consists of observation only;
- the embryo is not biologically fit for implantation and is used as part of a diagnostic investigation for the woman for whom the embryo was created;
- the use is prescribed in regulations made under the Commonwealth Human Embryo Act.

This provision is necessary to ensure that the relevant “exempt uses” of an excess ART embryo provided for in the new section 53W (which is inserted by clause 36) and section 10(2)(d) of the Commonwealth Human Embryo Act, are subject to RT Council approval.

All research or other uses of excess ART embryos (including those not fit for implantation) are subject to NHMRC licensing requirements.

Sub-clause 11(3)

The amendment in this sub-clause is consequential on amendments in clause 24, which amends section 29(5)(a) to provide that a body other than the RTAC may be prescribed for the purposes of accrediting providers of reproductive technology services.

Clause 12 – Section 17 amended

Section 17 deals with certain matters that must be prohibited in the Code of Practice provided for in section 15 of the Act.

Sub-section (a) is amended as a consequence of changes to the terminology for “egg”, “sperm”, “egg in the process of fertilisation” and “embryo”.

Sub-section (b) is repealed as the development of an embryo other than with a view to its future implantation into a particular woman is incorporated in new section 53H, which is inserted by the WA Cloning Bill. This amendment also removes the prohibition on creating an egg in the process of fertilisation other than with a view to its future implantation in a woman. This will allow some diagnostic investigations to assess the interaction of the egg and sperm of a couple undergoing treatment. Any such diagnostic procedure would require that the development of a human egg undergoing fertilisation must not be allowed to proceed beyond the stage of the appearance of 2 pro-nuclei, when it would become an embryo.

Clause 13 – Section 18 amended

Section 18 sets out matters that may be dealt with in the Code of Practice provided for in section 15 of the Act.

Section 18(1)(c) provides that the Code may make provision or impose conditions or prohibitions on the treatment of any gamete for use in an artificial fertilisation procedure, including their genetic modification. The genetic modification of a human gamete is prohibited by the new section 53L inserted by the WA Cloning Bill and the amendment in sub-clause 15(1) removes the possibility that the Code could make provision for such modification.

The remainder of the amendments in this clause are consequential on the changes in terminology for “gamete”, “egg in the process of fertilisation” and “embryo”.

Clause 14 – Section 20 amended

Section 20(2)(a) of the Act provides that research on gametes intended for use in an artificial fertilisation procedure, or embryos, must be approved by the RT Council. The amendment in sub-clause 14(b) provides that this requirement does apply in relation to excess ART embryos, which are subject to NHMRC licence requirements. Uses of excess ART embryos that are exempt from the NHMRC licensing requirements will require RT Council approval. This amendment clarifies that there is not a dual licensing scheme operating in relation to excess ART embryos and that approval from the RT Council is not required in addition to a licence from the NHMRC.

The other amendments in this clause are consequential on the changes in terminology for “gametes”, “egg in the process of fertilisation” and “embryo”.

Clause 15 – Section 21 amended

The amendments in this clause are consequential on the changes in terminology for “gametes”, “egg in the process of fertilisation” and “embryo”.

Clause 16 – Section 22 amended

The amendments in this clause, and the amendments to section 33 of the Act provide that the consents that are specified in section 22 are required to be complied with as a condition of a licence issued under Part 4, which deals with licences relating to clinical ART practice. Consent to use of excess ART embryos that are subject to an NHMRC licence is provided for in the new Part 4B inserted by clause 36.

The amendments do not change the consent requirements for clinical practice except as follows:

- the consent requirements that were included in section 33(2)(e) have been moved to section 22(1)(e)(ia) and (ib) for the sake of grouping consent provisions together;
- clause 16(5) amends section 22(5). The existing section 22(5), which is repealed by this sub-clause, provided that the consent to the use of an egg undergoing fertilisation or an embryo must specify a purpose relating to providing treatment for the person giving consent or another person. The new section 22(5) allows other purposes to be specified and is consequential on amendments that allow human eggs undergoing fertilisation and human embryos to be used for other limited purposes.

Clause 17 – Section 23 amended

The amendment in this clause clarifies that IVF treatment can be carried out where it would be likely to benefit a couple or woman whose child would otherwise likely be affected by a disease that is not a genetic disease. This clarifies that treatment could be provided to limit the possibility of a child being affected by diseases such as HIV or hepatitis.

Clause 18 – Section 24 amended

Section 24 of the Act deals with storage of genetic material.

<u>Sub-clause 18(1)</u>

The amendments in this sub-clause:

- are consequential to the changes in terminology for “gamete”, “egg”, “sperm”, “egg in the process of fertilisation” and “embryo” (sub-clause 18(1)(a),(d) and (e);
- are consequential to the changes made in the terminology for “embryo” and delete reference to “egg in the process of fertilisation” (sub-clause 18(1)(b). The effect of this change is that a human egg undergoing fertilisation may be stored for purposes other than future implantation;

- allow the continued storage of an embryo that is an excess ART embryo and which has been donated for a future use under an NHMRC licence (sub-clause 18(1)(c));

- specifies that the maximum period of allowed storage for an embryo or egg undergoing fertilisation without approval of the RT Council is 10 years (sub-clause 18(1)(f)). This period of storage is consistent with the storage provisions that are specified through the NHMRC guidelines applicable to all ART clinics accredited by the RTAC. As part of the COAG agreement, accreditation by the RTAC is the basis for a nationally consistent approach to the regulation of ART clinical practice. The 10 year storage period allows a reasonable time for treatment to be completed, but reflects the position that leaving an embryo "in limbo" indefinitely is not ethically acceptable.

Sub-clause 18(2)

The amendments in this sub-clause:

- insert a provision that specifies that the RT Council may only approve an extension of the storage period for an egg undergoing fertilisation or an embryo on the application of an eligible person. Eligible person is defined in the new section 24(2) that is inserted in sub-clause 18(4);

- are consequential to the changes in terminology for "egg in the process of fertilisation" and "embryo".

Sub-clause 18(3)

The amendment in this sub-clause is consequential on the amendment in sub-clause 18(1)(f) above, which specifies that the period of storage for an embryo or egg undergoing fertilisation is 10 years.

Sub-clause 18(4)

The amendments in this sub-clause repeal sub-sections 24(2), (3) and (4) and insert 3 new sub-sections.

Repealed sub-section 24(2) dealt with the situation where a person or couple for whom an embryo has been stored has died or cannot be located and has not left specific instructions for what should happen to the embryo in that circumstance. In that event, Commissioner of Health was to direct that, subject to any instruction or conditions imposed by the person or couple, the embryo be used for the treatment of a specific recipient. This clause is inconsistent with the requirements throughout the Act that appropriate consent is required before human reproductive material can be used for any purpose.

Repealed sub-section 24(3) requires a licensee to act in accordance with any direction given by the Commissioner to allow an embryo to succumb. It also provided that where a licensee was acting under the direction of the Commissioner that the licensee was not liable to any person. The new sub-sections that are to be added mean that the licensee will be required to make decisions about allowing an embryo to succumb in accordance with new

provisions of the Act.

Repealed sub-section 24(4) is consequential on the amendments in sub-clause 18(1)(f) that specifies the maximum period of storage without consent of the RT Council is 10 years.

New sub-section 24(2) defines who is an "eligible person" to make an application to the RT Council for an extension of storage. In the case of an embryo that is intended for use in an artificial fertilisation procedure, the application for extension can only be made by the person or persons who will be participants in the procedure in which the embryo is to be used, or the person for whom the embryo was developed. In the case of an excess ART embryo that has been donated for research, the licensee who is storing the embryo may seek an extension of storage. In each case the application for extension must be decided in accordance with the requirements in sub-section 24(1a) – that is, there must be "special reasons for doing so".

New sub-section 24(3) provides that a licensee must take reasonable steps to notify each person for whom an egg undergoing fertilisation or a human embryo is being stored that the storage period is coming to an end. This gives the persons an opportunity to apply for an extension of the storage period if they wish to.

New sub-section 24(4) provides that a licensee may allow an egg undergoing fertilisation or an embryo to succumb without being subject to any liability if the storage period has ended and no application for extension is made. The licensee must have taken reasonable steps to notify the persons in accordance with new sub-section 24(3). This sub-section also provides that the licensee is not liable for allowing the egg or embryo to succumb if the requirements in the Act are complied with. This provision retains a similar provision that was in the repealed sub-section 24(3).

Clause 19 – Section 25 amended

The amendments in this clause are consequential on changes of terminology for "gametes", "egg in the process of fertilisation", and "embryo".

Clause 20 – Section 26 amended

Sub-clause 20(1)

The amendments in this sub-clause insert a new section 26(1a) that provides that section 26, which deals with control, and decision making in relation to human eggs undergoing fertilisation and human embryos does not apply in relation to excess ART embryos which are subject to NHMRC licensing requirements. Section 26 applies to eggs and embryos that are not excess and to the exempt uses of ART embryos that are specified in the Commonwealth Human Embryo Act. Section 4B and the Commonwealth Human Embryo Act deal with issues of consent and control for excess ART embryos that are subject to NHMRC licensing requirements.

Sub-clause 20(2)

The amendments in this sub-clause provide:

- that the rights to control and deal with or dispose of human eggs undergoing fertilisation and human embryos is subject to the provisions in section 24(4). The provisions in section 24(4) provide that where a licensee has been unable to locate the persons on whose behalf the egg or embryo is being stored they may allow the egg or embryo to succumb at the end of any permitted storage period;
- that a human egg undergoing fertilisation or an embryo that is no longer required by the person or persons for whom it was created can consent to donate the egg or embryo for any purpose that is permitted under the Act;
- are consequential on the changes of terminology for "gametes", "egg in the process of fertilisation", and "embryo".

Sub-clause 20(3)

The amendments in this sub-clause are consequential on changes in terminology for "egg in the process of fertilisation" and "embryo".

Clause 21 – Section 27 amended

The amendments in this clause are consequential on:

- changes of terminology for "person responsible", "egg", "sperm", "egg in the process of fertilisation", and "embryo";
- the amendment to insert a new section 28A. The Commissioner of Health may grant an exemption from the requirement to hold a storage licence where the requirements in the new section 28A are complied with.

Clause 22 – Section 28 amended

The amendments in this clause are consequential on:

- changes in terminology for "person responsible";
- the introduction of Part 4B. The amendments clarify that an exemption from the licensing provisions for artificial insemination in certain circumstances only relates to exemption from requirements for a licence in Part 4 and not from the requirements for a licence in new part 4B inserted by clause 36.

Clause 23 – Section 28A inserted

The amendments in this clause insert a new section 28A. The new section 28A provides that a person who holds an NHMRC licence for the use of excess ART embryos, may apply to the Commissioner of Health for an exemption from the requirement to hold a storage licence to store embryos to which the licence applies. Section 10(2)(a)(i) of the Commonwealth Human Embryo Act specifies that storage of excess ART embryos is an exempt use and does not therefore require an NHMRC licence for that purpose. The new section 28A is necessary to ensure that there are no gaps in relation to storage of excess ART embryos. A person who holds an exemption under the new section is subject to the same disciplinary procedures as the holder of a storage licence.

Clause 24 – Section 29 amended

The amendments in this clause:

- require that an applicant for a storage or practice licence in relation to clinical ART practice must be accredited by the RTAC or another body if this is specified in regulations. This section reflects the COAG decision that the national approach to regulation of ART clinical practice should be based on the RTAC accreditation. It is also necessary as a result of the offences in section 11 of the Commonwealth Human Embryo Act which makes it an offence to use human embryos for a purpose related to the assisted reproductive technology treatment of a woman unless the use is in an accredited ART centre. An accredited ART centre is defined in the Commonwealth Human Embryo Act in the same terms as the new section 29(5)(aa);
- are consequential on the change in terminology for "person responsible".

Clause 25 – Section 30 amended

The amendments in this clause are consequential on changes of terminology for "person responsible", "gametes", "egg in the process of fertilisation", and "embryo".

Clause 26 – Section 32 amended

The amendment in this clause is consequential on the change of terminology for "person responsible".

Clause 27 – Section 33 amended

Section 33 provides for the conditions that are applied to all licences and exemptions.

Sub-clause 27(1)

The amendments in this sub clause:

- provide that the conditions set out in section 33 apply only to licences or exemptions issued under part 4 (sub-clause 27(1)(a)). Conditions that apply to NHMRC licences are in the new Part 4B, inserted by clause 36;
- are consequential on the changes of terminology for "person responsible", "gametes", "egg in the process of fertilisation", and "embryo" (sub-clauses 27(1)(b), (c) and (e));
- delete section 33(2)(e) (sub-clause 27(1)(d)). The consent requirements in section 33(2)(e) have been moved to section 22(1)(e)(ia) and (ib) for the sake of keeping all the consent requirements together;
- make it a condition of a licence that all the consent requirements set out in section 22 of the Act are complied with (sub-clause 27(1)(d));
- make it a requirement that the accreditation by the RTAC, which is a requirement for an application for a licence in section 29, is maintained (sub-clause 27(1)(d)).

Sub-clause 27(2)

The amendments in this sub-clause are consequential on the change of terminology for “gametes”, “egg in the process of fertilisation” and “embryo”.

Clause 28 – Section 40 amended

The amendments in this clause are consequential on the change of terminology for “person responsible”.

Clause 29 – Section 41 amended

The amendments in this clause are consequential on changes of terminology for “person responsible”, “gametes”, “egg in the process of fertilisation”, and “embryo”.

Clause 30 – Section 44 amended

The amendments in this clause are consequential on:

- changes of terminology for “person responsible”, “gametes”, “egg in the process of fertilisation”, and “embryo”;
- the amendment to insert a new section 28A. Holders of an exemption under section 28A are not subject to record keeping procedures set out in section 44. The Commonwealth Human Embryo Act and conditions on an NHMRC licence will provide that there is proper record keeping in relation to excess ART embryos subject to an NHMRC licence.

Clause 31 – Section 45 amended

The amendments in this clause:

- are consequential on changes of terminology for “person responsible”, “gametes”, “egg in the process of fertilisation”, and “embryo”;
- allow for information that is provided to the Commissioner of Health by the NHMRC Licensing Committee to be included on registers maintained by the Commissioner of Health.

Clause 32 – Section 48 amended

The amendments in this clause are consequential on changes of terminology for “gametes” and “embryo”.

Clause 33 – Section 49 amended

The amendments in this clause are consequential on changes of terminology for “gametes”, “egg in the process of fertilisation”, and “embryo”.

Clause 34 – Section 51 amended

The amendments in this clause are consequential on changes of terminology for “person responsible”, “gametes”, “egg in the process of fertilisation”, and “embryo”.

Clause 35 – Section 53 amended

The amendment in this clause is consequential on changes of terminology for

“person responsible”.

Clause 36 – Part 4B inserted

The new Part 4B that is inserted into the Act by this clause incorporates provisions that mirror the Commonwealth Human Embryo Act. The following details the effect of the proposed new sections, by reference to the new section numbers.

DIVISION 1 - GENERAL

Section 53S - Object of Act

This provides that the objects of Part 4B are:

- to address concerns, including ethical concerns, about scientific developments in relation to the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology;
- to adopt in Western Australia a uniform Australian approach to the regulation of activities that involve the use of excess ART embryos.

The provisions in Part 4B mirror provisions that exist in the Commonwealth Human Embryo Act.

Clause 53T - Definitions

This sets out a number of definitions for words and phrases used in Part 4B. Key definitions, which are essential to defining the scope of the legislation and describing how it will be administered, include the following:

*“***excess ART embryo**” which defines what is meant by an "excess ART embryo", requiring that:

- the embryo was created by assisted reproductive technology for use in the treatment of a woman; and
- the embryo is excess to the treatment needs of the woman for whom it was created and any spouse (at the time the embryo was created) of that woman.

Sub-paragraph 53T(2) provides that a human embryo is an "excess ART embryo", if:

- there is a determination in writing from the woman for whom the embryo was created (and her spouse, if any) that the embryo is excess to their treatment needs; or
- the woman for whom the embryo was created (and her spouse, if any) have provided authority, in writing, for the embryo to be used for a purpose other than achieving pregnancy (for example, research or training purposes). In such a case it is assumed that, by determining that the embryo may be used for another purpose, the couple consider that it is excess to their needs. It should be noted that a determination that an embryo is excess is distinct from a

consideration of whether there is proper consent, from all responsible persons, for use of the embryo.

"**licensed ART centre**" is defined as a person to provide ART clinical services under Part 4 of the Act. The amendments to Part 4 provide that it is a condition of licensing that the centre is accredited by:

(a) the RTAC; or

(b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a) - that other body or any of those other bodies, as the case requires.

"**NHMRC Licensing Committee**" is defined to mean the committee of that name established by the Commonwealth Human Embryo Act. The intention is that all applicants for a licence to use excess ART embryos (other than exempt uses) would make application to the NHMRC Committee and that there would not be a separate licensing committee established in Western Australia.

"**proper consent**" is defined to mean consent that is obtained in accordance with the current NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) or any other guidelines prescribed under the Commonwealth Human Embryo Act. The power to prescribe alternative (or supplementary) guidelines ensures that the most appropriate and recent guidelines describing the processes for consent are observed. For example, the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* are currently subject to review and it is likely that new guidelines will be issued in early 2004. These new guidelines could be prescribed under the Commonwealth Human Embryo Act and therefore replace the older guidelines.

"**responsible person**"*,* in relation to an excess ART embryo, is defined to mean:

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

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

(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

(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.

Sub-section 53T(3) defines "penalty units" and is required to allow financial penalties for offences in this Part to be calculated in accordance with the financial penalties that apply to the same offences under the Commonwealth Human Embryo Act.

Sub-section 53T(4) provides that a reference to a Commonwealth Act includes a reference to that Act as amended or a Commonwealth Act

enacted in substitution for that Act. This is intended so that changes to Commonwealth Acts that are ancillary to the operation of this Part (for example the *Administrative Appeals Tribunal Act 1975* referred to in proposed section 53ZL) will not necessitate amendment of the Act. This does not have the effect of changing the provisions in this Part that have been mirrored from the Commonwealth Human Embryo Act if there are subsequent amendments to the Commonwealth Human Embryo Act. If any amendments to the Commonwealth Human Embryo Act are made these would not become part of the Act unless similar amendments to part 4B are passed by the Western Australian Parliament.

DIVISION 2 – PERFORMANCE OF FUNCTIONS

This Division includes provisions that are intended to ensure the effective operation of the national scheme relating to the regulation of uses of excess ART embryos. Proposed sections 53Y and 53Z confer functions and powers on the NHMRC Licensing Committee to undertake licensing functions in respect of excess ART embryos. It is the intention that anyone wishing to undertake work using excess ART embryos (other than exempt uses) would need to apply for a licence from the NHMRC Licensing Committee whether or not they are technically organisations that come within the scope of the Commonwealth's constitutional powers or State powers. Sections 42 and 43 of the Commonwealth Human Embryo Act effectively enable the corresponding State laws to provide that the licensing functions exercised under a State law actually be undertaken by the NHMRC Licensing Committee.

Section 53U – Functions not affected by State law

This provides that the NHMRC Licensing Committee or other officers of the Commonwealth will exercise functions that have been conferred by this Part, in the same manner for all applicants, whether they come within the scope of the Commonwealth's constitutional powers or State powers.

Section 53V – Extent to which functions are conferred

This clarifies that the conferral of functions or powers, or the imposition of duties, on the NHMRC Licensing Committee or on other Commonwealth bodies is limited by any relevant constitutional doctrines and the legislative power of the State.

DIVISION 3 - OFFENCES

Section 53W - Offence - use of excess ART embryo

This essentially describes the scope of the regulatory scheme for excess ART embryos by describing the uses of excess ART embryos that require an NHMRC licence and those that do not.

In summary, all uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee unless such uses are "exempt uses" in accordance with new sub-section 53W(2). "Exempt uses" of excess ART embryos do not require a licence from the NHMRC Licensing Committee but will be subject to the requirements of the Act

(other than Part 4B), including licensing and approval requirements in Part 4.

Sub-section 53W(2) provides that the following uses of an excess ART embryo are exempt:

- storage of an excess ART embryo;
- removing an excess ART embryo from storage (provided that no subsequent use of the embryo is proposed that would otherwise require a licence);
- transport of an excess ART embryo;
- observation of an excess ART embryo (including taking a photograph of the embryo or taking a recording of the embryo from which a visual image can be produced);
- allowing the excess ART embryo to die (succumb);
- diagnostic investigations using excess ART embryos that are unsuitable for implantation (for example, chromosomally abnormal embryos) provided that the investigations are specifically related to achieving pregnancy in the woman for whom the embryo was created;
- donating the excess ART embryo to another woman for the purpose of achieving pregnancy in that other woman; and
- any other use prescribed in the regulations made under the Commonwealth Human Embryo Act.

All other uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee. This includes, for example, using excess ART embryos:

- for research (for example, to derive stem cells or to improve ART clinical practice);
- to train people in ART techniques;
- for Quality Assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and
- to examine the effectiveness of new culture media.

It is expected that the NHMRC Licensing Committee will consider options to streamline the administration of the legislation, where the NHMRC Licensing Committee is satisfied that the use of the excess ART embryos will not damage or destroy the embryo.

The effect of sub-section 53W(1) is to make it an offence to intentionally use an excess ART embryo unless the use is authorised by a licence or is one of the exempt uses detailed above. The maximum penalty that may be applied for use of an excess ART embryo without a licence, or without that use being an exempt use, is 5 years imprisonment or 300

penalty units, or both. The effect of the definition of penalty units in new section 53T, and section 40 of the *Sentencing Act 1995* is that the penalty units convert to a monetary penalty of up to $165,000 for a corporation and $33,000 for an individual. The inclusion of a "summary conviction penalty" means that a charge for an offence under this section may be dealt with summarily in accordance with the requirements in section 5 of *The Criminal Code.*

Section 53X - Offence - breaching a licence condition

This provides that a person is guilty of an offence if they intentionally do something, or fail to do something, that they know will result in a breach of a condition of licence or that they do so being reckless as to whether or not the action or omission will contravene a condition of licence.

The maximum penalty for breaching a condition of licence is 5 years imprisonment or 300 penalty units, or both. The effect of the definition of penalty units in new section 53T, and section 40 of the *Sentencing Act 1995* is that the penalty units convert to a monetary penalty of up to $165,000 for a corporation and $33,000 for an individual. The inclusion of a "summary conviction penalty" means that a charge for an offence under this section may be dealt with summarily in accordance with the requirements in section 5 of *The Criminal Code.*

DIVISION 4 – EMBRYO RESEARCH LICENSING COMMITTEE OF THE NHMRC

Section 53Y – Functions of Committee

This confers functions on the NHMRC Licensing Committee in relation to the licensing system, reporting and monitoring set out in Part 4B.

Section 53Z – Powers of Committee

This confers power on the NHMRC Licensing Committee to carry out its functions.

DIVISION 5 – LICENSING SYSTEM

Section 53ZA - Person may apply for licence

This provides that a person may apply to the NHMRC Licensing Committee for a licence. Such an application must be in accordance with the application requirements of the NHMRC Licensing Committee. The NHMRC Licensing Committee has issued application forms and detailed explanatory material about the Committee's expectations with respect to the information that should be included in any application.

The application must also be accompanied by an application fee if such an application fee is prescribed in the regulations made under the Commonwealth Human Embryo Act. There are no application fees currently prescribed.

Section 53ZB - Determination of application by Committee

This describes the matters that must be considered by the NHMRC Licensing Committee when deciding whether or not to issue a licence. The proposed section sets out certain things that the NHMRC Licensing Committee must be satisfied of before they issue a licence and other issues that the NHMRC Licensing Committee must have regard to when deciding whether or not to grant a licence. The proposed section is in the same terms as the Commonwealth Human Embryo Act.

Sub-section 53ZB(3) provides that the NHMRC Licensing Committee must not issue the licence unless it is satisfied that:

- appropriate protocols are in place to enable proper consent to be obtained before an excess ART embryo is used and to ensure that where the persons for whom the embryo was created have specified any restrictions on the use of an embryo, these restrictions will be observed;
- if the proposed use of the excess ART embryo may damage or destroy the embryo (as determined by the NHMRC Licensing Committee), that appropriate protocols are in place to ensure that the excess ART embryos used in the project (should the licence be approved) have been created before 5 April 2002; and
- the proposed project has been considered and assessed by a Human Research Ethics Committee (HREC) that is constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Research Involving Humans* (1999) issued by the NHMRC (or such other document that may replace the National Statement)
- there is no possibility that an excess ART embryo could be used for technical or commercial purposes in the testing, creation or manufacture of cosmetic products (this sub-clause was inserted by the Legislative Assembly).

Sub-section 53ZB(4) provides that in deciding whether to issue a licence, the NHMRC Licensing Committee must have regard to the following:

- the number of excess ART embryos likely to be necessary to achieve the goals of the activity or project proposed in the application;
- 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;
- any relevant guidelines, or parts of guidelines issued by the NHMRC. For example, the NHMRC (through the Australian Health Ethics Committee) is currently undertaking a review of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996). It is

anticipated that following the review, the NHMRC will issue revised guidelines that will include information about the criteria to be taken into account for the purposes of determining whether a use of an excess ART embryo will be likely to result in a significant advance in knowledge or improvement in technologies for treatment that could not reasonably be achieved by other means;

- the HREC assessment of the application; and
- such additional matters (if any) as are prescribed by the regulations made under the Commonwealth Human Embryo Act.

Sub-section 53ZB(5) provides that the NHMRC Licensing Committee must not issue a licence if 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 (this sub-clause was inserted by the Legislative Assembly).

Section 53ZC - Notification of decision

This requires the NHMRC Licensing Committee to notify its decision on an application to the applicant, the HREC that considered the application and the Western Australian Commissioner of Health. In addition, if the NHMRC Licensing Committee issues a licence to the applicant, a copy of the licence must also be provided to the HREC and to the Western Australian Commissioner of Health.

Section 53ZD - Period of licence

This provides that a licence comes into force on the day specified in the licence or if no such date is specified, the day that the licence is issued. The licence ceases operation on the day specified in the licence unless it is suspended, revoked or surrendered before that day.

Sub-section 53ZD(2) clarifies that a licence is not in force throughout any period of suspension.

Section 53ZE - Licence is subject to conditions

This describes the conditions to which all licences issued by the NHMRC Licensing Committee are subject and enables the NHMRC Licensing Committee to impose any other conditions that it considers necessary.

Sub-sections 53ZE(1), (2) and (3) describe the conditions that all licence holders must comply with. These sub-sections provide that before a person can commence using an excess ART embryo (under a licence issued by the NHMRC Licensing Committee), the licence holder must confirm with the NHMRC Licensing Committee (by notice in writing):

- that consent has been obtained for the use of all the embryos, in accordance with the protocol considered by the NHMRC Licensing Committee;
- any restrictions on the use of the embryos (as determined by the persons for whom the embryos were created); and

- in the case of uses of the embryos that may damage or destroy the embryos, that the embryos were created before 5 April 2002.

Once a licence holder has provided this information to the NHMRC Licensing Committee they may commence work with the excess ART embryos provided they do so in accordance with any restrictions imposed by the persons for whom the embryos were created. Further, if the work with the excess ART embryos may harm or destroy the embryos, then it must be carried out on embryos created before 5 April 2002.

Sub-section 53ZE(4) provides that 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 technical or commercial purposes for the testing or manufacture of cosmetic products (this sub-clause was inserted by the Legislative Assembly).

Sub-sections 53ZE(5) and (6) provide that the NHMRC Licensing Committee may impose any other conditions that are necessary and provides some examples of the types of conditions the NHMRC Licensing Committee may impose. For example, the NHMRC Licensing Committee may impose conditions relating to:

(a) the persons or classes of person, authorised by the licence to use the excess ART embryos;

(b) the number of excess ART embryos in respect of which use is authorised by the licence;

(c) reporting;

(d) monitoring; and

(e) information to be given by the licence holder to persons authorised by the licence to use excess ART embryos.

Sub-section 53ZE(6) provides that the conditions included in sub-sections 53ZE(1), (2) and (3) are applicable to all people who are authorised by the licence to use excess ART embryos as specified in the licence.

Sub-section 53ZE(7) provides that any other licence conditions are applicable to the licence holder and any other people who are authorised by the licence to use excess ART embryos as specified in the licence.

Section 53ZF - Variation of licence

This enables the NHMRC Licensing Committee to vary a licence. There are 2 possible circumstances in which the NHMRC Licensing Committee may need to vary a licence:

- on request of the licence holder. For example, if the licence holder wishes to change administrative details on the licence such as

contact details or more significant details such as the duration of the licence; and

- when the NHMRC Licensing Committee considers it necessary or desirable to vary a condition of licence. For example, should the NHMRC Licensing Committee wish to add additional conditions of licence, change the wording of existing conditions of licence or delete existing conditions of licence.

Sub-section 53ZF(4) clarifies that the NHMRC Licensing Committee can not vary a licence so that the varied licence would be contrary to the requirements set out in section 53ZB. For example, the NHMRC Licensing Committee could not vary the licence after it has been issued so as to allow a use of embryos that have been created after 5 April 2002 that may damage or destroy the embryos (unless, that requirement ceases to have effect - see proposed section 53ZV).

Section 53ZG - Suspension or revocation of licence

This enables the NHMRC Licensing Committee to suspend or revoke a licence that has been issued if they believe, on reasonable grounds, that a condition of the licence has been breached. This is a very important provision because it enables the NHMRC Licensing Committee to take immediate action in the event of apparent non-compliance. By suspending or revoking the licence the work can no longer continue.

The NHMRC Licensing Committee has the power to re-instate the licence should the suspected breach of condition fail to be established or should the licence holder rectify the situation and the Committee is convinced that the work can continue without risk of further breaches. Whether or not the licence is suspended, cancelled or subsequently reinstated would depend on the individual circumstances of the case and the extent, severity and importance of the alleged breach.

It is important that the NHMRC Licensing Committee has a degree of discretion in this respect given that breaches of licence can range from fairly minor infringements (for example, late submission of annual reports to the NHMRC Licensing Committee) through to very serious breaches such as using more embryos than has been authorised by the licence.

The NHMRC Licensing Committee is required to revoke each licence held by a licence holder who is convicted of an offence under Part 4B of the Act, the Commonwealth Human Embryo Act, the Commonwealth Cloning Act or corresponding laws in any other State or Territory.

Section 53ZH - Surrender of licence

This provides that a licence holder may surrender a licence by written notice given to the NHMRC Licensing Committee. An organisation may wish to surrender a licence if, for example, they have completed the work involving the use of the excess ART embryos.

Section 53ZI - Notification of variation, suspension or revocation of licence

This provides that if the NHMRC Licensing Committee varies, suspends or cancels a licence the NHMRC Licensing Committee must notify the changes to the Western Australian Commissioner of Health. This ensures that the Western Australian government is kept fully informed about any variations to licences. In addition, if the change to the licence impacts on the information that is included on the publicly available database, the database must also be amended to reflect the change.

DIVISION 6 - REPORTING AND CONFIDENTIALITY

Section 53ZJ - NHMRC Licensing Committee to make certain information publicly available

This provides that the NHMRC Licensing Committee must establish and maintain a comprehensive, publicly available database containing information about licences that have been issued by the NHMRC Licensing Committee.

Sub-section 53ZJ(1) provides that the database must include the following information in relation to each licence:

(a) the name of the person to whom the licence was issued. This may be a body corporate or other legal entity;

(b) the nature of the uses of the embryos authorised by the licence. For example, the record would state whether the embryos are proposed to be used for the derivation of stem cells, for use for testing culture medium, for training of technicians etc;

(c) the conditions of licence;

(d) the number of embryos proposed to be used. At the time that a licence is granted, one of the conditions would describe the maximum number of embryos permitted to be used as part of the project. Another condition of licence would describe reporting requirements including in relation to how many embryos were actually used and when they were used. It is proposed that the NHMRC Licensing Committee will update the database to reflect the number of embryos actually used in a project;

(e) the date on which the licence was issued; and

(f) the period of the licence.

It is expected that the database will be included on the NHMRC website and hard-copy extracts of the database will be available from the NHMRC Licensing Committee on request. The database will not include information that is confidential commercial information (refer proposed section 53ZK) or any personal information that would be prohibited from disclosure under the Commonwealth's *Privacy Act 1988*, including for example, names of individuals.

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

This is intended to protect, from public disclosure, certain information that is legitimately confidential commercial information. It creates an offence for the unauthorised disclosure of such information. The maximum penalty is 2 years imprisonment or 120 penalty units, or both. The effect of the definition of penalty units in new section 53T, and section 40 of the *Sentencing Act 1995* is that the penalty units convert to a monetary penalty of up to $66,000 for a corporation and $13,200 for an individual.

"**Confidential commercial information**" is defined in proposed section 53T to mean 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.

The effect of proposed section 53ZK is that the NHMRC Licensing Committee can decide not to release certain information into the public domain (for example, by inclusion on the database established by proposed section 53ZJ) if the NHMRC Licensing Committee is satisfied that the information is commercial information or "other" information (such as research findings) that has a value that would be, or could reasonably be expected to be, destroyed or diminished as the result of disclosure.

The NHMRC Licensing Committee would have access to the confidential commercial information in assessing applications and could disclose such information to the Western Australian Commissioner of Health but the Commissioner could not disclose the information to anyone else.

The information may also be disclosed by order of a court or with the consent of the person to whom the information has a commercial or other value.

DIVISION 7 - REVIEW PROVISIONS

Section 53ZKA Annual Reports

This requires the NHMRC to provide copies of any report prepared under section 19(3) of the Commonwealth Human Embryo Act to the Minister who must cause copies of such report to be laid before each house of Parliament. (This clause was inserted by the Legislative Assembly.)

Section 53ZL - Meaning of terms

This describes those persons who are able to seek review in relation to various types of decisions made by the NHMRC Licensing Committee. In summary, the clause provides that an "eligible person" in relation to a decision of the NHMRC Licensing Committee means:

- a licence applicant - in relation to a decision by the NHMRC Licensing Committee not to issue a licence; and

- the licence holder in relation to:
- a decision by the NHMRC Licensing Committee relating to the period of a licence;
- a condition of licence imposed by the NHMRC Licensing Committee; and
- a decision by the NHMRC Licensing Committee to vary, refuse to vary, suspend or revoke a licence.

Section 53ZM - Review of decisions

Sub-section 53ZM(1) provides that an eligible person (as defined in section 53ZL) 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;

(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 sub-section 53ZE(4);

(d) a decision to vary or refuse to vary a licence under section 53ZF; or

(e) a decision to suspend or revoke a licence under section 53ZG.

Sub-section 53ZM(2) provides that section 53ZM has effect subject to the *Administrative Appeals Tribunal Act 1975*.

DIVISION 8 - MONITORING POWERS

Section 53ZN - Appointment of inspectors

Sub-section 53ZN(1) enables the Chairperson of the NHMRC Licensing Committee to appoint inspectors for the purposes of exercising all the powers under this Division. The persons the Chairperson of the NHMRC Licensing Committee may appoint as inspectors are Commonwealth employees and Western Australian State employees. The Chairperson of the NHMRC Licensing Committee must also ensure that each person appointed as an inspector has appropriate skills and experience (sub-section 53ZN(3)).

Sub-section 53ZN(2) requires a person appointed as an inspector to comply with any directions of the Chairperson of the NHMRC Licensing Committee when exercising powers or performing functions in that capacity.

Section 53ZO - Identity card

Sub-sections 53ZO(1) and 53ZO(2) require the Chairperson of the NHMRC Licensing Committee to issue an identity card, in a form prescribed by the regulations made under the Commonwealth Human Embryo Act, to every person appointed as an inspector. The identity card must have a recent photograph of the inspector.

Sub-section 53ZO(3) provides that it is an offence for a person who ceases to be appointed as an inspector to fail to return his or her identity card, as soon as practicable, to the Chairperson of the NHMRC Licensing Committee. The offence attracts a maximum penalty of 1 penalty unit which is equivalent to $110.

Sub-section 53ZO(4) requires the inspector to carry his or her identity card at all times when exercising powers or performing functions as an inspector.

Section 53ZP - Powers available to inspectors for monitoring compliance

Sub-section 53ZP(1) confers powers upon an inspector to enter any premises and to exercise any or all of the powers set out in proposed section 53ZQ for the purposes of establishing whether or not Part 4B is being complied with.

Sub-section 53ZP(2) provides that an inspector may only enter premises under this section if he or she has the consent of the occupier of the premises or if the occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

Section 53ZQ - Monitoring powers

This describes the monitoring powers that an inspector may exercise for the purposes of finding out whether Part 4B has been complied with. In addition to the monitoring powers that are mirrored from the Commonwealth Human Embryo Act, the Commissioner of Health may confer on an inspector appointed by the NHMRC Licensing Committee the enforcement powers provided for in section 54 of the Act.

Section 53ZR - Power to secure

This provides that if an inspector, during the course of inspecting premises, finds something that may be evidence in relation to an offence committed under the Act, the inspector may secure the thing pending the obtaining of a warrant to seize it.

Section 53ZS - Inspector must produce identity card on request

This provides that an inspector cannot exercise any of the powers under this Division in relation to premises unless he or she produces his or her identity card upon being requested to do so by the occupier of those premises.

Section 53ZT - Consent

This provides that, before obtaining consent from a person to enter premises (under section 53ZP(2)(a)), the inspector must inform the person that he or she may refuse consent.

Sub-section 53ZT(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

Section 53ZU - Compensation for damage

This clause provides that if damage is caused to equipment or other facilities as a result of it being operated by an inspector and the damage resulted from insufficient care being exercised by the inspector in operating the equipment, compensation is payable to the owner.

An application for compensation is to be made to the NHMRC Licensing Committee. In determining the amount payable, regard is to be had to whether the occupier (or his or her employees and agents) had provided any warning or guidance as to the operation of the equipment or facility. This is to minimise compensation in cases where, for example, there has been a deliberate programming of software to destroy or cause damage if not accessed in a particular manner, or where the occupier failed to mitigate damage by providing warning or guidance.

DIVISION 9 - EXPIRY

Section 43ZV – Expiry of certain sections

This clause gives effect to the COAG decision that the regulation restricting the use of excess ART embryos created after 5 April 2002 will cease to have effect on 5 April 2005. (This clause was amended in the Legislative Assembly.)

DIVISION 10 – CONSCIENTIOUS OBJECTION TO USE OF EXCESS ART EMBRYOS

Section 43ZVA – Conscientious objection to use of excess ART embryos

This clause provides that a person who conscientiously objects to using an excess ART embryo pursuant to an NHMRC licence is not required to do so. (This clause was inserted in the Legislative Assembly.)

DIVISION 11 - REVIEW OF PART

Section 53ZW - Review of Part

This provides that the Minister must cause an independent review of Part 4B to be undertaken commencing 19 December 2004, which is two years after the date that the Commonwealth Human Embryo Act received Royal Assent. The review required under the Act may be undertaken as part of the review of the Commonwealth Human Embryo Act, the requirements for which are set out in the Commonwealth legislation. In summary, the review required by the Commonwealth legislation must:

- be undertaken by persons chosen by the Commonwealth Minister with the agreement of all States and Territories;
- include a consideration of the scope and operation of the Act particularly taking into account developments in assisted reproductive technology, scientific and medical research developments, the potential therapeutic applications of any research,

community standards and the applicability of establishing a National Stem Cell Bank;

- contain recommendations about any amendments that should be made to the Act;
- be informed by consultation with the Commonwealth, States, Territories and a broad range of stakeholders;
- include information about the views of the Commonwealth, States and Territories (to the extent that it is reasonably practicable to do so); and
- be completed within 3 years of the Commonwealth Cloning Act receiving Royal Assent with the report of the review being provided to the Council of Australian Governments. The Provisions in the Commonwealth Human Embryo Act will ensure the reviews of both the Commonwealth Cloning Act and the Commonwealth Human Embryo Act are undertaken concurrently and by the same people.

Clause 37 – Section 54 amended

The amendments in this clause are consequential on changes of terminology for “gametes”, “egg in the process of fertilisation”, and “embryo”.

Clause 38 – Section 56 amended

The amendment in this clause is consequential on changes to the offence sections and provides that the Commissioner of Health may institute proceedings for simple offences. Proceedings in relation to indictable offences will be instituted by the Director for Public Prosecutions.

Clause 39 – Section 57 amended

The amendments in this clause are consequential on changes of terminology for “person responsible”, “gametes”, “egg in the process of fertilisation”, and “embryo”.

Clause 40 – Section 59 amended

The amendment in this clause provides that the Commissioner shall issue a certificate of identity to a person on whom he has conferred monitoring powers in accordance with new section 53ZQ(4) inserted by clause 36.

Attachment 1

GLOSSARY

Act	The *Human Reproductive Technology Act 1991*
ART	assisted reproductive technology
COAG	Council of Australian Governments
Commonwealth Cloning Act	The Commonwealth's *Prohibition of Human Cloning Act 2002*
Commonwealth Human Embryo Act	The Commonwealth's *Research Involving Human Embryos Act 2002*
Commonwealth legislation	The Commonwealth Cloning Act and the Commonwealth Human Embryo Act
FSA	The Fertility Society of Australia
ICSI	intracytoplasmic sperm injection
NHMRC	The National Health and Medical Research Council
RT Council	The Reproductive Technology Council
RTAC	The Reproductive Technology Accreditation Committee