Explanatory note

This explanatory note relates to this Bill as introduced into Parliament. Overview of Bill

The object of this Bill is to amend the Human Cloning and Other Prohibited Practices Act 2003 to mirror amendments made to corresponding Commonwealth legislation by the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 of the Commonwealth (the Commonwealth amending Act). Similar amendments have been enacted in Victoria by the Infertility Treatment Amendment Act 2007 of that State (the Victorian amending Act).

The Commonwealth amending Act, the Victorian amending Act and this Bill are in line with recommendations made in December 2005 by the Legislation Review Committee (also known as the Lockhart Committee) appointed to review the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 of the Commonwealth.

In particular, this Bill:

- (a) retains the existing prohibitions on (among other practices):
- (i) human reproductive cloning, and

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- (ii) developing a human embryo outside the body of a woman for more than 14 days, and
- (iii) collecting a viable human embryo from the body of a woman, and
- (iv) creating or developing a human embryo by fertilisation of a human egg by a human sperm outside the body of a woman for any purpose other than the assisted reproductive technology treatment of a particular woman, and
- (v) placing in the body of a woman any embryo other than a human embryo created by the fertilisation of a human egg by a human sperm, and
- (vi) commercial trading in human eggs, human sperm or human embryos, and
- (b) enables somatic cell nuclear transfer (also known as therapeutic cloning) and other practices involving the creation of human embryos other than by the fertilisation of human eggs by human sperm, but only under licence for research purposes and not for reproductive purposes.

This Bill also makes a number of amendments to the Research Involving Human Embryos (New South Wales) Act 2003. That Act applies the Research Involving Human Embryos Act 2002 of the Commonwealth as a law of this State. Accordingly, amendments made to that Act by the Commonwealth amending Act are applied in this State.

Outline of provisions

Clause 1 sets out the name (also called the short title) of the proposed Act. Clause 2 provides that the proposed Act is taken to commence on 12 June 2007 so as to coincide with the date on which the Commonwealth amending Act will commence.

Clause 3 is a formal provision that gives effect to the amendments to the Human Cloning and Other Prohibited Practices Act 2003 set out in Schedule 1. Clause 4 is a formal provision that gives effect to the amendments to the Research Involving Human Embryos (New South Wales) Act 2003 set out in Schedule 2. Clause 5 provides for the repeal of the proposed Act after all the amendments made by the proposed Act have commenced. Once the amendments have commenced the proposed Act will be spent and section 30 of the Interpretation Act 1987 provides that the repeal of an amending Act does not affect the amendments made by that Act.

Schedule 1 Amendment of Human Cloning and

Other Prohibited Practices Act 2003

Schedule 1 [1] amends the long title of the Human Cloning and Other Prohibited Practices Act 2003 (the Principal Act) to read "An Act to adopt in this State a uniform Australian approach to the prohibition of human cloning for reproduction and certain other practices associated with reproductive technology; and for other Explanatory note page 3

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purposes." The amendment to the long title reflects the fact that, if the proposed Act is made, the Principal Act will no longer prohibit the creation, for research purposes, of embryos using techniques such as therapeutic cloning.

Schedule 1 [2] amends the name of the Principal Act to read "Human Cloning for Reproduction and Other Prohibited Practices Act 2003".

Schedule 1 [3] amends section 3 of the Principal Act in line with the amendments made by Schedule 1 [1] and [2].

Schedule 1 [4] is consequential on the amendment made to the name of the Prohibition of Human Cloning Act 2002 of the Commonwealth by the Commonwealth amending Act.

Schedule 1 [5] replaces the definition of human embryo with a new definition developed by the National Health and Medical Research Council (the NHMRC).

Schedule 1 [6] inserts a definition of licence for the purposes of the Principal Act.

Schedule 1 [7] clarifies a number of terms used in the proposed Act.

Schedule 1 [8] replaces Part 2 of the Principal Act with a new Part containing 2 Divisions. Division 1 describes those practices that are completely prohibited. Under Division 2, certain practices that are currently completely prohibited under the Principal Act are prohibited unless they are authorised by a licence issued by the Embryo Research Licensing Committee of the NHMRC (the Embryo Research Licensing Committee) established under the Research Involving Human Embryos Act 2002 of the Commonwealth.

Proposed Division 1 of Part 2 of the Principal Act comprises proposed sections 5–16. Most of these provisions involve the recreation of existing offences, but with an increase in the maximum penalties for those offences from 10 to 15 years imprisonment. In particular, the following practices continue to be prohibited:

(a) placing a human embryo clone in a human body or the body of an animal (proposed section 5, which recreates the existing section 6 of the Principal Act),

- (b) developing a human embryo outside the body of a woman for more than 14 days (proposed section 9, which recreates the existing section 11 of the Principal Act).
- (c) making heritable alterations to a human genome (proposed section 10, which recreates the existing section 13 of the Principal Act).
- (d) collecting a viable human embryo from the body of a woman (proposed section 11, which recreates the existing section 14 of the Principal Act),
- (e) creating a chimeric embryo (proposed section 12, which recreates the existing section 15 (1) of the Principal Act),

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- (f) placing a human embryo in an animal, a human embryo in the body of a human (other than in a woman's reproductive tract) or an animal embryo in the body of a human (proposed section 14, which recreates the existing section 16 of the Principal Act),
- (g) commercial trading in human eggs, human sperm or human embryos

(proposed section 16, which recreates the existing section 18 of the Principal Act),

- (h) placing in the body of a woman a prohibited embryo (proposed section 15, which recreates the existing section 17 of the Principal Act). A prohibited embryo continues to be defined as follows:
- (i) a human embryo created by a process other than the fertilisation of a human egg by human sperm, or
- (ii) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman, or
- (iii) a human embryo that contains genetic material provided by more than 2 persons, or
- (iv) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended (for example, while the embryo is frozen), or (v) a human embryo created using precursor cells taken from a human embryo or a human foetus, or
- (vi) a human embryo that contains a human cell whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered, or
- (vii) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo, or (viii) a chimeric embryo or a hybrid embryo.

Proposed section 6 recreates the existing section 7 of the Principal Act to provide that it is not a defence to the offence of placing a human embryo clone in a human body or the body of an animal (proposed section 5) that the human embryo clone did not survive or could not have survived.

Under proposed section 7 the creation of a human embryo by fertilisation of a human egg by human sperm outside the body of a woman may only be for the assisted reproductive technology treatment of a particular woman and not for the purposes of research. The creation of a human embryo other than by fertilisation of a human egg by human sperm (including therapeutic cloning) may occur for research (but not reproductive) purposes under a licence issued by the Embryo Research Licensing Committee. (See explanation of proposed sections 17, 18 and 18A below.) Explanatory note page 5

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Proposed section 8 provides for a further offence of creating or developing a human embryo by fertilisation of a human egg by human sperm outside the body of a woman where the human embryo contains genetic material provided by more than 2 persons. The proposed section should be read in conjunction with proposed section 18. (See further explanation below.)

Proposed section 13 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 (for example, while the embryo is frozen). The proposed section should be read in conjunction with proposed section 18B. (See further explanation below.)

Proposed Division 2 of Part 2 of the Principal Act comprises proposed sections 17, 18, 18A and 18B. Proposed section 17 prohibits the creation or development of a human embryo by a process other than the fertilisation of a human egg by human sperm without the authorisation of a licence issued by the Embryo Research Licensing Committee.

Proposed section 18 further prohibits the creation of a human embryo by a process other than the fertilisation of a human egg by human sperm where the embryo

contains genetic material provided by more than 2 persons without the authorisation of a licence issued by the Embryo Research Licensing Committee.

Proposed section 18A prohibits the use of precursor cells taken from a human embryo or a human foetus to create (or develop) an embryo without the authorisation of a licence issued by the Embryo Research Licensing Committee.

Proposed section 18B prohibits the creation or development of a hybrid embryo without the authorisation of a licence issued by the Embryo Research Licensing Committee. As a result of amendments to the Research Involving Human Embryos Act 2002 of the Commonwealth by the Commonwealth amending Act, such a licence may authorise the use of a hybrid embryo up to, but not including the first cell division (which occurs in less than 48 hours after fertilisation) and only for the purposes of testing sperm quality.

Schedule 1 [9] inserts proposed section 19A into the Principal Act to require the Minister to review that Act, as amended by the proposed Act, as soon as possible after the period of 3 years from the date of assent to the proposed Act. A report on the outcome of the review is to be tabled in each House of Parliament within 12 months after the end of the period of 3 years. The Minister may undertake the review under proposed section 19A at the same time as the review required by section 25A of the Prohibition of Human Cloning for Reproduction Act 2002 of the Commonwealth, in which case the report on the outcome of the review under proposed section 19A is to be tabled in each House of Parliament as soon as practicable after the Minister has completed the review.

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Schedule 2 Amendment of Research Involving Human Embryos (New South Wales) Act 2003

As noted in the Overview, the Research Involving Human Embryos (New South Wales) Act 2003 (the NSW Embryo Research Act) applies the Research Involving Human Embryos Act 2002 of the Commonwealth as a law of this State. Accordingly, the amendments made to that Act by the Commonwealth amending Act are applied in this State without any direct amendments to the NSW Embryo Research Act being required other than the minor and machinery amendments set out in Schedule 2 to the proposed Act.

Schedule 2 [1] provides for the amendment of section 3 (1) of the NSW Embryo Research Act to reflect the fact that, if the proposed Act is made, the NSW Embryo Research Act will extend to the regulation of activities involving the use of human embryos created by means additional to assisted reproductive technology, such as therapeutic cloning.

Schedule 2 [2] is consequential on the amendment made to the name of the Prohibition of Human Cloning Act 2002 of the Commonwealth by the Commonwealth amending Act.

Schedule 2 [3] is consequential on the amendment made by Schedule 1 [2] to the name of the Human Cloning and Other Prohibited Practices Act 2003.

Schedule 2 [4] inserts proposed section 23 into the NSW Embryo Research Act to require the Minister to review the Research Involving Human Embryos Act 2002 of the Commonwealth, as applied in this State by the NSW Embryo Research Act and amended by the Commonwealth amending Act, as soon as possible after the period of 3 years from the date of assent to the proposed Act. A report on the outcome of the review is to be tabled in each House of Parliament within 12 months after the end of the period of 3 years. The Minister may undertake the review under proposed section 23 at the same time as the review required by section 47A of the Research Involving Human Embryos Act 2002 of the Commonwealth, in which case the report on the

outcome of the review under proposed section 23 is to be tabled in each House of Parliament as soon as practicable after the Minister has completed the review.