

Explanatory Memorandum

Human Reproductive Technology Amendment Bill 2007

INTRODUCTION

In April 2002, the Council of Australian Governments (COAG) agreed to develop nationally consistent legislation to regulate human embryo research and ban human cloning. The Commonwealth's *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* (the Commonwealth Acts) were passed in December 2002. In 2004, The *Human Reproductive Technology Act 1991* (the Act) was amended to incorporate a new Part 4A (Prohibited practices) and Part 4B (Regulation of certain uses involving excess ART embryos) that mirrored the Commonwealth Acts.

The Commonwealth Acts required independent reviews of their operation by December 2005. The Act also required a review of Parts 4A and 4B and this was undertaken as part of the review of the Commonwealth Acts. In June 2005, the Commonwealth Government, with the agreement of all the States and Territories, appointed a Legislative Review Committee to undertake the reviews. The Committee was chaired by the late John Lockhart AO QC, a former judge of the Federal Court. The Committee consulted the community extensively in the course of the review and presented its report ('the Lockhart Report') to COAG on 19 December 2005. The Lockhart report contained 54 recommendations and was tabled in the State Legislative Council on 23 March 2006 and in the Legislative Assembly on 29 March 2006.

Senator Kay Patterson introduced a private member's bill, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (the Patterson Bill), based on the recommendations in the Lockhart report. The Patterson Bill was passed in the Senate on 7 November 2006 and in the House of Representatives on 6 December 2006.

The Bill amends the Act to include the amendments made to the Commonwealth Acts by the Patterson Act. The amendments will provide for continued consistency with the Commonwealth Acts.

Long Title

The long title sets out the purpose of the Bill, which is to amend the *Reproductive Technology Act 1991*.

Clause 1 Short Title

This clause provides the short title of the Act.

Clause 2 Commencement

This clause provides for the Act to come into operation on the later of the date of receipt of Royal Assent or on 12 June 2007, which is the day that the Patterson Act comes into operation.

Clause 3 *The Act amended*

The Act amended is the *Human Reproductive Technology Act 1991*.

Clause 4 *Long title amended*

The long title of the Act is amended to specifically reflect the inclusion of provisions regulating research involving embryos.

Clause 5 *Preamble repealed*

The preamble currently provides that Parliament considers that the only justification for the creation of embryos is for reproduction purposes and to assist the medically infertile. The amendments to the Act contained in the Bill will allow the creation of certain embryos for research purposes and specifically provide that those embryos may not be used for reproduction. The preamble is repealed as it does not reflect the proposed amendments to the Act.

Clause 6 *Section 1 amended*

This clause amends the short title of the Act to reflect the fact that the Act will deal with embryo research that is not directly related to human reproduction. The new short title will be the *Human Reproductive Technology and Embryo Research Act 1991*.

Clause 7 *Section 3 amended*

This clause inserts some additional definitions into section 3 and amends other definitions. The definitions of “animal”, “chimeric embryo”, “hybrid embryo” and “precursor cell” have been moved from section 53B of the Act and are effectively the same as the existing definitions. The definition of “NHMRC Licensing Committee” has been moved from section 53T of the Act and is the same as the existing definition.

The definition of “human egg” is amended to clarify that a reference to a human oocyte is the same as a reference to a human egg. This provision recognises that the new definition of a human embryo refers to a human oocyte whereas the existing prohibitions in the Part 4A refer to a human egg. Rather than changing all of the existing references from human egg to human oocyte, the amendment is intended to make it clear that both expressions are intended to have exactly the same meaning.

Section 3(3) is amended to clarify that a reference to an embryo is a reference to a living embryo. The effect of this is that licensing requirements in relation to embryos do not apply to embryos that are no longer living.

Other minor amendments are made because of changed drafting conventions.

Clause 8 *Section 3A amended*

This clause amends the definition of human embryo to replace the existing definition with a new definition developed by the National Health and Medical Research Council (NHMRC).

The NHMRC arrived at this definition by forming the Biological Definition of Embryo Working Party, comprising three NHMRC Embryo Research Licensing Committee members and three other Australian experts. Their Draft Report of the Biological Definition of Embryo Working Party was peer reviewed by Australian and international experts.

This definition differs slightly from the definition included in the Lockhart Report but the Lockhart Committee have agreed that their intention was that the definition of human embryo used should be that developed by the NHMRC.

The key differences between the new definition and the existing definition are that:

- ↓ the new definition recognises that fertilization is a process and provides that an embryo does not arise until the process of fertilization is completed. Completion of fertilization occurs when the first mitotic division occurs. The effect is that a human embryo that is created by fertilization of a human egg by human sperm is defined to commence existence at the first mitotic division. This is a later stage than the existing definition which commences at the appearance of two pro nuclei; and
- ↓ the new definition includes a definition for embryos created other than by human egg and sperm. In the new definition, the capacity to develop to the stage of the appearance of the 'primitive streak' is taken as the marker of an entity that is an embryo. This is a conservative definition and acknowledges that entities such as those that have arisen by SCNT are indeed embryos.

It is intended that paragraph (b) of the definition would capture the following types of embryos:

- ↓ a human egg which has had its nucleus replaced by the nucleus of a somatic cell (that is a cell from a human body) by the process referred to as somatic cell nuclear transfer (SCNT); and
- ↓ a parthenogenic 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 limited development in a similar manner to a human embryo created by fertilisation.

Subsection 3A(2) is retained and this 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 9 Section 5 amended

This clause amends the reference to the Schedule, which has been renamed Schedule 1.

Clause 10 Section 5A amended

This clause provides that Division 2, which contains offences relating to reproductive technology, does not apply to embryos that have been created other than by fertilisation of a human egg by human sperm. These embryos are regulated under Part 4A and Part 4B.

Clause 11 Section 7 amended

This clause clarifies that offences in section 7 relate only to research or diagnostic procedures involving human embryos. Chimeric and hybrid embryos are not human embryos and are regulated under Part 4A and Part 4B.

Clause 12 Section 8 amended

This clause amends the reference to the Schedule, which has been renamed Schedule 1.

Clause 13 Section 28A amended

Section 28A is amended to extend the exemption from the requirement to hold a storage licence to include any embryo to which an NHMRC licence applies.

Clause 14 Section 45 amended

This amendment is consequential on the movement of the definition of NHMRC Licensing Committee from section 53T to section 3 of the Act.

Clause 15 Section 53A amended

This amendment is consequential on the change of the name of the *Prohibition of Human Cloning Act 2002* (Cth).

Clause 16 Section 53B amended

The definitions of “animal”, “chimeric embryo”, “hybrid embryo” and “precursor cell” have been deleted. These definitions are moved to section 3 of the Act.

Clause 17 Heading to Part 4A Division 2 and section 53C replaced

The heading of Division 2 is amended and repositioned to reflect changes in the organisation of offences provided for in Part 4A.

Section 53C containing a prohibition on the creation of human embryo clones is repealed. Human embryo clones are created by a process other than fertilization of a human egg by human sperm and will be allowed to be created for research only up to 14 days and provided the creation is licensed by the NHMRC (see clause 31 and section 53J of the Act).

New Section 53C (Meaning of reckless)

A new section 53C is inserted to explain the meaning of “reckless” with respect to circumstances. This interpretation is required for sections 53P and 53QC of the Act.

Clause 18 Section 53F

This amendment is consequential on the repeal of section 53C.

Clause 19 Heading to Part 4A Division 3 repealed

The repeal of this heading is required because of changes in the organisation of offences provided for in Part 4A.

Clause 20 Section 53G repealed

The prohibition on the creation of a human embryo other than by fertilisation is repealed. The creation of an embryo other than by the fertilisation will be allowed provided that the creation is licensed by the NHMRC and the embryo is not developed beyond 14 days (see clause 31 and section 53J of the Act).

Clause 21 Section 53H amended

This clause amends the provision that creates an offence of creating a human embryo outside the body of a woman unless the intention is to achieve a pregnancy in a particular woman. The amendment means that embryos created by fertilisation of a human egg by human sperm may only be created for the purpose of achieving pregnancy. Embryos created by other means may only be created under an NHMRC licence and must not be used for purposes of reproduction.

The penalty is increased to a maximum penalty of 15 years imprisonment as for other practices that are completely prohibited.

Clause 22 Section 53I replaced

This clause replaces the provision that makes it an offence to create or develop a human embryo containing genetic material from more than one person. The new provisions makes it an offence to create or develop an embryo by the fertilisation of a human egg by human sperm that contains genetic material provided by more than two persons. Embryos containing genetic material from more than two persons may only be created by other means under an NHMRC licence and must not be used for the purposes of reproduction.

The penalty is increased to a maximum penalty of 15 years imprisonment as for other practices that are completely prohibited.

Clause 23 Section 53J amended

This clause increases the penalty for developing a human embryo outside the body of a woman for a period of more than 14 days to a maximum penalty of 15 years imprisonment as for other practices that are completely prohibited.

Clause 24 Section 53K repealed

The offence of using precursor cells from a human embryo or a human fetus to create a human embryo is repealed. New section 53QC provides for this practice to be permitted in accordance with an NHMRC licence.

Clause 25 *Section 53L amended*

This clause increases the penalty for altering the genome of a human cell in such a way that the alteration is heritable to a maximum of 15 years imprisonment as for other practices that are completely prohibited.

Clause 26 *Section 53M amended*

This clause increases the penalty for collecting a viable human embryo from the body of a woman to a maximum of 15 years imprisonment as for other practices that are completely prohibited.

Clause 27 *Section 53N replaced by sections 53N and 53NA*

The offences of creating a chimeric embryo and of creating a hybrid embryo are set out in two new sections.

New Section 53N (Offence—creating a chimeric embryo)

This prohibits the intentional creation of a chimeric embryo (as defined in section 3 of the Act) and is the same as existing section 53N(1). A chimeric embryo is a human embryo into which a cell of an animal, or any component part of a cell of an animal, has been introduced. A chimeric embryo is also defined to include anything else that is declared by the regulations to be a chimeric embryo. As at September 2006, there were no additional types of chimeric embryo prescribed in the regulations.

The penalty is increased to a maximum penalty of 15 years imprisonment as for other practices that are completely prohibited.

New Section 53NA (Offence—developing a hybrid embryo)

This provides that a person commits an offence if the person intentionally develops a hybrid embryo for a period of more than 14 days, excluding any period when development is suspended.

This clause should be read in conjunction with proposed new section 53QD that is inserted by clause 30 of the Bill. This allows the creation and development of certain hybrid embryos under licence. New section 53NA makes it clear that even if a person is authorised to create a hybrid embryo under a licence issued by the NHMRC Licensing Committee they are not ever permitted to develop such a hybrid embryo beyond 14 days.

Clause 28 *Section 53O amended*

This clause increases the penalty for offences relating to the placement of certain embryos to a maximum of 15 years imprisonment as for other practices that are completely prohibited.

Clause 29 *Section 53P amended*

The amendments in this clause make specific provision to insert the element of knowledge or recklessness into offences related to the importing, exporting and placement of prohibited

embryos. In order for an offence to have been created the person must have known that the embryo was a prohibited embryo or be reckless as to whether it was a prohibited embryo.

The penalties for offences under section 53P are increased to a maximum of 15 years imprisonment as for other practices that are completely prohibited.

Clause 30 Section 53Q amended

This clause increases the penalty for commercial trading in human eggs, sperm or embryos to a maximum of 15 years imprisonment as for other practices that are completely prohibited.

Clause 31 Part 4A Division 3 inserted

This clause inserts a new division into Part 4A that deals with practices that are prohibited unless they have been authorised by an NHMRC licence.

New Section 53QA (Offence—creating a human embryo other than by fertilisation, or developing such an embryo)

This provides that a person must not create a human embryo by a process other than the fertilisation of a human egg by a human sperm (or develop a human embryo so created) unless they are authorised to do so by a licence issued by the NHMRC Licensing Committee.

This allows researchers to apply to the NHMRC Licensing Committee to create embryos using techniques such as somatic cell nuclear transfer. Rather than specifically prohibiting human somatic cell nuclear transfer without a licence, the clause has been drafted more generally to cover creation of embryos by any means other than fertilisation of human egg by human sperm. This is consistent with the new definition of a human embryo and recognises that technology may change and that all embryos however created must be captured by the legislation.

This new section should be read in the context of section 53J of the Act which bans the development of a human embryo outside the body of a woman for more than 14 days and sections 53D and 53P(3) which ban the placement in the body of a woman of a human embryo clone, or any other human embryo created other than by the fertilisation of a human egg by a human sperm.

The maximum penalty for failure to comply with this provision is imprisonment for 10 years.

New Section 53QB (Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons)

This provides that a person may only create or develop a human embryo (by a process other than the fertilisation of human egg by human sperm) that contains genetic material provided by more than 2 persons if it is authorised by a license issued by the NHMRC Licensing Committee.

This clause only allows creation of embryos containing genetic material from 2 or more people if the embryo has been created by a means other than fertilisation. This new section should be read in the context of section 53J of the HRT Act which bans the development of a

human embryo outside the body of a woman for more than 14 days and section 53P(3) which bans the placement in the body of a woman of a human embryo created other than by the fertilisation of a human egg by a human sperm.

The maximum penalty for an offence against this provision is imprisonment for 10 years.

New Section 53QC (Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo)

This clause provides that a person commits an offence if the person uses precursor cells taken from a human embryo or a human fetus to create (or develop) an embryo without being authorised to do so by a licence issued by the NHMRC Licensing Committee.

The Lockhart Review recommended that creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

The maximum penalty for non-compliance with this clause is imprisonment for 10 years.

New Section 53QD (Offence—creating a hybrid embryo)

This clause bans the creation or development of a hybrid embryo unless the creation or development of the hybrid embryo is authorised by a licence issued by the NHMRC Licensing Committee. It is important that this clause be read in conjunction with proposed amendments to section 21 53ZA of the Act that further restrict the circumstances in which someone may apply for a licence to create or develop a hybrid embryo.

Proposed amendments to section 53ZA of the HRT Act make it clear that a licence may only be issued in the following circumstances:

- ↓ for the purposes of testing sperm quality in an accredited ART centre. In this case, the hybrid embryo may only be developed up to (but not including) the first mitotic division. This would enable ART tests that were carried out by some ART clinics prior to the commencement of the *Prohibition of Human Cloning Act 2002*, to once again be permitted; and
- ↓ for the creation of a hybrid embryo created by introducing the nucleus of a human cell into an animal egg. In this case, the hybrid embryo may be developed up to 14 days. This is consistent with Lockhart Recommendation 24 that states that “In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.”

This offence attracts a maximum penalty of 10 years imprisonment.

Clause 32 Section 53R amended

This clause amends section 53R to provide for the Minister to cause a further review of Part 4A to be undertaken. In summary:

- ↓ the review must be undertaken as soon as possible after 12 December 2009 (which is the third anniversary of Patterson Act received the Royal Assent);
- ↓ the review may be undertaken as part of the review of the Commonwealth Acts. The review of the Commonwealth Acts is to be undertaken by persons chosen by the Commonwealth Minister, with the agreement of each State;
- ↓ the Minister is to table a report based on the review within 12 months of the commencement of the review, and is also to table a copy of the review of the Commonwealth Acts; and
- ↓ the review must examine issues such as:
 - developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
 - developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research;
 - community standards;
 - a brief analysis of international developments and legislation relating to the use of human embryos and related research;
 - an analysis of research resulting from NHMRC licences granted;
 - any National Stem Cell Centre and any national register of donated excess ART embryos;
 - an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent;
 - an evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;
 - an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions;
 - the extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings; and
 - the extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter.

Clause 33 Heading to Part 4B replaced

The heading to Part 4B is replaced to reflect the expansion of the regulatory regime for excess ART embryos to also cover other human embryos, hybrid embryos and human eggs.

Clause 34 Section 53S amended

The Object of Part 4B is amended to reflect the expansion of the regulatory regime for excess ART embryos to also cover other human embryos, hybrid embryos and human eggs.

Clause 35 Section 53T amended

The definition of NHMRC Licensing Committee is deleted. The definition has been moved to section 3.

The definitions of “proper consent” and “responsible person” are replaced and definitions of “unsuitable for implantation” and “use” are inserted.

The new definition of *proper consent*, in relation to the use of an excess ART embryo or a human egg, or the creation or use of any other embryo, means consent obtained in accordance with guidelines issued by the CEO of the NHMRC and prescribed by the regulations under the Commonwealth Act.

The new definition of *responsible person* retains existing provisions in relation to excess ART embryos and adds provisions relating to other embryos and human eggs. In relation to an embryo other than an excess ART embryo a responsible person is each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo. In relation to a human egg the responsible person is the woman who was the biological donor of the egg.

The additional provisions have been added to ensure that all appropriate people provide consent in relation to the use of a human egg for research or the creation and use of an embryo created by means other than fertilisation of human egg by human sperm.

The definition of *unsuitable for implantation*, is a human embryo that:

- ↓ is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*; or
- ↓ is determined to be unsuitable for implantation in accordance with objective criteria to be specified in guidelines developed by the NHMRC and prescribed in regulations.

The definition of **use** is defined to include develop, or development, as the case requires. This has been included for convenience only so that when the Act refers to use of an embryo (for example, as authorized by the Act) this includes development of an embryo. It should be noted that all of the provisions that reference “use” (including development) also operate in conjunction with section 53J which prohibits development of an embryo beyond 14 days.

Clause 36 Sections 53WA and 53WB inserted

This clause inserts the following two new offences related to use of other embryos and human eggs.

New Section 53WA (Offence—use of other embryos)

This provides that a person commits an offence if a person uses the following types of embryos without a licence issued by the NHMRC Licensing Committee:

- ↓ a human embryo created by a process other than the fertilisation of a human egg by a human sperm;
- ↓ a human embryo that contains genetic material provided by more than 2 persons;

- ↓ a human embryo created using precursor cells from a human embryo or a human fetus; or
- ↓ a hybrid embryo.

There are offences in Part 4A relating to creation and development of these embryos and the requirement for licensing in these circumstances. This provision relates to “use” of embryos that have been created or developed under licence. This provision makes it clear that not only must the creation or development of these types of embryos be authorised by a licence but the use of such embryos must also be authorised by a licence.

This offence attracts a maximum penalty of 5 years imprisonment. This is consistent with the existing offences in Part 4B.

New Section 53WB (Offence—certain activities involving use of human eggs)

This establishes an offence of undertaking research or training involving the fertilisation of a human egg by human sperm, up to but not including the first mitotic division, outside the body of a woman for the purposes of ART research or training without a licence issued by the NHMRC Licensing Committee. This reflects amendments to the licensing provisions that allow a licence to be issued authorizing such research or training.

This offence attracts a maximum penalty of 5 years imprisonment. This is consistent with the existing offences in Part 4B.

Clause 37 Section 53ZA amended

Subsection 53ZA(1) currently provides that a person may apply to the NHMRC Licensing Committee for a licence authorising the use of excess ART embryos.

The purpose of the amendment to subsection 53ZA(1) is to set out the additional activities for which a person may request a licence from the NHMRC Licensing Committee. If the activity does not fall within this list, it is not able to be licensed by the NHMRC Licensing Committee.

A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

- ↓ use of excess ART embryos;
- ↓ creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
- ↓ creation of human embryos (other than by fertilisation of a human egg by a human sperm) and containing genetic material provided by more than 2 persons, and use of such embryos;
- ↓ creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
- ↓ research and training involving the fertilisation of a human egg, up to the first mitotic division, outside the body of a woman for the purposes of research or training;
- ↓ creation of hybrid embryos by the fertilisation of an animal egg by human sperm, and use of such embryos up to the first mitotic division, if:
 - the creation or use is for the purposes of testing sperm quality; and
 - the creation or use will occur in an accredited ART centre.

New subsection 53ZA(1a) is inserted to make it clear that amended section 53ZA(1) does not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.

Clause 38 Section 53ZB amended

The amendments in this clause provide that the conditions relating to the issue of licences applies to a licence authorising the creation or use of other human embryos, human eggs and hybrid embryos. This reflects the increased range of licences that the NHMRC Licensing Committee may issue.

Clause 39 Section 53ZE amended

Section 53ZE deals with conditions that attach to each licence issued by the NHMRC Licensing Committee.

Subsection (1) relates to requirements to obtain proper consent to the use of excess ART embryos and report to the NHMRC Licensing Committee that the consent has been obtained and any restrictions that are placed on that consent. Subsection (1) is replaced with a new provision that extends these requirements to all other types of activities that may be licensed.

Subsections (2), (5), (6) and (7) are amended so that wherever there is a reference to “excess ART embryos” (or similar), this is replaced with a reference to excess ART embryos, human eggs, other human embryos or hybrid embryos. This ensures that all of the licensing conditions that can be imposed in relation to the use of excess ART embryos can also be imposed in relation to the use of human eggs under licence and the creation and use of any other embryos under licence.

A new subsection (8) is inserted. It provides that a condition on a licence in relation to excess ART embryos that are unsuitable for implantation (as defined in section 53T) may provide that the NHMRC guidelines referred to in the definition of proper consent apply in a modified form. This new provision was inserted to clarify that if the NHMRC Licensing Committee considers it appropriate, they may approve the use of fresh embryos that are unsuitable for implantation and alter the cooling-off period that would be “normally at least two weeks” under existing guidelines.

Clause 40 Section 53ZG amended

This amendment reflects the change of name of the Commonwealth’s *Prohibition of Human Cloning Act 2002*.

Clause 41 Section 53ZJ amended

Section 53ZJ is amended so that wherever there is a reference to “excess ART embryos” (or similar), this is replaced with a reference to excess ART embryos, human eggs, other human embryos or hybrid embryos. This ensures that information that the NHMRC is to maintain on its database includes information about licences relating to the uses of human eggs and the creation and use of other embryos.

Clause 42 Section 53ZL amended

Amendments in this clause provide that the licence holder is an eligible person for the purpose of applying for a review of a decision of the NHMRC Licensing Committee to modify guidelines in respect of consent to use excess ART embryos that are unsuitable for implantation.

Clause 43 Section 53ZM amended

This allows an eligible person to apply to the Administrative Appeals Tribunal for a review of a decision of the NHMRC Licensing Committee to modify guidelines in respect of consent to use excess ART embryos that are unsuitable for implantation.

Clause 44 Section 53ZP amended

Section 53ZP is amended to provide that an inspector may enter premises to find out if Part 4A or 4B is being complied with if the entry is made under a warrant.

Clause 45 Section 53ZQ amended

Section 53ZQ is amended to provide additional powers to inspectors where entry to premises is made under a warrant. In those circumstances an inspector may require any person in or on the premises to answer questions or produce records or documents.

Clause 46 Section 53ZR amended

Amendment made to the power of an inspector to secure evidence relates to all embryos and human eggs that are subject to regulation under Parts 4A and 4B.

Clause 47 Sections 53ZRA to 53ZRD inserted

New section 53ZRA to 53ZRD provide for the issue of a warrant to an inspector appointed for the purposes of Parts 4A and 4B and conditions applying to the execution of a warrant.

New Section 53ZRA (Monitoring warrants)

The new section provides that an inspector may apply to a magistrate for a warrant and the magistrate may issue a warrant if he/she is satisfied that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether Part 4A or Part 4B have been complied with.

The warrant enables one or more inspectors to enter premises and exercise the powers set out in section 53ZQ in relation to the premises.

New Section 53ZRB (Details of warrant to be given to occupier etc.)

This provides that if a warrant under section 53ZRA is being executed and the occupier of the premises or another person who represents the occupier is present at the premises, then the inspector must:

- ↓ make a copy of the warrant available to the person; and

↓ identify himself or herself to that person.

New Section 53ZRC (Announcement before entry)

This provides that an inspector must, before entering premises under a warrant, announce that he or she is authorised to enter the premises and give any person at the premises an opportunity to allow entry to the premises.

New Section 53ZRD (Occupier entitled to be present during search)

This provides that if a warrant is being executed and the occupier of the premises (or another person who represents the occupier) is present at the premises, the person is entitled to observe the search being conducted but must not impede the search.

Clause 48 Part 4B Division 9 repealed

Division 9 is repealed as it is spent.

Clause 49 Part 4B Division 10 heading amended

The amendment is consequential on the expansion of Part 4B to regulate the use of other human embryos, hybrid embryos and human eggs.

Clause 50 Section 53ZVA amended

The amendment is consequential on the expansion of Part 4B to regulate the use of other human embryos, hybrid embryos and human eggs and means that a person can exercise a right of conscientious objection in relation to any activity that may be conducted under a licence issued under Part 4B.

Clause 51 Section 53ZW amended

This clause amends section 53ZW to provide for the Minister to cause a further review of Part 4B to be undertaken. The requirements for the review are the same as for the review of Part 4A as set out above in relation to clause 31.

Clause 52 Section 53ZX inserted

The Patterson Act requires the Commonwealth Minister to prepare:

- ↓ A report on:
 - the establishment of a National Stem Cell Centre and a national register of donated excess ART embryos; and
 - on the making of guidelines under the Commonwealth Act.
- ↓ A report on the feasibility of establishing a national legislative or regulatory approach for effective governance of non-blood human tissue based therapies.

New section 53ZX requires the State Minister to lay a copy of each report before each House of Parliament.

Clause 53 Section 61 replaced

Section 61 of the Act required a review to be undertaken within 5 years of the commencement of the Act. That review has been undertaken and section 61 is spent.

The new section 61 provides that savings and transitional provisions are set out in Schedule 2.

Clause 54 Schedule amended

As a consequence of adding a new schedule the existing Schedule is renamed as Schedule 1.

Clause 55 Schedule 2 inserted

Schedule 2 – Savings and transitional provisions is inserted to provide for applications for licences made before the amendments to the Act to be taken as applications under the amended Act.

Clause 56 Amendments relating to the amended title of the Human Reproductive Technology Act 1991

References to the *Human Reproductive Technology Act 1991* in other legislation is amended as a consequence of the change of name of the Act.