THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

SOMATIC CELL NUCLEAR TRANSFER (SCNT) AND RELATED RESEARCH AMENDMENT BILL 2006

DRAFT EXPLANATORY MEMORANDUM

SOMATIC CELL NUCLEAR TRANSFER (SCNT) AND RELATED RESEARCH AMENDMENT BILL

GENERAL OUTLINE

The purpose of the Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill (the Bill) is to permit the continuing development of techniques to explore the therapeutic potential of stem cells and to allow improvements in assisted reproductive technology (ART) research, training and practice.

It amends two Acts – the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002.*

The *Prohibition of Human Cloning Act 2002* sets out activities in the field of reproductive and therapeutic medical research that are prohibited. The *Research Involving Human Embryos Act 2002* provides a framework for the conduct of medical research using ART embryos that are excess to requirements and have been donated to research with informed consent.

Research on embryos and materials derived from them is useful to both discover the potential therapeutic benefits of embryonic stem cells and to improve the practice of ART. The existing Acts permit only the use of excess ART embryos for research purposes, which limits the extent to which Australian researchers can explore the potential applications of embryonic stem cells and also places Australia at a competitive disadvantage to countries, such as the United Kingdom, which have fewer restrictions on this technology. The Acts have also had the unintended consequence of restricting certain ART practices that had previously been allowed.

In 2005, the Lockhart Review Committee, chaired by the late the Hon John Lockhart AO QC, conducted a review of the scope and operation of both Acts and published their final report in December 2005. This Bill is intended to capture those scientific recommendations of the Lockhart Review of the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* which require legislation, to allow the further development of responsible research into stem-cell based therapies and improved ART practices.

FINANCIAL IMPACT

The amendments in this Bill have no financial impact on Government revenue.

NOTES ON CLAUSES

Clause 1 Short title

This clause provides for the Act, when it is enacted, to be cited as the *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Act 2006*.

Clause 2 Commencement

This clause provides for the commencement of the Act on the day on which it receives the Royal Assent.

Clause 3 Object of the Act

This clause states that the object of this Bill principally is to allow for the continued development of responsible research into the therapeutic potential of stem cells, including via techniques such as somatic cell nuclear transfer. Further, this Bill will redress some of the unintended consequences of the current legislation that prevented previously allowed research into improved methods for achieving pregnancy via ART and also allow the development of improved techniques in clinical ART practice.

Clause 4 Schedule(s)

This clause is the formal enabling provision for the Bill. It provides that each Act specified in a Schedule is amended in accordance with the applicable items of the Schedule. This Bill amends the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*.

This clause also provides that any other item in a Schedule has effect according to its terms.

SCHEDULE 1 – AMENDMENT OF THE PROHIBITION OF HUMAN CLONING ACT 2002

Item 1

This item repeals the definition of *human embryo* as provided in the Act and substitutes it with the definition arrived at by the National Health and Medical Research Council Embryo Research Licensing Committee in their discussion paper *'A Human Embryo – A Biological Definition'* (2005), that is:

> ***human embryo*** *means a discrete entity that has arisen from either:*
>
> *(a) the first mitotic division when fertilisation of a human egg by a human sperm is complete; or*
>
> *(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;*
>
> *and has not yet reached 8 weeks of development since the first mitotic division.*

The key difference is the identification of the 'primitive streak' as the marker of a developing embryo, a more advanced stage of development than the 'pro-nuclei' stage given in the original Act. This definition allows medical science more options in research involving embryos, but it maintains the limitation in the original Act that the embryo must have undergone no more than 14 days of development.

The NHMRC Licensing Committee 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 and was the subject of a public consultation process.

This definition relates to Recommendation 28 of the Lockhart Review. The Licensing Committee passed their definition to the Lockhart Committee as it evolved, but the definition was not finalised before the Lockhart Report was published – hence the discrepancy between the definition of human embryo in the Lockhart Report and the final definition of the NHMRC Committee.

Item 2

The Lockhart Review recommended that ART embryos that are unsuitable for implantation, as defined by objective criteria and diagnosed by pre-implantation genetic diagnosis, should be permitted to be used under licence for research, training, and improvements in clinical practice (Recommendations 21 and 22).

This Bill allows for that practice by stating that an 'unsuitable for implantation embryo' is defined by diagnostic guidelines and objective criteria established by the NHMRC. This definition is given as a separate item under the broader definition of an excess ART embryo.

Item 3

Two additional definitions are added to the Act under this item. The first provides for a definition of "licence", meaning a licence issued to conduct approved related research under this Bill. The second defines the "NHMRC Licensing Committee" as the body responsible for issuing and monitoring licences under the *Research Involving Human Embryos Act 2002.*

Item 4

Prohibited practices are listed under Part 2 of the *Prohibition of Human Cloning Act 2002*, divided into Division 1 (Prohibited Practices) and Division 2 (Other Prohibited Practices). The Lockhart Recommendations allow for a wider scope of research than under existing legislation. Therefore, some of the practices currently prohibited under the Act are allowed under this Bill, provided a license has been obtained as set out in Division 4 of the *Research Involving Human Embryos Act 2002*.

This Bill combines the prohibited practices of *Prohibition of Human Cloning Act 2002* into two sections – those practices prohibited outright and those prohibited except under licence. This Bill strengthens the penalties for some prohibited practices.

Item 5

Division 1 of Part 2 of the *Prohibition of Human Cloning Act 2002* sets out the prohibitions against human cloning.

This Bill repeals that Division and establishes a new Division 1 entitled 'Prohibited practices', which are those that are prohibited outright under this Bill.

This Division 1 no longer includes 'creating a human embryo clone' or 'importing or exporting a human embryo clone', both of which are allowable under licence in this Bill (see Division 2 - Practices prohibited unless authorised by licence).

The Lockhart Review recommended maintaining several prohibitions. As such, the Bill brings the following offences under the banner of Division 1 – Prohibited Practices:

1. Developing a human embryo outside the body of a woman for more than 14 days (Lockhart Recommendation 4);
2. Creating or developing a human embryo containing nuclear genetic material provided by more than 2 persons (Lockhart Recommendation 8);
3. Intentionally conducting heritable alterations to the genome of a human cell (Lockhart Recommendation 10);
4. Collecting a viable human embryo from the body of a woman, (Lockhart Recommendation 11);
5. Placing of a human embryo in an animal; implanting a human embryo anywhere in a human body other than a woman's reproductive tract; placing an animal embryo into the body of a human for any period of gestation; and placing a non-ART embryo in the body of a woman for any purpose other than achieving pregnancy (Lockhart recommendations 3, 5, 7, 8, 9, and 10);
6. Commercial trading in human eggs, human sperm or human embryos (Lockhart recommendations 33 and 44).

In so doing, this Bill strengthens the prohibitions against the offences listed in points 1 to 6 above, increasing the maximum penalty from 10 years imprisonment in the original legislation to 15 years under this Bill, for consistency with Division 1 prohibitions under the *Prohibition of Human Cloning Act 2002*.

A clause is also listed stated that using a human embryo that did not survive or could not have survived for research in any way contrary to the offences listed in Division 1 is not a defence and still counts as an offence.

Item 6

Part 2, Division 2 of the *Prohibition of Human Cloning Act 2002* sets out practices, other than human cloning, which are prohibited under the Act.

This Bill repeals that Division and establishes a new Division 2 entitled 'Practices prohibited unless authorised by licence'. This Division lists the activities that are allowed under this Bill provided the licensing system set out in Division 4 of the *Research Involving Human Embryos Act 2002* is adhered to.

This Division 2 differs from the current one in the *Prohibition of Human Cloning Act 2002* in that it now includes 'creating a human embryo clone' and 'importing or exporting a human embryo clone' in Division 2 (Practices prohibited unless authorised by licence), in accordance with Lockhart recommendations 23, 24, and 25 (in the case of human embryo cloning) and recommendations 42 and 43 (in the case of importing or exporting human embryo clones).

The activities now deemed eligible under licence in this Bill are as follows:

1. Creating a human embryo clone (Lockhart recommendations 23 to 25;
2. Importing or exporting a human embryo clone (Lockhart recommendations 42 and 43);
3. Importing or exporting a human embryo (Lockhart recommendations 41 and 42);
4. Creating a human embryo other than by fertilisation (Lockhart recommendations 23 to 27);
5. Developing a human embryo created other than by fertilisation (Lockhart recommendations 23 to 27);
6. Creating a human embryo for a purpose other than achieving pregnancy in a woman;
7. Creating or developing a human embryo containing mitochondrial genetic material provided by more than 2 persons (Lockhart recommendation 26);
8. Using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo (Lockhart recommendation 27); and
9. Creating a chimeric embryo or a hybrid embryo (Lockhart recommendations 17, 24).

The maximum penalty for offences under Division 2 of this Bill is 10 years imprisonment in all cases except for the creation of a human embryo clone under Item 19 and for intentionally developing a chimeric or hybrid embryo for a period of more than 14 days under Item 23(3). Where this occurs without a licence, these offences retain the maximum penalty listed under the *Prohibition of Human Cloning Act 2002* of 15 years.

SCHEDULE 2 – AMENDMENT OF THE RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002

Item 1

This item repeals the definition of *human embryo* as provided in the Act and substitutes it with the definition arrived at by the National Health and Medical Research Council Embryo Research Licensing Committee in their discussion paper *'A Human Embryo – A Biological Definition'* (2005), that is:

> ***human embryo*** *means a discrete entity that has arisen from either:*
>
> *(a) the first mitotic division when fertilisation of a human egg by a human sperm is complete; or*

(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

and has not yet reached 8 weeks of development since the first mitotic division.

The key difference is the identification of the 'primitive streak' as the marker of a developing embryo, a more advanced stage of development than the 'pro-nuclei' stage given in the original Act. This definition allows medical science more options in research involving embryos, but it maintains the limitation in the original Act that the embryo must have undergone no more than 14 days of development.

The NHMRC Licensing Committee 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 and was the subject of a public consultation process.

This definition relates to Recommendation 28 of the Lockhart Review. The Licensing Committee passed their definition to the Lockhart Committee as it evolved, but the definition was not finalised before the Lockhart Report was published – hence the discrepancy between the definition of human embryo in the Lockhart Report and the final definition of the NHMRC Committee.

Item 2

The heading of Part 2 of the *Research Involving Human Embryos Act 2002* refers only to the use of excess ART embryos.

As this Bill allows research on embryos beyond the scope of those declared excess for ART purposes, this heading will now read "Regulation of certain uses involving excess ART embryos *or licensed embryos*".

Item 3

As this Bill allows research on human embryos beyond those declared excess for ART purposes, a new definition, for 'licensed embryo' has been added.

Item 4

Under the *Research Involving Human Embryos Act 2002*, the definition of 'proper consent' relates only to excess ART embryos.

As this Bill allows research on embryos beyond the scope of those declared excess for ART purposes, the definition of proper consent will now apply to licensed embryos as well.

Item 5

The Lockhart Review recommended that ART embryos that are unsuitable for implantation, as defined by objective criteria and diagnosed by pre-implantation genetic diagnosis, should be permitted to be used under licence for research, training, and improvements in clinical practice (Recommendations 21 and 22).

This Bill allows for that practice by stating that an 'unsuitable for implantation embryo' is defined by diagnostic guidelines and objective criteria established by the NHMRC. This definition is given as a separate item under the broader definition of an excess ART embryo.

Item 6

The *Research Involving Human Embryos Act 2002*, states under Section 10 that it is an offence to use an excess ART embryo unless authorised by a licence.

As this Bill allows research on embryos beyond the scope of those declared excess for ART purposes, the title of this section is amended to include the use or creation of licensed embryos.

Item 7

The *Research Involving Human Embryos Act 2002* refers only to excess ART embryos under Section 10(1).

As this Bill allows research on embryos beyond the scope of those declared excess for ART purposes, this section is amended to include reference to the use or creation of licensed embryos.

Item 8

This Bill differs from existing legislation in that it allows the creation of human embryos for research under licence. As such, the *Research Involving Human Embryos Act 2002* needs to include reference to the "creation" of embryos in its description of what does and does not constitute an offence.

Item 9

Section 11 of the Act currently labels as an offence any use of a human embryo, outside the body of a woman, which is not an excess ART embryo and is not for ART purposes.

As this Bill allows research on embryos beyond those declared excess for ART purposes the heading now also refers to licensed embryos.

Item 10

The *Research Involving Human Embryos Act 2002* states that it is an offence to use an embryo, outside the body of a woman, that is not an excess ART embryo.

This Bill broadens the scope of embryos that may be used for research under licence and as such it amends paragraphs 11(a) and (b) to include allowance for the use of licensed embryos with a licence issued under section 21.

Item 11

The *Research Involving Human Embryos Act 2002* establishes the NHMRC Embryo Research Licensing Committee (the Licensing Committee) to manage the licensing regime for research involving human embryos. Members of the Licensing Committee are appointed by the Minister, who must seek nominations from the States and relevant agencies. This is an involved process that has led to delays in the filling of vacancies on the Licensing Committee.

In accordance with Lockhart Recommendation 36, this Bill states that any vacancy on the Licensing Committee must be filled as soon as possible. The Lockhart Review further suggested that if a vacancy exists for two months, the Minister must, within three sitting days of the expiration of that two month period, table in each House of Parliament a written statement of reasons for the failure to fill the vacancy. The feasibility of this option needs to be considered in consultation with the States, as they will need to enact comparable legislation if this suggested clause is to be practicable.

Item 12

This amendment highlights that Division 4 of the *Research Involving Human Embryos Act 2002* is intended to licence practices listed under Division 2 of Part 2 of the *Prohibition of Human Cloning Act 2002.*

Item 13

Subsection 20(1) of the *Research Involving Human Embryos Act 2002* stipulates that a person may apply to the Licensing Committee for a licence authorising the use of excess ART embryos.

As this Bill broadens the scope of embryos that may be used for research, the Subsection is amended to state merely that a person may apply to the Licensing Committee for a licence.

Item 14

Paragraph 21(3)(a) of the *Research Involving Human Embryos Act 2002* currently requires the Licensing Committee to have protocols in place to enable proper consent for the use of excess ART embryos.

Under this Bill, that consent requirement is broadened to cover licensed embryos and the need for the protocols to reflect NHMRC Guidelines.

Item 15

Paragraph 21(4)(a) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, this paragraph is broadened to include licensed embryos.

Item 16

Paragraph 21(4)(b) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, this paragraph is broadened to include licensed embryos.

Item 17

Subsection 24(1) of the *Research Involving Human Embryos Act 2002* states that proper consent must have been secured before an excess ART embryo can be used for research purposes.

This Bill substitutes that subsection to include the requirement to seek consent for the use not just of excess ART embryos but also the egg donor or somatic cell donor for embryos that have been created for research purposes.

Item 18

Subsection 24(2) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, this subsection is broadened to include licensed embryos.

Item 19

Subsection 24(5) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, reference to excess ART embryos in this subsection is broadened to include licensed embryos.

Item 20

Subsection 24(6) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, this subsection is broadened to include licensed embryos.

Item 21

Paragraph 24(7)(b) of the *Research Involving Human Embryos Act 2002* currently refers only to excess ART embryos.

Under this Bill, this subsection is broadened to include licensed embryos.

Item 22

Section 28 of the *Research Involving Human Embryos Act 2002* declares the Licensing Committee must provide notification to the licence holder, the Human Research Ethics Committee and the relevant State body in the event that a licence is varied, suspended or revoked.

Based on Lockhart recommendation 52 an additional section has been added to this Bill which states that if a person conducts research in good faith upon the granting of a licence, the validity of that action is not questioned if the issuing of that licence is later found to suffer irregularities.

This does not apply where a licence was issued based on fraudulent or false information.

Item 23

Lockhart Recommendation 39 calls for a more strict monitoring regime to ensure compliance with the Act not just amongst those who have applied for licenses but also amongst those who are unlicensed yet are reasonably suspected of carrying out activities in breach of the Act.

This Bill amends paragraph 35(2)(a) of the *Research Involving Human Embryos Act 2002* to include the power for an inspector to gain entry *via a warrant* to any premises believed to be in breach of legislation.

Item 24

Under Section 35, the Bill will give inspectors the power to enter *any* premises, which is stated in this item as including premises that are not currently licensed to conduct activity but is reasonably suspected of carrying out activities in breach of either Act.

Item 25

Lockhart Recommendation 39 calls for a more strict monitoring regime to ensure compliance with the Act not just amongst those who have applied for licenses but also amongst those who are unlicensed yet are reasonably suspected of carrying out activities in breach of the Act.

Section 36A states that an inspector may apply to a magistrate for a warrant to authorise one or more inspectors to enter the premises and exercise the monitoring powers listed in Section 36 of the Act. To be issued with a warrant, the inspector must provide the magistrate with any information the magistrate deems necessary to satisfy the grounds on which the warrant is sought.

Item 26

Section 47 of the Act called for the Act to be independently reviewed as soon as possible after the second anniversary of Royal Assent.

In accordance with Lockhart Recommendation 53, this Bill, inserts two new sections under Section 47 – 47A and 47B.

Section 47A calls for a further review as soon as possible after the third anniversary of the amending Act receiving Royal Assent, for delivery of a report to the Government and both Houses of Parliament within a year.

Section 47B seeks the establishment of an interdepartmental working group to consider a framework of a national stem cell bank, looking primarily at any required legislation, the structure of the bank, and a code of practice for its operation. The report of this interdepartmental group must be tabled in both Houses of Parliament by 30 November 2007.