2007

THE LEGISLATIVE ASSEMBLY FOR THE
AUSTRALIAN CAPITAL TERRITORY

HUMAN CLONING AND EMBRYO RESEARCH AMENDMENT BILL 2007

EXPLANATORY STATEMENT

Presented by
Ms Katy Gallagher MLA
Health Minister

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Human Cloning and Embryo Research Amendment Bill 2007

EXPLANATORY STATEMENT

Overview

The object of this Bill is to give effect in this Territory to a nationally consistent scheme for the regulation of activities involving the use of certain excess ART embryos, other embryos and human eggs.

This Bill amends the *Human Cloning and Embryo Research Act 2004* to mirror in ACT legislation the amendments that were made by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cwlth), which received Royal Assent on 12 December 2006. The Commonwealth legislation amended the *Prohibition of Human Cloning Act 2002* (Cwlth) and the *Research Involving Human Embryos Act 2002* (Cwlth) consistent with the recommendations of the Commonwealth Legislative Review Committee (also known as the Lockhart Committee). In the ACT the provisions contained in the two Commonwealth laws are contained in the *Human Cloning and Embryo Research Act 2004.*

BACKGROUND

This amending legislation is required by the intergovernmental *Research Involving Human Embryos and Prohibition of Human Cloning Agreement (2004)* (the Agreement) to which the Territory is a party. The Agreement committed jurisdictions to introducing nationally consistent legislation to ban human cloning and establish a national regulatory regime in relation to the use of excess assisted reproductive technology (ART) embryos.

At the Council of Australian Governments (COAG) meeting of 13 April 2007 the Commonwealth, States and the ACT signed a notice of variation to the 2004 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 amending legislation is consistent with the COAG Agreement and the ACT Government response to the Lockhart Review Report recommendations.

NOTES ON CLAUSES

PART 1 PRELIMINARY

Clause 1 - Short title

This is a formal provision that sets out the name (also called the short title) of the proposed Act, namely the *Human Cloning and Embryo Research Amendment Act 2007*.

Clause 2 - Commencement

This clause provides that the Act commences on the day after it is notified on the ACT Legislation Register.

Clause 3 - Amended

This clause provides that this Act amends the *Human Cloning and Embryo Research Act 2004*.

Clause 4 – Long title

This item amends the long title of the *Human Cloning and Embryo Research Amendment Act 2007* to read “An Act to prohibit human cloning for reproduction and other unacceptable practices associated with reproductive technology and to regulate certain activities involving the use of human embryos".

Clause 5 – Object of the Act

This item reflects the fact that the Bill no longer prohibits the creation, for research purposes, of embryos using techniques such as somatic cell nuclear transfer (SCNT). The Act does, however, continue to absolutely prohibit the development of embryos beyond 14 days and the implantation of human embryo clones in the body of a woman (cloning for the purposes of reproduction).

Clause 6 – Meaning of human embryo

This item 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. This is because the NHMRC had not finalised its recommended definition at the time that the Lockhart Report was finalised in December 2005. Following the release of the Lockhart Report, the NHMRC finalised the definition of a human embryo and this was slightly different from the draft definition that was referenced in the Lockhart Report.

This issue has been discussed with the members of the Lockhart Committee and they have agreed that their intention was that the definition of human embryo used should be that developed by the NHMRC.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

The key differences between the NHMRC definition (as endorsed by the Lockhart Committee since the release of their Report) and the existing definition in the *Human Cloning Act and Embryo Research Act 2004* are as follows:

- the point at which a human embryo is defined to commence existence. The identification of the first mitotic division as the time when fertilization is complete and the time at which the fertilized egg becomes an embryo. This recognises that fertilization is a process and that an embryo does not arise until the process is complete; and

- the definition used for embryos created other than by human egg and sperm. In the new NHMRC 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 NHMRC 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.

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.

PART 2 PROHIBITED PRACTICES

Clause 7

This item repeals Part 2 of the *Human Cloning Act and Embryo Research Act 2004* and replaces it with a new Part 2, which contains two Divisions. Division 2.1 describes those practices which are completely prohibited and Division 2.2 describes practices which are prohibited unless they are authorised by a licence issued by the NHMRC Licensing Committee. While many of the sections in Part 2 remain the same, they have been repealed and restated in order to provide clarity and better equip people to understand the proposed changes to the *Human Cloning Act and Embryo Research Act 2004*.

A notable change has been made to the level of penalties. The 10-year penalties which previously applied to sections 13 - 22 (sections 10 – 19 in the amending legislation) have all been increased to 15-year penalties. The amendment was moved in order to make all custodial penalties relating to prohibitions consistent throughout division 2.1.

Section 10 has been deleted from the amending legislation as it refers to the import and export of human embryo clones into or out of Australia, which is covered by the relevant Commonwealth legislation.

Following is a table explaining the other main changes.

Table 1: Summary of proposed changes to prohibitions detailed in the *Human Cloning and Embryo Research Act 2004*

	Current Section	New section	Short description of the change
Offence - creating a human embryo clone	8	Deleted	Human embryo clones will be allowed to be created for research only up to 14 days & provided the creation is licensed
Offence - placing human embryo clone in body of human or animal	9	8	No change
Offence - importing or exporting human embryo clone	10	Deleted	Deleted. Only relevant to Commonwealth legislation.
No defence that human embryo clone could not survive	11	9	No change (except to internal cross referencing of sections)
Offence - creating human embryo otherwise than by fertilisation etc	12	Deleted	Creation of an embryo other than by fertilisation, or developing such an embryo by human sperm and egg will only be permitted under licence and only up to 14 days
Offence - creating a human embryo for a purpose other than achieving pregnancy	13	10	Embryos created using sperm and egg may only be created for achieving pregnancy. Embryos created by any other means will only be able to be created under licence. Penalty increased to 15 yrs.
Offence - creating or developing human embryo containing genetic material from more than 2 people	14	11 & 21	Creation of an embryo by human sperm & egg & involving genetic material from 2 or more people will be prohibited. Penalty increased to 15 yrs. Creation of an embryo by other means (where it includes genetic material from 2 or more people) will only be permitted under licence.
Offence – developing human embryo outside body of woman for longer than 14 days	15	12	Only change - penalty increased to 15 yrs.
Offence – using precursor cells to create human embryo etc	16	21A	Only permitted under licence (up to 14 days development)
Offence – heritable alterations to genome	17	13	Only change - penalty increased to 15 yrs.
Offence – collecting viable human embryo from woman's body	18	14	Only change - penalty increased to 15 yrs.
Offence – creating chimeric embryo	19 (1)	15	Only change - penalty increased to 15 yrs.
Offence – creating hybrid embryo	19 (2)	16 & 21B	Creating & developing a hybrid embryo will only be permitted under licence and in very limited circumstances
Offence – placing of embryo	20	17	Only change - penalty increased to 15 yrs.
Offence – importing, exporting or placing prohibited embryo	21	18	Internal cross referencing of "human cell" to section 13. Penalty increased to 15 yrs.
Offence – commercial trading in human eggs etc	22	19	The order of (b) (i) and (ii) reversed. Penalty increased to 15 yrs.

Division 2.1 Practices that are completely prohibited

8 Offence - placing human embryo clone in body of human or animal

This section bans a person intentionally placing a human embryo clone in the body of a human or in the body of an animal. This is identical to the existing section 9 of the *Human Cloning and Embryo Research Act 2004*. The effect of this provision is to ban human cloning for the purposes of reproduction.

The maximum penalty for this offence is imprisonment for 15 years. This is the same as it currently is in section 9 of the *Human Cloning and Embryo Research Act 2004*.

The retention of this ban is consistent with Recommendation 2 of the Lockhart Report.

9 No defence that human embryo clone could not survive

This section clarifies that it is no defence that the human embryo clone could not survive. It differs from existing section 11 of the *Human Cloning and Embryo Research Act 2004* in that it no longer refers back to existing section 10, an offence to import or export human embryo clone.

The effect of this provision is that a human embryo clone does not have to survive to the point of live birth in order for an offence to be established under provisions 7 or 8 (existing sections 8 and 9). For example, an offence would still be committed if:

- a human embryo clone is placed in a woman's reproductive tract, but does not successfully implant in the uterus;
- a human embryo clone is successfully implanted and begins to develop and then spontaneously terminates;
- a human embryo clone is successfully implanted and begins to develop and is deliberately terminated; or
- if a human embryo clone is successfully implanted, develops to full term but is still-born.

10 Offence - creating human embryo for a purpose other than achieving pregnancy in a woman

This section prohibits a person from intentionally creating a human embryo by a process of the fertilisation of a human egg by a 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 offence attracts a maximum penalty which has been increased to 15 years imprisonment.

The effect of this prohibition is that a person must not create an embryo by the fertilisation of human egg and human sperm for the purposes of research. Such an embryo may only be created for the ART treatment of a particular woman.

This provision reflects Recommendations 12 and 13 of the Lockhart Report.

11 Offence - creating or developing human embryo by fertilisation that contains genetic material provided by more than 2 people

This section provides that a person commits an offence if the person intentionally creates or develops a human embryo by a process of the fertilisation of a human egg by a human sperm outside the body of a woman and the human embryo contains genetic material provided by more than 2 persons.

The maximum penalty for this offence has been increased to 15 years imprisonment.

The Lockhart Committee recommended that development of a human embryo using genetic material from more than two people be permitted under licence. However, if this involves the creation of an embryo by fertilisation of human egg by human sperm then this would be inconsistent with Lockhart Recommendation 13 that recommends that embryos, created by human egg and human sperm, should not be created for the purposes of research. If the creation of the human embryo involves genetic material from more than two people but it has been created by other means (i.e. not by fertilisation of human egg by human sperm) then this can potentially be licensed by the NHMRC Licensing Committee (refer proposed sub-clause 20). This approach reflects the spirit of both Recommendation 13 and Recommendation 26 of the Lockhart Review.

12 Offence - developing a human embryo outside body of woman for more than 14 days

This section requires that a human embryo must not be allowed to develop, outside of a body of a woman, beyond 14 days (excluding any time that the embryo's development is suspended whilst frozen in storage).

This provision applies regardless of how the embryo was created and whether or not it was created using human sperm and human egg or by any other means. This means that a human embryo created by asexual means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer, cannot be developed beyond 14 days.

In the case of embryos created for ART, this provision does not adversely impact ART clinical practice where it is standard clinical practice for embryos to be implanted when they have reached between three and seven days of development.

The maximum penalty for developing a human embryo outside the body of a woman for more than 14 days has been increased to 15 years imprisonment.

This section differs from existing section 15 only in that the penalty has been increased and reflects Recommendation 4 of the Lockhart Review (development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited).

13 Offence - heritable alterations to genome

This section is the same as existing section 17 and prohibits any manipulation of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations of humans.

This provision bans what is commonly referred to as germ line gene therapy. In germ line gene therapy, 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.

The maximum penalty for manipulating the human genome so that the change is heritable to future generations has been increased to 15 years imprisonment.

14 Offence - collecting viable human embryo from body of woman

This section prevents the removal of viable human embryos from the body of a woman after fertilisation has taken place *in vivo*, a practice sometimes referred to as embryo flushing. Embryo flushing is commonly used in animal husbandry and while there have been no recent reports of it being used in humans there is a concern that a healthy human embryo could be removed from a woman's uterus before it implants so that it could be used for research or for transfer to another woman.

This provision continues to ban such a practice (in the current *Human Cloning and Embryo Research Act 2004* this is banned in section 18).

The maximum penalty for intentionally collecting a viable human embryo from a woman has been increased to 15 years imprisonment.

The retention of this prohibition reflects recommendation 11 of the Lockhart Report (collection of a viable human embryo from the body of a woman should continue to be prohibited).

15 Offence - creating chimeric embryo

This section prohibits the intentional creation of a chimeric embryo (as defined in the Act) and is the same as existing section 19(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 retention of this prohibition is consistent with the Lockhart review which recommended that chimeric embryos should continue to be prohibited (Recommendation 6).

Recommendation 6 also addressed the issue of human-animal hybrid embryos and notes that in certain limited circumstances, human-animal hybrids should be permitted to be created under licence. There are no recommendation suggesting that chimeric embryos be permitted to be created under licence. As such, the complete ban on the creation of any chimeric embryos has been retained through this section.

Failure to comply with the prohibition attracts an increased maximum penalty of 15 years imprisonment.

16 Offence - developing hybrid embryo

This section 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 provision should be read in conjunction with section 22A which enables the creation and development of certain hybrid embryos under licence.

This provision is consistent with Recommendations 17 and 24 of the Lockhart Review. In these Recommendations, the Lockhart Committee suggests that only very specific types of interspecies fertilisation and hybrid embryos be permitted. In order to implement this intent, three interacting provisions are proposed.

This section bans the development of a hybrid embryo beyond 14 days (but does not ban the creation of hybrid embryos).

Section 22A provides that if someone wishes to create a hybrid embryo they must only do so in accordance with a licence.

Section 29(1)(f) as it will be following the amendments in this Bill makes it clear that the only type of hybrid embryos for which a licence may be granted are to enable the testing of sperm viability in an accredited ART centre (refer to proposed section 22A of this Explanatory Statement).

17 Offence - placing of embryo

This section is the same as existing section 20 of the *Human Cloning and Embryo Research Act 2004* and reflects Recommendation 7 of the Lockhart Review. The provision prevents the placement of:

- a human embryo in an animal;
- a human embryo into the body of a human, including a man or any part of a woman's body, other than the female reproductive tract; or
- an animal embryo in a human, for any period of gestation.

This provision should be read in conjunction with proposed section 8 which bans the placement of a human embryo clone in the body of a woman or animal and proposed section 18(3) which bans the placement of any "prohibited embryo" in the body of a woman.

18 Offence - importing, exporting or placing prohibited embryo

Other than the penalty increase, this section is the same as existing section 21 of the *Human Cloning and Embryo Research Act 2004*.

The provision prevents the intentional import into the ACT, intentional export from the ACT, or the intentional placement in the body of a woman of "prohibited embryos". A "prohibited embryo" is defined to mean:

- a human embryo created by a process other than the fertilisation of a human egg by human sperm;

- 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;
- a human embryo that is created using human egg and human sperm and contains genetic material provided by more than 2 persons;
- human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period throughout which development is suspended;
- a human embryo created using precursor cells taken from a human embryo or a human fetus;
- 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;
- a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or
- a chimeric embryo or a hybrid embryo.

The maximum penalty for importing, exporting or placing a prohibited embryo in the body of a woman has been increased to 15 years imprisonment.

19 Offence - commercial trading in human eggs, human sperm or human embryos

Other than the increase in penalty, this section is the same as existing section 22 of the *Human Cloning and Embryo Research Act 2004* and reflects recommendation 33 of the Lockhart Report which states that the present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.

The provision prevents the commercial trading of human eggs, sperm and embryos. Both parties involved in commercial trading of such material would be committing an offence (for example, the person who sells the egg, sperm or embryo and the person who purchases the egg, sperm or embryo). The only consideration which may be given in relation to the supply of gametes or embryos is reimbursement of reasonable expenses related to that supply, including expenses incurred for the collection, storage and transport where relevant. This means if, for example, semen is transferred from one clinic to another, the second clinic could reimburse the first clinic for the costs of storage and transport of the semen. A further example is where a woman who is to be treated with donated eggs could pay for the cost of the egg retrieval from another woman.

Reasonable expenses in relation to the supply of a human embryo, where that embryo is donated to another couple, do not include any expenses incurred by the person or couple (for whom the embryo was originally created), before the embryo was determined to be excess to their needs. That is, if a person has excess embryos and they wish to donate the embryos to other people, they cannot have the costs of their IVF treatment reimbursed by the person receiving the donated embryos.

This provision is not intended to address the issue of surrogacy. It is proposed that surrogacy continue to be dealt with through State and Territory legislation and that it not be addressed as part of this particular national scheme.

The maximum penalty for trading in human embryos, sperm or eggs has been increased to 15 years imprisonment.

Division 2.2 Practices that are prohibited unless authorised by licence

20 Offence - creating human embryo other than by fertilisation, or developing such embryo

This section 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. This reflects Recommendation 23 of the Lockhart Report. 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 NHMRC definition of a human embryo, which recognises that technology may change and that all embryos however created must be captured by the legislation.

It is important that this provision be read in the context of proposed section 12 - which bans the development of a human embryo outside the body of a woman for more than 14 days - and proposed sections 8 and 18(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.

21 Offence - creating or developing human embryo containing genetic material provided by more than 2 persons

This section provides that it is an offence to create or develop embryos containing genetic material from 2 or more people if the embryo has been created by fertilisation.

This section provides that a person who has been issued a licence the NHMRC Licensing Committee to 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 would not fall within the offence set out in this section.

As noted in relation to proposed section 11, the Lockhart Committee recommended that development of a human embryo using genetic material from more than two people be permitted under licence. However, if this involves the creation of an embryo by fertilisation of human egg by human sperm then this would be inconsistent with Lockhart recommendation 13 that suggests that embryos, created by human egg and human sperm, should not be created for the purposes of research. This approach reflects the spirit of both Recommendation 13 and Recommendation 26 of the Lockhart Review.

The notes at the base of the provision remind readers that the development of a human embryo outside the body of a woman for more than 14 days is prohibited by proposed section 12.

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

22 Offence - using precursor cells from a human embryo or human fetus to create human embryo, or developing such embryo

This section 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 unless they are authorised to do so by a licence issued by the NHMRC Licensing Committee.

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

This section implements Recommendation 27 of the Lockhart Review which provided 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.

22A Offence - creating hybrid embryo

This section makes it an offence to create or develop 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 section be read in conjunction with the explanatory statement for proposed section 29(1) which sets out the activities for which a person may apply for a licence.

This offence attracts a maximum penalty of 10 years imprisonment.

PART 3 REGULATION OF THE USE OF EXCESS ART EMBRYOS, OTHER EMBRYOS AND HUMAN EGGS

Clause 8 - Part 3 heading

This clause repeals the current heading of Part 3 of the *Human Cloning and Embryo Research Act 2004* (which is currently entitled "Regulation of certain uses involving excess ART embryos") and replaces it with a new heading, "Part 3 - Regulation of the use of excess ART embryos, other embryos and human eggs". The heading for Part 3 has been changed to reflect the fact that regulations now cover certain uses of embryos created using techniques such as SCNT, not just uses of excess ART embryos.

Clause 9 – Definitions for part 3 – Licence

This clause removes the definition of “licence” from the definitions section of Part 3. The definition will be inserted in the dictionary for the Act by proposed clause 42 in accordance with ACT legislative conventions.

Clause 10 – definition of proper consent

This clause repeals the definition of proper consent and replaces it with a new definition as follows:

> 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 under the *National Health and Medical*

Research Council Act 1992 and prescribed by the regulations for the purposes of this definition.

Clause 11 – definition of responsible person

This clause defines responsible person to mean:

(a) in relation to an excess ART embryo:
   i. each person who provided the egg or sperm from which the embryo was created; and
   ii. the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and
   iii. any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that paragraph was provided; and
   iv. any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or

(b) in relation to an embryo other than an excess ART embryo - 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; or

(c) in relation to a human egg - the woman who was the biological donor of the egg.

There has been no change to the definition of responsible person in relation to an excess ART embryo. Sub-clauses (b) and (c) 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.

Clause 12 – definitions of "unsuitable for implantation" and "use"

This clause inserts into Section 23 of the *Human Cloning and Embryo Research Act 2004*, new definitions for "unsuitable for implantation" and "use".

In summary, a human embryo that is unsuitable for implantation, is one that:

- is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2007)*; or

- is determined to be unsuitable for implantation in accordance with objective criteria specified in guidelines developed by the NHMRC and prescribed in regulations.

For the purposes of this Act, "use" includes 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 authorised 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 13 of the *Human Cloning and Embryo Research Act 2004* which prohibits development of an embryo beyond 14 days.

Clause 13 – New sections 25A and 25B

This clause inserts the following two new offences related to licensing.

25A Offence - use of other embryos

This section provides that a person commits an offence if a person intentionally 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; or
- a human embryo that contains genetic material provided by more than 2 persons; or
- a human embryo created using precursor cells from a human embryo or a human fetus; or
- a hybrid embryo.

This provision is needed because the *Human Cloning and Embryo Research Act 2004* relates specifically to creation and development of 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.

The maximum penalty for non-compliance with this provision is imprisonment for 5 years. This is consistent with the existing offences in this Part of the *Human Cloning and Embryo Research Act 2004*.

25B Offence - certain activities involving use of human eggs

This section establishes an offence if someone undertakes 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 implements Recommendations 15 and 16 of the Lockhart Review.

The offence attracts a maximum penalty of imprisonment for up to 5 years. This is consistent with the existing offences in this Part of the *Human Cloning and Embryo Research Act 2004*.

Clause 14 – Substitute Section 26(a)

Section 26 of the *Human Cloning and Embryo Research Act 2004* currently bans the use, outside the body of a woman, of an embryo that is not an excess ART embryo unless the use is for the purposes of ART. The purpose of existing section 26 is to prohibit people from using non-excess ART embryos for research purposes. This item amends that section by continuing the ban on the use of non-excess ART embryos created by the fertilisation of human egg by human sperm but making it clear that the ban does not extend to use of embryos that have been created by means other than fertilisation of human egg by human sperm. Use of any such embryos is only permitted under licence by the NHMRC Licensing Committee. This is an amendment that is consequential to the recommendations of the Lockhart Review which allow the creation of embryos for research if such embryos are created other than by fertilisation of a human egg by human sperm.

Clause 15 – New Section 27A

This item inserts a new section 27A after section 27.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

27A Person not liable for conduct purportedly authorised

This section clarifies that a person is not criminally responsible for an offence against the Act if:

- the conduct by the person is purportedly authorised by a provision of a licence; and
- the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and
- the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.

This section is intended to address the underlying policy objective of Recommendations 50 and 52 of the Lockhart Review. Those recommendations suggest that the NHMRC Licensing Committee should be given the power to give legally binding rulings on the interpretation of the legislation and that a person who conducts research on the basis of a ruling should be protected from liability under the legislation.

This recommendation raises significant constitutional issues relating to the impermissible exercise of judicial power by a non-judicial body. For example, in the Brandy case, the High Court unanimously held that the power of Human Rights and Equal Opportunities Commission to decide whether conduct was unlawful and to award damages was an impermissible conferral of judicial power, because of the binding and conclusive nature of the Commission's determinations.

Recognising these concerns, a provision has been included in the Bill (clause 27A) which avoids these constitutional issues, but attempts to address the basic concern of the Lockhart Committee which appeared to be the potential liability of researchers where they are acting in good faith in accordance with a licence but where the NHMRC Licensing Committee in fact had no power to issue the licence.

Clause 16 – Substitute Section 29(1) and insert sub-clause 29(1A)

Subsection 29(1) of the *Human Cloning and Embryo Research Act 2004* currently provides that a person may apply to the NHMRC Licensing Committee for a licence authorising the use of excess ART embryos.

Consistent with the recommendations of the Lockhart Review, the proposed amendments to the *Human Cloning and Embryo Research Act 2004* enable certain activities to be undertaken provided that a licence has been granted by the NHMRC Licensing Committee.

The purpose of this amendment to subsection 29(1) is to set out all of the 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 (this means that it is either prohibited absolutely or does not fall within the scope of this legislation).

It is proposed that 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 or development of hybrid embryos, and use of such embryos up to the first mitotic division, if:

  the creation or use is 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 is consistent with Recommendation 17 of the Lockhart Review and would enable ART tests that were carried out by ART clinics prior to the commencement of the *Human Cloning and Embryo Research Act 2004*, to once again be permitted. In the context of the changes that this Bill proposes, it could be argued that there may be doubt surrounding whether the definition of a "hybrid embryo" captures sperm quality tests where the animal egg is combined with human sperm but does not develop past the first mitotic division. To put this beyond doubt, it is suggested that Regulations be made prescribing animal eggs in the process of fertilisation by a human sperm (but yet to reach the first cell division) as hybrid embryos.

Sub-clause 29(1A) has been included to make it clear that amended section 29(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.

Clauses 17, 18 and 19 – amend "embryo" and "ART embryo"

These clauses amend section 30 so that wherever there is a reference to "excess ART embryos" (or similar), 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 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.

Clause 20 – omit "prescribed under the regulations"

This clause replaces "prescribed under the regulations" with "prescribed by the *Research Involving Human Embryos Regulations 2003* (Cwlth) in section 30(4)(c) to ensure there is no confusion between versions of regulations.

Clause 21, 22, 23, 24 and 25 – amend "embryo" and "ART embryo"

These clauses amend section 33 so that wherever there is a reference to "excess ART embryos" (or similar), 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 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.

Clause 26 – New Section 33(7)

This clause inserts a new subsection (7) at the end of section 33 which provides that a licence in relation to embryos that are unsuitable for implantation (as defined) 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 purpose of this provision is to address Lockhart Recommendations 20, 21 and 22. The Lockhart 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.

Currently the *Human Cloning and Embryo Research Act 2004* does not expressly prohibit this. However, there is a statutory condition of licence that the responsible people in relation to an excess ART embryo must give proper consent to any research, in accordance with NHMRC guidelines. The relevant guidelines are the Australian Health Ethics Committee (AHEC) Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research (2004) as revised in 2007 to take into account the changes in legislation. These Guidelines provide that:

"A person responsible for an embryo must be free at any time to withdraw consent to further involvement in the research. In view of the fact that once an embryo has been destroyed it cannot be restored, it is recommended that the consent of the persons responsible to a use that will damage or destroy an embryo must not be acted upon until a suitable fixed period of time for reconsideration has been allowed, normally at least two weeks after their consent to such research. This `cooling-off' period before consent becomes effective must be explained to the persons responsible when consent is obtained." (section17.19, page 75)

Based on the Lockhart Committee discussion of the issue, it would appear that researchers and the NHMRC Licensing Committee has been interpreting this requirement such that embryos that are unsuitable for implantation and are not frozen (because they are unable to be frozen or because they are unsuitable for implantation), cannot be used for research because the 14 day cooling-off period would preclude this.

In order to address this issue, it is proposed that a new sub-clause be added into section 33 (subsection 33(7)) that clarifies that if the NHMRC Licensing Committee considers it appropriate, they may approve the use of embryos that are unsuitable for implantation and alter the cooling-off period that would be "normally at least two weeks" as recommended by the NHMRC. This would allow the use of excess ART embryos that are unsuitable for implantation and would still ensure that appropriate consent is obtained from the responsible people. In no circumstances would embryos that are not excess be able to be used.

It is proposed that the NHMRC develop clear and objective criteria defining those embryos that are unsuitable for implantation.

Clauses 27 and 28 – amend “embryo” and “ART embryo”

These clauses amend section 38 so that wherever there is a reference to "excess ART embryos" (or similar), 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 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.

Clause 29 and 30 – insert new sections 40 (ca) and 41(1)(ca)

Recognising the new decision-making role of the NHMRC under proposed subsection 33(7) (in terms of being able to modify a statutory condition of licence such that different rules should apply in relation to proper consent for use of embryos that are unsuitable for implantation), these items amend sections 40 and 41 to make this decision reviewable by the Administrative Appeals Tribunal.

These amendments are consequential to the amendment to section 33 which implements Lockhart Recommendations 20-22.

PART 4 MONITORING POWERS

Clause 31 – New Section 44(2)(c)

The Lockhart review recommends that the monitoring powers available under the Acts be strengthened to enable entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation (Recommendation 39).

In order to give effect to this recommendation, changes have been made throughout Part 4 of the *Human Cloning and Embryo Research Act 2004* to enable inspectors to apply to a Magistrate for a search warrant in relation to non-licensed premises. The approach adopted is consistent with the approach detailed in the *Gene Technology Act 2000* (as referenced by the Lockhart Committee) and with general ACT Government law enforcement policy.

Clause 31 amends section 44 (which deals with powers available to inspectors for monitoring compliance) to enable inspectors to enter premises where the entry is made under a warrant under proposed section 46A.

Clause 32 – omit "human embryo" and substitute "human embryo, other embryo, human egg" Section 45(1)(b)

This item ensures that the power to monitor applies not just to a human embryo but also to any other embryo or human egg.

Clause 33 – New Section 45(1)(g)

This item amends subsection 45(1) by adding two additional powers that may be exercised by inspectors authorised to enter premises by a warrant under proposed section 46A. An inspector may require any person in or on the premises to answer any questions put by the inspector and produce any book, record or document requested by the inspector.

Clause 34 – Substitute new section 46

This item ensures that the power to secure applies not just to a human embryo but also to any other embryo or human egg.

Clause 35 – New Sections 46A, 46B, 46C and 46D

46A – Monitoring warrants

This item inserts a new clause (clause 46A) in the *Human Cloning and Embryo Research Act 2004*. The new clause 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 the *Human Cloning and Embryo Research Act 2004* (or Regulations) have been complied with.

The warrant enables one or more inspectors to enter premises and exercise the powers set out in clause 45 in relation to the premises.

46B - Details of warrant to be given to occupier etc.

This clause provides that if a warrant under clause 46A 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.

46C - Announcement before entry

This clause 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.

46D – Occupier entitled to be present during search

This clause 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.

PART 5 MISCELLANEOUS

Clause 36 – Substitute new Section 51

This clause relates to the reports to be produced as a result of reviews mentioned in the *Prohibition of Human Cloning for Reproduction Act 2002* (Cwlth), section 25A and the *Research Involving Human Embryos Act 2002* (Cwlth), section 47A. This clause requires the Minister to present a copy of these reports to the Legislative Assembly as soon as practicable after they have been tabled in a house of the Commonwealth Parliament.

Clause 37 – Insert Part 10

10 – Transitional

This clause provides that, if a person applied for a licence under section 29(1) before these amendments take effect and the licence application has not been decided by the NHMRC Licensing Committee, then the person is taken, on and from the commencement of the new legislation, to have applied for the licence under subsection 29(1) of the amended Act. The standard expiry provision has been included in this clause.

This clause does not refer to continuation of existing licences issued under the *Human Cloning and Embryo Research Act 2004* before the proposed amendments because the continuation of a licence that has been issued under a law that is later amended is covered by section 94 of the *Legislation Act 2001*.

Clauses 38 - 43

These clauses clarify the definitions of the following terms as they occur in the Dictionary to ensure they correspond with the terms as they are described in the amended legislation: Disclose; embryo; human egg; licence; proper consent; relevant Territory entity; responsible person; unsuitable for implantation; and use.

For example, the clause 38 clarifies that "human embryo" refers to a living embryo only and does not include a human embryonic stem cell line or a hybrid embryo. While this should be clear from the definition of "human embryo" itself, it is considered important that this be put beyond doubt.

Clause 39 inserts a new definition, clarifying that a reference to a human oocyte is the same as a reference to a human egg. This provision recognises that the NHMRC definition of a human embryo refers to a human oocyte whereas the existing prohibitions in the *Human Cloning and Embryo Research Act 2004* refer to a human egg. Rather than changing all of the existing references from human egg to human oocyte, a new definition has been included to make it clear that both expressions are intended to have exactly the same meaning.