Research Involving Human Embryos And Prohibition Of Human Cloning Amendment Bill 2007

Explanatory Notes

Title of the Bill

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Objectives of the Amendments

In 2002, the Council of Australian Governments (COAG) agreed to nationally consistent legislation to regulate human embryo research and prohibit human cloning. The Commonwealth *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* ("the Commonwealth Acts") were passed in December 2002.

The complementary Queensland *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* ('the Queensland Act') was passed in March 2003. Queensland also signed an Inter-Governmental Agreement on 31 March 2004 to facilitate the national scheme.

The Commonwealth Acts required independent reviews of their operation by 19 December 2005. A Legislation Review Committee chaired by retired Federal Court Judge the Hon John Lockhart AO QC ('The Lockhart Review Committee') tabled a report with 54 recommendations in both Houses of Parliament on 19 December 2005.

The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), which amended the Commonwealth Acts to give effect to most of the Lockhart Review Committee's recommendations, commenced on 12 June 2007.

The corresponding Queensland Act requires the Minister to review the Act as soon as possible after December 2005, and stipulates the review may be undertaken as part of the review of the Commonwealth Acts. Queensland participated in the Lockhart Review and extensive community and stakeholder consultation was undertaken by the Lockhart Review

Committee. Consequently, the Lockhart Review is sufficient for the review of the Queensland Act.

On 13 April 2007, the Commonwealth, States and the Australian Capital Territory (ACT) signed a notice of variation to the intergovernmental agreement to renew their commitment to nationally consistent arrangements for the prohibition of human cloning for reproduction and the regulation of human embryo research. The States and the ACT undertook to use their best endeavours to introduce corresponding legislation into their Parliaments by 12 June 2008.

In summary, the amendments enable the following research activities, subject to the activity being licensed by the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee:

- creating human embryos other than by fertilisation of a human egg by human sperm, and use of such embryos;
- creating human embryos (by a process other than by fertilisation of human egg by human sperm containing genetic material provided by more than 2 persons) and use of such embryos;
- creating human embryos using precursor cells from a human embryo or a human foetus, and use of such embryos;
- undertaking research and training involving the fertilisation of a human egg up to but not including the first mitotic division, outside the body of a woman for the purposes of research and training; and
- creating hybrid embryos by the fertilisation of an animal egg by human sperm, and developing the embryos up to, but not including, the first mitotic division provided that the creation is for the purposes of testing sperm quality and will occur in an accredited Artificial Reproductive Technology (ART) centre.

Licences may only authorise the development of embryos up to 14 days (excluding any period during which development is suspended). In no circumstances can any embryo be developed, outside the body of a woman, beyond 14 days.

The amendments will also retain existing prohibitions on activities such as:

- placing a human embryo clone in the human body or the body of an animal;
- creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving a pregnancy in a woman;

- creating or developing a human embryo by fertilisation of a human egg by human sperm which contains genetic material provided by more than 2 persons;
- making heritable alterations to a human genome;
- collecting a viable human embryo from the body of a woman for research;
- creating or developing a chimeric embryo (i.e. a human embryo into which a cell of an animal has been introduced); and
- placing a human embryo into an animal or into the body of a human other than into the female reproductive tract, or placing an animal embryo into a human.

Achievement of the Objectives

The objective is to be achieved by amending the Queensland Act to maintain consistency with the Commonwealth Acts. The amendments in the proposed Bill mirror the changes made to the Commonwealth legislation.

Alternative Ways of Achieving Policy Objectives

There are no alternatives considered appropriate for achieving these policy objectives.

Estimated Cost for Government Implementation

The Queensland Act (as part of the national regulatory scheme) authorises the NHMRC Embryo Research Licensing Committee to administer the Act. All implementation of procedural changes and education programs will be undertaken by the NHMRC as part of its role to implement the Commonwealth amendments. There is therefore no cost to Government for implementation of the proposed amendments.

Consistency with Fundamental Legislative Principles

Section 4 (4)(c) of the *Legislative Standards Act 1992* provides that a Bill should only authorise the amendment of an Act by another Act.

Clause 16 of the Bill amends section 32 of the Queensland Act to provide that a licence issued by the NHMRC Embryo Research Licensing

Committee is subject to the condition that before an excess ART embryo or human egg is used, or any embryo is created or used, as authorised by the licence, each responsible person must give proper consent. New section 32(8) provides that, in applying this condition, a licence may provide that the guidelines referred to in the definition of proper consent apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation.

The definition of 'proper consent' refers to consent obtained in accordance with guidelines issued by the NHMRC and prescribed by regulation. The power to change the definition through alteration of the NHMRC guidelines and through regulation is necessary to respond quickly to regulate changing technology and unforeseen advances in scientific methods. Timely government response to technological changes is expected to be necessary to achieve the objects of the national regulatory scheme.

Further, the definition of 'proper consent' is being amended only slightly from the current definition. In addition to the current application of the definition to excess ART embryos, the Bill provides that the definition will also apply in relation to a human egg or the creation or use of any other embryo. The Bill also omits paragraph (a) as the 2004 NHMRC guidelines are now obsolete. However, the way in which the scheme operates (that is, defining the term by reference to NHMRC guidelines and regulation) remains the same.

In addition, the NHMRC guidelines in relation to the use of excess ART embryos for research currently provide a recommended 'cooling off' period for consent to take affect of 14 days. The Lockhart Review Committee recommended that fresh ART embryos that are unsuitable for implantation, as defined by objective criteria, be able to be licensed for use for training and research. To implement this recommendation, the Bill will insert a new provision enabling the NHMRC Embryo Research Licensing Committee to approve, via a licence for using excess ART embryos that are unsuitable for implantation, the application of the NHMRC guidelines in modified form. This will enable the NHMRC recommended 'cooling off' period for consent to be altered so that fresh excess ART embryos can be used for research or training.

Consultation

This Bill is complementary to the amendments to the Commonwealth Acts, which in turn were based on recommendations of the Lockhart Review Committee's report. The committee consulted the community extensively as required by the Commonwealth Acts, through a review website, written submissions, face-to-face meetings, public hearings, facilitated stakeholder discussions, and selected site visits.

Notes On Provisions

Clause 1 sets out the short title of the amending Act which is the *Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007* ('the amending Act').

Clause 2 provides that the amending Act amends the *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* ('the Queensland Act').

Clause 3 amends the long title of the Queensland Act to reflect that the legislation no longer prohibits the creation, for research purposes, of embryos using techniques such as somatic cell nuclear transfer. However, the Act continues to prohibit human cloning for the purposes of reproduction.

Clause 4 amends the short title of the Queensland Act to the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*.

Clause 5 amends the object of the Queensland Act to acknowledge that embryos can be lawfully created other than via assisted reproductive technology, such as by somatic cell nuclear transfer (if the activity is licensed by the NHMRC Embryo Research Licensing Committee).

Clause 6 clarifies a number of terms used in the Queensland Act.

Clause 7 repeals Part 2 of the Queensland Act and replaces it with a new Part 2, which comprises two Divisions. Division 1 sets out those practices that are completely prohibited and Division 2 describes those practices that

are prohibited unless authorised by licence issued by the NHMRC Embryo Research Licensing Committee.

Part 2 Prohibited Practices

Division 1 Practices that are completely prohibited

New section 7 prohibits a person from intentionally placing a human embryo clone in the body of a human or in the body of an animal. The effect of this provision is to ban human cloning for reproductive purposes.

The section also provides that it is not a defence to argue that the human embryo clone did not survive or could not have survived.

New section 8 prohibits a person from intentionally creating a human embryo by a process of fertilisation of a human egg by human sperm outside the body of a woman, unless the person's intention in creating the embryo is to attempt to achieve pregnancy in a particular woman. This means that an embryo cannot be created by fertilisation of a human egg by human sperm for the purposes of research. Such an embryo may only be created for assisted reproductive technology (ART) treatment of a particular woman.

New section 8(2) differs from the corresponding provision in the Commonwealth legislation because Queensland does not have a provision in the Queensland Criminal Code that is similar to s13.3(3) of the Commonwealth Criminal Code in relation to an evidential burden of proof. Section 8(2) has the same effect as the corresponding Commonwealth provision, to ensure that a defendant does not bear the burden of proving any matter in subsection 1.

New section 9 prohibits a person from intentionally creating or developing a human embryo by fertilisation of human egg by a human sperm outside the body of a woman that contains genetic material provided by more than two people.

However, the creation by means other than by fertilisation of a human egg by human sperm (such as through somatic cell nuclear transfer), of a human embryo involving genetic material from more than two persons, is

permitted if authorised under licence issued by the NHMRC Embryo Research Licensing Committee.

New section 10 makes it an offence to intentionally develop a human embryo outside the body of a woman beyond 14 days (excluding any period where the embryo's development is suspended). This provision applies regardless of how the embryo was created.

For embryos created for ART purposes, it is standard clinical practice to implant embryos when they have reached between three and seven days of development. As such, the development of embryos for ART treatment is not affected by this provision.

New section 11 makes it an offence to alter a human genome in a way that is intended to be heritable. This clause bans what is commonly known as germ line gene therapy, where changes would be made to the genome of egg or sperm cells, or even to the cells of the early embryo. The genetic modification would then be passed on to any offspring born to the person whose cell was genetically modified and also to subsequent generations.

New section 12 prohibits the removal of a viable human embryo from the body of a woman after fertilisation has taken place.

New section 13 prohibits the intentional creation of a chimeric embryo, which is a human embryo into which a cell, or any component part of a cell, of an animal has been introduced.

New section 14 prohibits the intentional development of a hybrid embryo for a period of more than 14 days, excluding any period where development is suspended.

This clause should be read in conjunction with the new section 20A, which enables the creation and development of hybrid embryos for one specific purpose under licence. To give effect to this intent, three interacting clauses are proposed. New section 14 prohibits the development of a hybrid embryo beyond 14 days (but does not ban the creation of hybrid embryos), new section 20A provides that hybrid embryos may only be created if authorised by licence issued by the NHMRC Embryo Research Licensing Committee, and new section 29 clarifies the only type of hybrid embryo that is allowed to be developed.

New section 15 prevents the placement of: a human embryo in an animal; a human embryo in the body of a human, including a man or any part of a woman's body, other than the reproductive tract; or an animal embryo in a human, for any period of gestation.

New section 16 prohibits the intentional placement in the body of a woman of a 'prohibited embryo'. A prohibited embryo is defined in subsection 2.

New section 17 prevents the commercial trading of human eggs, sperm and embryos. Both parties involved in such commercial trading would commit an offence. The only consideration that may be given for the supply of gametes or embryos is reimbursement of reasonable expenses related to that supply, such as expenses for the collection, storage and transport where relevant.

Division 2 Practices that are prohibited unless authorised by a licence

New section 18 prohibits a person from creating or developing a human embryo by a process other than the fertilisation of a human egg by a human sperm unless authorised by a licence issued by the NHMRC Embryo Research Licensing Committee.

This enables scientists to apply to the NHMRC Embryo Research Licensing Committee for a licence to create embryos using techniques such as somatic cell nuclear transfer. However, this clause should also be read in the context of new section 10 which bans the development of a human embryo outside the body of a woman for more than 14 days and new sections 7 and 16(2)(a) which ban the placement in the body of a woman of a human embryo clone or any other human embryo created other than by fertilisation of a human egg by a human sperm.

New section 19 provides that a person may only create or develop a human embryo by a process other than by fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons if it is authorised by a licence issued by the NHMRC Embryo Research Licensing Committee.

The note for new section 19 makes it clear that new section 10 prohibits the development of any embryo outside the body of a woman for more than 14 days and new section 16 prohibits the placement in the body of a woman of a human embryo created other than by fertilisation of a human egg by human sperm.

New section 20 makes it an offence for a person to use a precursor cell taken from a human embryo or a human foetus to create or develop an

embryo, unless authorised by licence issued by the NHMRC Embryo Research Licensing Committee.

New section 20A prohibits the creation or development of a hybrid embryo unless the creation or development of the hybrid embryo is authorised by licence issued by the NHMRC Embryo Research Licensing Committee. It is important that this clause be read in conjunction with amended section 29 of the Queensland Act which clarifies that a licence may only be issued to create and develop a hybrid embryo for the purposes of testing sperm quality in an accredited ART centre and only up to, but not, including, the first mitotic division.

Clause 8 amends the name of the heading of Part 3 of the Queensland Act.

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

Clause 9 repeals the definition of proper consent and replaces it with a new definition. The definition of 'responsible person' is also amended to ensure that all appropriate people provide consent in relation to the use of a human egg for research and use of an embryo created by means other than by fertilisation of a human egg by human sperm.

Clause 10 amends section 23 of the Queensland Act to ensure that a defendant does not bear the burden of proof for the offences.

Clause 11 inserts new sections 23A and 23B.

New section 23A provides that a person commits an offence if a person intentionally uses the following types of embryos without a licence issued by the NHMRC Embryo Research Licensing Committee: a human embryo created by a process other than the fertilisation of a human egg by a human sperm; a human embryo which contains genetic material provided by more than 2 persons; a human embryo created using precursor cells from a human embryo or human foetus; or a hybrid embryo.

This provision relates to the 'use' of embryos that have been created or developed under licence issued by the NHMRC Embryo Research Licensing Committee. This is intended to clarify that not only must the

creation or development of these embryos be authorised by licence but also the use of such embryos.

New section 23B makes it an offence to undertake 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 Embryo Research Licensing Committee.

Clause 12 amends section 24 of the Queensland Act to ban the use, outside the body of a woman, of an embryo that is not an excess ART embryo, created by fertilisation of a human egg by human sperm, unless the use is for the purpose of ART. This is to prohibit people from using non-excess ART embryos for research. This prohibition does not, however, extend to the use of embryos that have been created by means other than fertilisation of a human egg by human sperm, which may be authorised under licence issued by the NHMRC Embryo Research Licensing Committee.

Clause 13 inserts a new section 25A.

New section 25A clarifies that a person is not criminally responsible for an offence against the Queensland Act if: the conduct is purportedly authorised by a provision of a licence; the licence or provision is invalid; and the person did not know and could not reasonably have been expected to have known, of the invalidity of the licence or provision.

Clause 14 amends section 28 of the Queensland Act to enable a person to apply to the NHMRC Embryo Research Licensing Committee for a licence authorising specified research activities. In addition, to avoid any doubt, amended section 28 does not permit the NHMRC Embryo Research Licensing Committee to authorise any use of excess ART embryos or other embryos 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 15 amends section 29 of the Queensland Act to include human eggs and other embryos, as well as excess ART embryos.

Clause 16 amends section 32 so that wherever there is a reference to ‘excess ART embryos’, this is replaced with a reference to ‘excess ART embryos, human egg and other embryos’. This ensures that all of the licensing conditions that can be imposed in relation to excess ART embryos will now also be imposed in relation to the use of human eggs and other embryos under licence.

Clause 16 also inserts a new subsection 8 into section 32. New subsection 8 provides that a licence in relation to embryos that are unsuitable for

implantation may provide that the NHMRC guidelines referred to in the definition of 'proper consent' may apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation.

The NHMRC guidelines in relation to the use of excess ART embryos for research currently provide a recommended 'cooling off' period for consent to take affect of 14 days. The Lockhart Review Committee recommended that fresh ART embryos that are unsuitable for implantation, as defined by objective criteria, be able to be licensed for use for training and research. The above clause implements this recommendation, which will enable the NHMRC recommended 'cooling off' period for consent to be altered so that fresh excess ART embryos can be used for research or training.

Clause 17 amends section 37 so that wherever there is a reference to 'excess ART embryos', this is replaced with a reference to excess ART embryos, human eggs and other embryos. This means that the NHMRC must now also include on its database information about licences issued authorising the creation and use of other embryos and the use of human eggs.

Clauses 18 and 19 amend sections 39 and 40 respectively to enable the new decision-making role of the NHMRC described in Clause 16 above to be reviewable by the Administrative Appeals Tribunal.

Clause 20 amends section 43 to enable inspectors to apply to a Magistrate for a search warrant in relation to non-licensed premises.

Clause 21 amends section 44 to insert the words 'other embryo and human egg' and to add two additional powers that may be exercised by inspectors authorised to enter premises by warrant under section 43.

Clause 22 ensures that the power to secure applies not only to a human embryo, but also to any other embryo or human egg.

Clause 23 inserts new sections 45A to 45D.

New section 45A provides that an inspector may apply to a magistrate for a warrant and the magistrate may issue the warrant if satisfied that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether the Queensland Act is being complied with.

New section 45B provides that if a warrant is being executed under new section 45A 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 45C provides that an inspector must, before entering the premises under 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 45D 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 24 inserts a new section 49 into the Queensland Act.

New section 49 provides for a further review of the operation of the Queensland Act as amended as soon as possible after the third anniversary of the day on which the amending Act commenced.

Clause 25 inserts a new Part 6.

Part 6 Savings provisions

New section 54 sets out a savings provision to clarify that the amendments to the Queensland Act do not invalidate any existing licences that may have been issued by the NHMRC Embryo Research Licensing Committee.

Clause 26 amends the definitions of certain terms in the schedule.

Importantly, the definition of human embryo has been amended to adopt a new definition developed by the NHMRC. The new definition alters the point at which a human embryo is defined to commence existence. The identification of the first mitotic division is identified to be the time when fertilisation is complete and the fertilised egg becomes an embryo.

In addition, the new definition of human embryo now recognises embryos created other than by fertilisation of a human egg by human sperm (such as somatic cell nuclear transfer and parthenogenesis). The new definition specifies that 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.