2003

LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

Human Cloning and Embryo Research Bill 2003

EXPLANATORY STATEMENT

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Overview

This Bill forms part of a national regulatory scheme to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos. The Bill achieves this by complementing the Commonwealth legislative framework, to regulate activities that involve the use of certain human embryos created by assisted reproductive technology.

The *Human Cloning and Embryo Research Bill 2003* operates so as to implement the two Commonwealth Acts, the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002.* Thus Part 2 of the *Human Cloning and Embryo Research Bill 2003* dealing with human cloning prohibits the creation, importation, exportation or implantation of a human embryo clone. The prohibitions in Part 2 also apply in relation to certain other embryos for ethical and safety reasons.

Part 3 of the *Human Cloning and Embryo Research Bill 2003* regulates activities that involve the use of certain types of human embryos created by assisted reproductive technology (ART).

Part 3 also supports the establishment of a principal committee of the National Health and Medical Research Council (NHMRC). Its purpose is to perform functions and exercise powers under the national regulatory scheme outlined in the Commonwealth *Research Involving Human Embryos Act 2002.* Part 3 also establishes a scheme for the assessment and licensing of certain activities involving excess ART embryos. Provision has also been made for a centralised, publicly available database of information about all licenses issues by the NHMRC Licensing Committee.

The objectives of the *Human Cloning and Embryo Research Bill 2003* are to address ethical and safety concerns about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology.

NOTES ON CLAUSES

PART 1 PRELIMINARY

Clause 1—Name of Act

This is a formal provision that specifies the name of the proposed Act as the *Human Cloning and Embryo Research Bill 2003.*

Clause 2—Commencement

Clause 2 provides that the Act will take effect on the day after it is notified on the ACT Legislation Register.

Clause 3—Dictionary

Clause 3 provides that the dictionary at the end of the Act is a part of the Act.

Clause 4—Notes

This clause provides that notes contained in the Act are explanatory and are not a part of the Act.

Clause 5—Offences against Act—application of Criminal Code etc

This clause provides that other legislation will apply in relation to offences against the *Human Cloning and Embryo Research Bill 2003.*

Clause 6—Object of Act

This clause provides that the object of this Bill is to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos:

a. by prohibiting certain practices; and
b. by regulating activities that involve the use of certain human embryos created by assisted reproductive technology.

Clause 7—Meaning of *human embryo*

This clause defines the term human embryo to mean a live embryo that has a human genome or an altered genome, that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means. In determining the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

This definition is intended to include:

a. *a human embryo created by the fertilisation of a human egg by human sperm.*

The Bill relies upon the appearance of 2 pro-nuclei to establish the existence of a human embryo that has been created by the fertilisation of a human egg by human sperm. The appearance of the pro-nuclei indicates that the nuclei from the sperm and the egg are aligning prior to possible fusion. For the purposes of this legislation, the 8 weeks of development is taken to start with the appearance of 2 pro-nuclei. The legislation does not rely on defining when fertilisation commences or is complete.

b. *a human embryo that has had its development initiated by any means other than by the fertilisation of a human egg by human sperm.*

It is intended that the definition include the following types of embryos:

- a human egg that has had its nucleus replaced by the nucleus of a somatic cell (ie a cell from the body) by the process referred to as somatic cell nuclear transfer (SCNT); and

- a parthenogenetic 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 has the capacity to continue its development in a similar manner to a human embryo created by fertilisation.

It should be noted that the procedures outlined above are provided as examples only as there may be other ways that the development of an embryo may be initiated. For the purposes of the legislation the 8 weeks of development is taken to start with the initiation of development by other means

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Subclause 7(2) clarifies that for the purposes of the definition of “human embryo”, in working out the length of period of development of a human embryo, any period when development of the embryo is suspended (for example, while it is frozen) is not included. For example, if an embryo is placed in storage 2 days after fertilisation and is held in storage for 10 weeks, it is still considered to be a 2 day embryo in terms of its development.

Clause 8—Meaning of *human embryo clone*

Clause 8 defines “human embryo clone”, which is defined to mean a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.

The reference to a human embryo clone not including a human embryo created by the fertilisation of a human egg by human sperm is to ensure that identical twins (or other identical multiples) that occur through the spontaneous division of an embryo (created by fertilisation) into two (or more) identical embryos are not defined as human embryo clones.

Subclause 8(2) clarifies that in order to establish that a ”human embryo clone” is a genetic copy of a living or dead human, it is sufficient to establish that a copy has been made of the genes in the nuclei of the cells of another living or dead human. Further, the copy of the genes does not have to be an identical genetic copy. This means that the human embryo clone does not have to be genetically identical to the original human. This allows for:

- the presence of DNA outside the nucleus (ie mitochondrial DNA) that is not identical to the living or dead human from which the nuclear DNA was taken, as would occur in an embryo created using the somatic cell nuclear transfer technique;

- spontaneous changes to the nuclear DNA that may occur during the development of a human embryo clone; and

- the deliberate alteration of the DNA so that the intention is to produce a clone of another human, but where the nuclear DNA could no longer be considered an identical copy of the original DNA. This point is also addressed within the definition of “human embryo”, which includes one that has an altered human genome. As such, an embryo that is a clone of another human and has had its genome deliberately altered will still be considered a human embryo and therefore, as its original genome was copied, a human embryo clone.

Subclause 8(3) clarifies that for the purposes of the definition of ”human embryo clone”, a human embryo created by the technological process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by human sperm and is therefore considered to be a human embryo clone. Embryo splitting is a technique that may be carried out on an embryo created by in vitro fertilisation, whereby micro-surgical techniques are used to divide an embryo in the early stages of development to produce two or more identical embryos.

PART 2 PROHIBITED PRACTICES

DIVISION 2.1—Human cloning

Clause 9—Offence—creating a human embryo clone

This clause makes it an offence to intentionally create an embryo that is a genetic copy of another living or dead human.

Creating a human embryo clone by any means is an offence. That is, if any current procedures, like somatic cell nuclear transfer, embryo splitting, or any future procedures are used in an attempt to create a human embryo clone, then an offence is committed.

This clause is not intended to capture the circumstance where a human embryo created by assisted reproductive technology, spontaneously divides into two or more identical embryos (commonly known as identical twins, triplets etc). Clause 8 clarifies that identical twins (created by the fertilisation of a human egg by human sperm) are not “human embryo clones”.

The maximum penalty that may be applied for creating a human embryo clone is 15 years imprisonment.

Clause 10—Offence-placing human embryo clone in body of human or animal

This clause makes it an offence to intentionally place into the body of a human or an animal a human embryo that is a genetic copy of another living or dead human.

The maximum penalty that may be applied for placing a human embryo clone in the human body or the body of an animal is 15 years imprisonment

Clause 11—Offence—importing or exporting human embryo clone

This clause makes it an offence to intentionally import a human embryo clone into the ACT or intentionally export a human embryo clone from the ACT. This ensures that all avenues for obtaining a human embryo clone in the ACT are covered, whilst ensuring that a person cannot export a human embryo clone that has been illegally created or obtained.

The maximum penalty that may be applied for importing or exporting a human embryo clone is 15 years imprisonment.

Clause 12—No defence that human embryo clone could not survive

This clause provides that any human embryo clone that is intentionally created, implanted, imported or exported does not have to survive to the point of live birth in order for an offence to be established under clauses 9, 10 or 11.

This would include, but is not necessarily limited to, the following situations:

- where an unsuccessful attempt to create a human embryo clone is made;
- where a human embryo clone is created and then allowed to die;
- where a human embryo clone is created and deliberately destroyed without attempting implantation;
- where a human embryo clone is placed in a woman's reproductive tract, but does not successfully implant in the uterus;
- where a human embryo clone is successfully implanted and begins to develop and then spontaneously terminates;
- where a human embryo clone is successfully implanted and begins to develop and is deliberately terminated; or
- where a human embryo clone is successfully implanted, develops to full term but is still-born.

DIVISION 2.2—Other prohibited practices

Clause 13—Offence-creating a human embryo other than by fertilisation etc

The effect of this clause is that a human embryo intentionally created outside the body of a woman must only be created by the fertilisation of a human egg by human sperm. As such, an embryo must not be created by embryo splitting, by parthenogenesis, by somatic cell nuclear transfer or by any other technique that does not involve fertilisation of a human egg by human sperm. It is also an offence to develop a human embryo created by a means other than the fertilisation of a human egg by human sperm.

The maximum penalty that may be applied for creating a human embryo other than by fertilisation of a human egg by human sperm is 10 years imprisonment.

Clause 14—Offence—creating human embryo for purpose other than achieving pregnancy in woman

The effect of this clause is that a person can only create a human embryo outside the body of a woman if it is intended, at the time of creation, that the

embryo could be implanted in an attempt to achieve pregnancy in a particular woman.

It is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use. This clause is not intended to prohibit certain uses of human embryos that are carried out as a part of attempting to achieve pregnancy in a woman in ART clinical practice, such as carrying out diagnostic procedures (such as Pre-Implantation Genetic Diagnosis) or undertaking therapeutic procedures on the embryo.

Further it is not intended that this clause:

- restrict the number of embryos that may be created for the purposes of achieving pregnancy in a particular woman. The number of embryos created for the reproductive treatment of a particular woman needs to be determined on a case by case basis as a part of routine ART clinical practice; or

- prevent the circumstance whereby a human embryo created by an ART clinic, originally intended for implantation into a woman, may be found not to be suitable for implantation, or may at some point not be required by the woman for whom it was originally created.

The maximum penalty that may be applied for creating a human embryo for a purpose other than achieving pregnancy in a woman is 10 years imprisonment.

Clause 15—Offence—creating or developing human embryo containing genetic material provided by more than 2 people

This clause makes it an offence to intentionally create a human embryo containing genetic material provided by more than 2 people. It is also an offence to develop a human embryo containing genetic material provided by more than 2 people.

One of the effects of this clause is to ban a relatively new ART technique known as cytoplasmic transfer. Cytoplasmic transfer involves the injection of some of the cytoplasm (the part of the cell outside the nucleus) from a healthy, donor egg into a recipient patient's egg, with the aim of overcoming certain problems that the patient has with regards to achieving pregnancy. It has been reported that this procedure may be particularly valuable to older women to assist them to become pregnant.

Both safety and ethical concerns have been raised regarding cytoplasmic transfer. Firstly, the technique is a very new technique and its safety with respect to babies created using the technique is yet to be established. Additionally, any live born child may have DNA from three separate people, posing ethical concerns. The DNA from the third party (the donor of the

healthy egg) would be mitochondrial DNA, which is thought not to have an impact on the physical characteristics of the child. However, the impact (if any) of the third party mitochondrial DNA on normal development is not totally clear at this stage.

The wording of this clause avoids any references to cytoplasmic transfer explicitly and instead utilises wording that reflects the concern that it results in the creation of human embryos with genetic material from more than two people. In this way the prohibition is drafted sufficiently broadly to include other techniques, current or emerging, that may also involve the presence in a human embryo of a third party's DNA.

The maximum penalty that may be applied for creating or developing a human embryo containing genetic material provided by more than 2 persons is 10 years imprisonment.

Clause 16—Offence—developing human embryo outside body of woman for more than 14 days

This clause requires that a human embryo created outside the body of a woman must not be allowed to develop beyond 14 days. This does not include any time that the embryo's development is suspended whilst in storage (for example while the embryo is frozen).

In practice, this means that human embryos created by assisted reproductive technology must be implanted, stored or allowed to die (if unsuitable for implantation or excess to the needs of the couple for whom the embryo was created) before the 14th day of their development. It is standard ART clinical practice for embryos to be implanted when they have reached between three and seven days of development.

It is important that this clause be read subject to clause 13 that bans the creation of a human embryo by any means other than the fertilisation of human egg by human sperm. This means that a human embryo created by asexual means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer, cannot be created or developed to any stage.

This clause provides that the maximum penalty for developing a human embryo outside the body of a woman for more than 14 days is 10 years imprisonment.

Clause 17—Offence—using precursor cells from human embryo or human foetus to create human embryo etc

This clause prevents the creation of a human embryo with cells taken from another human embryo or a human foetus that have the potential to develop into egg or sperm cells. It is also an offence to develop a human embryo created by precursor cells of eggs or sperm taken from an embryo or foetus.

The purpose of this clause is to prevent individuals from obtaining precursor cells and using these cells in an attempt to develop a human embryo whether for reproductive or any other purposes. The reasons for this practice being prohibited is that if precursor cells were to be used in such an attempt then children could potentially be born (using ova and/or sperm derived from a foetus or embryo) never having had a living genetic parent.

The maximum penalty for using precursor cells from a human embryo or a human foetus to create a human embryo, or develop such an embryo, is 10 years imprisonment.

Clause 18—Offence—heritable alterations to genome

This clause 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 clause 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 is 10 years imprisonment.

Clause 19—Offence—collecting viable human embryo from woman's body

This clause 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 clause bans such a practice.
The maximum penalty for intentionally collecting a viable human embryo from a woman is 10 years imprisonment.

Clause 20—Offence—creating chimeric or hybrid embryo

This clause makes it an offence to intentionally create a chimeric embryo or to intentionally create a hybrid embryo.

It is not intended that this clause prohibit the creation of transgenic animals. Transgenic animals are created through the insertion of one or more foreign genes (including human genes) into an animal embryo. It is important to note that transgenic animals are regulated under the *Gene Technology Act 2000* as a genetically modified organism. Before anyone could genetically modify an animal embryo, a licence must be sought from the Gene Technology

Regulator. The Gene Technology Regulator would conduct a comprehensive risk assessment and may seek advice on the ethical issues posed by this practice from the Gene Technology Ethics Committee. Any such work would also need to meet the requirements of an Animal Welfare Committee (in accordance with NHMRC Guidelines).

The maximum penalty for creating, or developing, a hybrid or chimeric embryo is 10 years imprisonment.

Clause 21—Offence—placing of embryo

This clause 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;
- an animal embryo in a human, for any period of gestation.

Some concern has also been expressed about the possibility, in the future, of a human embryo being developed into a foetus, outside the body of a woman. This would be prevented by clause 16 that prohibits the development of an embryo *in vitro* for any period longer than 14 days.

The maximum penalty for any of the offences under this clause is 10 years imprisonment.

Clause 22—Offence—importing, exporting or placing a prohibited embryo

This clause prevents the intentional import into the ACT, intentional export from the ACT or the intentional placement in the body of a woman of any embryo that is referenced in clauses 13, 14, 15, 16, 17, 18, 19 and 20. For the purposes of this clause, such embryos are referred to as prohibited embryos. That is:

- 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 contains genetic material provided by more than 2 persons;
- a 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 fêtes;

- 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.

By including both importation and implantation within this clause it removes the possibility that one person will be able to import a prohibited embryo and give it to another person to be implanted in a woman. In this case both people would be in breach of the legislation. Including exportation of a prohibited embryo as an offence ensures that a person cannot export a prohibited embryo that has been illegally created or obtained.

The maximum penalty for importing, exporting or placing in the body of a woman, a prohibited embryo is 10 years imprisonment.

Clause 23—Offence–commercial trading in human eggs, human sperm or human embryos.

This clause prevents the commercial trading of human eggs, sperm and embryos. Both parties that are 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 that 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 embryos that are excess to their needs 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 clause 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 is 10 years imprisonment.

PART 3 REGULATION OF CERTAIN USES INVOLVING EXCESS ART EMBRYOS

DIVISION 3.1—Interpretation for part 3

Clause 24—Definitions for part 3

This clause sets out a number of definitions for words and phrases used in Part 3 of the Bill. These definitions determine the meaning that is to be attributed to certain words or phrases whenever they are used in this Part. Key definitions include:

accredited ART centre - This is defined to mean a person or body accredited to carry out assisted reproductive technology by:

a. the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
b. if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a), that other body or any of those other bodies, as the case requires.

The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia currently oversees a system of industry based regulation for clinics using ART or carrying out associated research and sets professional and laboratory standards for clinical practice. ART clinics are usually accredited by the RTAC for three years. Accredited ART clinics are expected to comply with the RTAC *Code of Practice for Centres using Assisted Reproductive Technology* and any relevant Guidelines issued by the RTAC.

proper consent is defined to mean consent that is obtained in accordance with the current NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) or any other guidelines that are notified in the Commonwealth Government Gazette as determined by the Chairperson of the NHMRC Licensing Committee. The power to identify alternative (or supplementary) guidelines in the Commonwealth Government Gazette ensures that the most appropriate and recent guidelines describing the processes for consent are observed. For example, the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* are currently subject to review and it is likely that new guidelines will be issued in early 2003. These new guidelines could be referenced in the Commonwealth Government Gazette and therefore replace the older guidelines.

responsible person, in relation to an excess ART embryo, is defined to mean:

a. each person who provided the egg or sperm from which the embryo was created; and
b. the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and
c. any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and
d. any person who was the spouse of the woman mentioned in paragraph (b) at the time the embryo was created.

Clause 25—Meaning of *excess ART embryo*

This clause defines what is meant by an "excess ART embryo", requiring that:

- the embryo was created by assisted reproductive technology for use in the treatment of a woman; and
- the embryo is excess to the needs of the woman for whom it was created and any spouse (at the time the embryo was created) of that woman.

Sub-clause 25(2) provides that a human embryo is an "excess ART embryo", if:

- there is a determination in writing from the woman for whom the embryo was created (and her spouse, if any) that the embryo is excess to their needs; or
- the woman for whom the embryo was created (and her spouse, if any) has provided authority, in writing, for the embryo to be used for a purpose other than achieving pregnancy (for example, research or training purposes). In such a case it is assumed that, by determining that the embryo may be used for another purpose, the couple consider that it is excess to their needs. It should be noted that a determination that an embryo is excess is distinct from a consideration of whether there is proper consent, from all responsible persons, for use of the embryo.

DIVISION 3.2—Offences

Clause 26—Offence—use of excess ART embryo

This clause essentially describes the scope of the regulatory scheme for excess ART embryos by describing the uses of excess ART embryos that require a licence and those that do not.

In summary, all uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee unless such uses are "exempt uses" in accordance with sub-clause 26(3).

Sub-clause 26(3) provides that the following uses of an excess ART embryo are exempt (and therefore do not require licensing):

- storage of an excess ART embryo;
- removing an excess ART embryo from storage (provided that no subsequent use of the embryo is proposed that would otherwise require a licence);
- transport of an excess ART embryo;
- observation of an excess ART embryo (including taking a photograph of the embryo or taking a recording of the embryo from which a visual image can be produced);
- allowing the excess ART embryo to die (succumb);
- diagnostic investigations using excess ART embryos that are unsuitable for implantation (for example, chromosomally abnormal embryos) provided that the investigations are specifically related to achieving pregnancy in the woman for whom the embryo was created. In some cases, as a part of routine clinical practice, it may be beneficial to the woman for whom the embryo was created for diagnostic tests to be undertaken on ART embryos that are unsuitable for implantation to determine the reason why they are not suitable for implantation so as to improve the likelihood of successful pregnancy in the next attempt;
- donating the excess ART embryo to another woman for the purpose of achieving pregnancy in that other woman; and
- any other use prescribed in the regulations.

All other uses of an excess ART embryo are required to be licensed by the NHMRC Licensing Committee. This includes, for example, using excess ART embryos:

- for research (for example, to derive stem cells or to improve ART clinical practice);

- to train people in ART techniques;
- for Quality Assurance testing to ensure that pre-implantation diagnostic tests give accurate results; and
- to examine the effectiveness of new culture media.

The NHMRC Licensing Committee will consider options to streamline the administration of the legislation, where the NHMRC Licensing Committee is satisfied that the use of the excess ART embryos will not damage or destroy the embryo. For example, ART service providers could apply for one licence to undertake quality assurance work using an approved list of techniques and a defined number of excess ART embryos. It may also be appropriate to consider similar arrangements for certain uses of excess ART embryos that may damage the embryo but are a part of routine ART clinical practice, such as the use of embryos for training people in the techniques of assisted reproductive technology.

The effect of sub-clause 26(1) is to make it an offence to intentionally use an excess ART embryo unless the use is authorised by a licence or is one of the exempt uses detailed above.

The maximum penalty that may be applied for use of an excess ART embryo without a licence, or without that use being an exempt use, is 5 years imprisonment.

Clause 27—Offence—use of embryo that is not excess ART embryo

This clause provides that it is an offence to intentionally use a non-excess ART embryo unless the use is part of an ART program carried out by an accredited ART clinic.

The effect of this clause is to ensure that there is no loophole for the inappropriate use of ART embryos that are not excess to the needs of the woman (and any spouse) for whom they were created. For example, it would be illegal to use an ART embryo that has not been declared “excess” in the training of ART technicians or to derive embryonic stem cells.

The maximum penalty for an offence under this clause is 5 years imprisonment.

Clause 28—Offence—breaching licence condition

This clause provides that a person is guilty of an offence if they intentionally do something, or fail to do something, that they know will result in a breach of a condition of licence or that they do so being reckless as to whether or not the action or omission will contravene a condition of licence.

The maximum penalty for breaching a condition of licence is 5 years imprisonment

DIVISION 3.3—Embryo research licensing committee of the NHMRC

Clause 29—Functions of Committee

This clause sets out the functions of the NHMRC Licensing Committee. In essence, the NHMRC Licensing Committee will be tasked with:

- considering licence applications;
- refusing licences or granting licences including subject to conditions;
- notifying relevant people of the Committee's decision regarding the application for licence including the applicant, the relevant Human Research Ethics Committee (HREC) and the relevant State authority;
- varying, suspending or cancelling licences, should this be necessary;
- establishing and maintaining a publicly available database containing information about work involving excess ART embryos that has been licensed by the Committee;
- providing information about the Committee's functions for inclusion in the NHMRC annual report; and
- providing advice to applicants on the licensing requirements and the preparation of applications.

DIVISION 3.4—Licensing system

Clause 30—Person may apply for licence

This clause provides that a person may apply to the NHMRC Licensing Committee for a licence. Such an application must be in accordance with the application requirements of the NHMRC Licensing Committee. It is proposed that the NHMRC Licensing Committee will issue application forms and detailed explanatory material about the Committee's expectations with respect to the information that should be included in any application.

It is expected that the 'person' who applies for a licence will be the organisation in which the work with excess ART embryos is proposed to be undertaken, rather than the individual proposing to undertake the work.

The application must also be accompanied by an application fee if such an application fee is prescribed in the regulations.

Clause 31—Committee decision on application

This clause describes the matters that must be considered by the NHMRC Licensing Committee when deciding whether or not to issue a licence. The clause sets out certain things that the NHMRC Licensing Committee must be satisfied of before they issue a licence and other issues that the NHMRC Licensing Committee must have regard to when deciding whether or not to grant a licence.

Sub-clause 31(3) provides that the NHMRC Licensing Committee must not issue the licence unless it is satisfied that:

- appropriate protocols are in place to enable proper consent to be obtained before an excess ART embryo is used and to ensure that where the couple for whom the embryo was created have specified any restrictions on the use of an embryo, these restrictions will be observed;
- if the proposed use of the excess ART embryo may damage or destroy the embryo (as determined by the NHMRC Licensing Committee), that appropriate protocols are in place to ensure that the excess ART embryos used in the project (should the licence be approved) have been created before 5 April 2002; and
- the proposed project has been considered and assessed by a Human Research Ethics Committee (HREC) that is constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Research Involving Humans* (1999) issued by the NHMRC (or such other document that may replace the National Statement).

Sub-clause 31(4) provides that in deciding whether to issue a licence, the NHMRC Licensing Committee must have regard to the following:

- the number of excess ART embryos likely to be necessary to achieve the goals of the activity or project proposed in the application;
- the likelihood of significant advance in knowledge, or improvement in technologies for treatment, as a result of the use of excess ART embryos proposed in the application which could not reasonably be achieved by other means;
- any relevant guidelines, or parts of guidelines issued by the NHMRC. For example, the NHMRC (through the Australian Health Ethics Committee) is currently undertaking a review of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996). It is anticipated that following the review, the NHMRC will issue revised guidelines that will include information about the criteria to be taken

into account for the purposes of determining whether a use of an excess ART embryo will be likely to result in a significant advance in knowledge or improvement in technologies for treatment that could not reasonably be achieved by other means;

- the HREC assessment of the application; and
- such additional matters (if any) as are prescribed by the regulations

Clause 32—Notification of decision

This clause requires the NHMRC Licensing Committee to notify its decision on an application to the applicant, the HREC that considered the application and the relevant State body (as notified by the State government). In addition, if the NHMRC Licensing Committee issues a licence to the applicant, a copy of the licence must also be provided to the HREC and to the relevant State body.

Clause 33—Period of licence

This clause provides that a licence comes into force on the day specified in the licence or if no such date is specified, the day that the licence is issued. The licence ceases operation on the day specified in the licence unless it is suspended, revoked or surrendered before that day.

Sub-clause 33(2) clarifies that a licence is not in force throughout any period of suspension.

Clause 34—Licence is subject to conditions

This clause describes the conditions to which all licences issued by the NHMRC Licensing Committee are subject and enables the NHMRC Licensing Committee to impose any other conditions that it considers necessary.

Sub-clauses 34(1), (2) and (3) describe the conditions that all licence holders must comply with. These sub-clauses provide that before a person can commence using an excess ART embryo (under a licence issued by the NHMRC Licensing Committee), the licence holder must confirm with the NHMRC Licensing Committee (by notice in writing):

- that consent has been obtained for the use of all the embryos, in accordance with the protocol considered by the NHMRC Licensing Committee;
- any restrictions on the use of the embryos (as determined by the couples for whom the embryos were created); and

- in the case of uses of the embryos that may damage or destroy the embryos, that the embryos were created before 5 April 2002.

Once a licence holder has provided this information to the NHMRC Licensing Committee they may commence work with the excess ART embryos provided they do so in accordance with any restrictions imposed by the couples for whom the embryos were created. Further, if the work with the excess ART embryos may harm or destroy the embryos, then it must be carried out on embryos created before 5 April 2002.

Sub-clauses 34(4) and (5) provide that the NHMRC Licensing Committee may impose any other conditions that are necessary and provides some examples of the types of conditions the NHMRC Licensing Committee may impose. For example, the NHMRC Licensing Committee may impose conditions relating to:

a. the persons authorised by the licence to use the excess ART embryos;

b. the number of excess ART embryos in respect of which use in authorised by the licence;

c. reporting;

d. monitoring; and

e. information to be given by the licence holder to persons authorised by the licence to use excess ART embryos.

Sub-clause 34(6) provides that the conditions included in sub-clauses 34(1), (2) and (3) are applicable to all people who are authorised by the licence to use excess ART embryos as specified in the licence.

Sub-clause 34(7) provides that any other licence conditions are applicable to the licence holder and any other people who are authorised by the licence to use excess ART embryos as specified in the licence.

Clause 35—Variation of licence

This clause enables the NHMRC Licensing Committee to vary a licence. There are two possible circumstances in which the NHMRC Licensing Committee may need to vary a licence:

- on request of the licence holder. For example, if the licence holder wishes to change administrative details on the licence such as contact details or more significant details such as the duration of the licence; and

- when the NHMRC Licensing Committee considers it necessary or desirable to vary a condition of licence. For example, should the NHMRC Licensing Committee wish to add additional conditions of

licence, change the wording of existing conditions of licence or delete existing conditions of licence.

Clause 36—Suspension or revocation of licence

This clause enables the NHMRC Licensing Committee to suspend or revoke a licence that has been issued if they believe, on reasonable grounds, that a condition of the licence has been breached. This is a very important provision because it enables the NHMRC Licensing Committee to take immediate action in the event of apparent non-compliance. By suspending or revoking the licence the work can no longer continue.

The NHMRC Licensing Committee has the power to re-instate the licence should the suspected breach of condition fail to be established or should the licence holder rectify the situation and the Committee is convinced that the work can continue without risk of further breaches. Whether or not the licence is suspended, cancelled or subsequently reinstated would depend on the individual circumstances of the case and the extent, severity and importance of the alleged breach.

It is important that the NHMRC Licensing Committee has a degree of discretion in this respect given that breaches of licence can range from fairly minor infringements (for example, late submission of annual reports to the NHMRC Licensing Committee) through to very serious breaches such as using more embryos than has been authorised by the licence.

Clause 37—Surrender of licence

This clause provides that a licence holder may surrender a licence by written notice given to the NHMRC Licensing Committee. An organisation may wish to surrender a licence if, for example, they have completed the work involving the use of the excess ART embryos.

Clause 38—Notice of variation, suspension or revocation of licence

This clause provides that if the NHMRC Licensing Committee varies, suspends or cancels a licence the Committee must notify the changes to the relevant State or Territory body to which it notified its original decision. This ensures that State and Territory governments are kept fully informed about any variations to licences. In addition, if the change to the licence impacts on the information that is included on the publicly available database, the database must also be amended to reflect the change.

DIVISION 3.5—Reporting and confidentiality

Clause 39—NHMRC Licensing committee to make certain information publicly available

This clause provides that the NHMRC Licensing Committee must establish and maintain a comprehensive, publicly available database containing information about licences that have been issued by the NHMRC Licensing Committee.

Sub-clause 39(1) provides that the database must include the following information in relation to each licence:

a. the name of the person to whom the licence was issued. ;

b. the nature of the uses of the embryos authorised by the licence. For example, the record would state whether the embryos are proposed to be used for the derivation of stem cells, for use for testing culture medium, for training of technicians etc;

c. the conditions of licence;

d. the number of embryos proposed to be used. At the time that a licence is granted, one of the conditions would describe the maximum number of embryos permitted to be used as part of the project. Another condition of licence would describe reporting requirements including in relation to how many embryos were actually used and when they were used. It is proposed that the NHMRC Licensing Committee will update the database to reflect the number of embryos actually used in a project;

e. the date on which the licence was issued; and

f. the period of the licence.

It is proposed that the database would be included on the NHMRC website and that hard-copy extracts of the database would be available from the NHMRC Licensing Committee on request. The database would not include information that is confidential commercial information or any personal information that would be prohibited from disclosure under the Commonwealth *Privacy Act 1988*, including for example, names of individuals.

Clause 40—Confidential commercial information may only be disclosed in certain circumstances

This clause is intended to protect, from public disclosure, certain information that is legitimately confidential commercial information.

"Confidential commercial information" is defined in clause 24 of the Bill to mean information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

The information may also be disclosed by order of a court or with the consent of the person to whom the information has a commercial or other value.

DIVISION 3.6—Review provisions

Clause 41—Definitions for division 3.6

This clause describes those persons who are able to seek review in relation to various types of decisions made by the NHMRC Licensing Committee. In summary, the clause provides that an "eligible person" in relation to a decision of the NHMRC Licensing Committee means:

- a licence applicant - in relation to a decision by the NHMRC Licensing Committee not to issue a licence; and
- the licence holder in relation to:
- a decision by the NHMRC Licensing Committee relating to the period of a licence;
- a condition of licence imposed by the NHMRC Licensing Committee; and
- a decision by the NHMRC Licensing Committee to vary, refuse to vary, suspend or revoke a licence.

Clause 42—Review of decisions

Sub-clause 42(1) provides that an eligible person (as defined in clause 41) may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee:

a. a decision under clause 31 not to issue a licence;

b. a decision in respect of the period throughout which the licence is to be in force under clause 33;

c. a decision to specify a licence condition under sub-clause 34(4);

d. a decision to vary or refuse to vary a licence under clause 35; or

e. a decision to suspend or revoke a licence under clause 36.

Sub-clause 42(2) provides that clause 42 has effect subject to the *Administrative Appeals Tribunal Act 1975*.

PART 4 MONITORING POWERS

Clause 43—Appointment of inspectors

Sub-clause 43(1) enables the Chairperson of the NHMRC Licensing Committee to appoint inspectors for the purposes of exercising all the powers under this Part. The persons the Chairperson of the NHMRC Licensing Committee may appoint as inspectors, can be Commonwealth employees and/or Territory employees. The Chairperson of the Licensing Committee must also ensure that each person appointed as an inspector has appropriate skills and experience (sub-clause 43(3)).

Sub-clause 43(2) requires a person appointed as an inspector to comply with any directions of the Chairperson of the NHMRC Licensing Committee when exercising powers or performing functions in that capacity.

Clause 44— identity card

Sub-clauses 44(1) and 44(2) require the Chairperson of the NHMRC Licensing Committee to issue an identity card, in a form prescribed by the regulations, to every person appointed as an inspector. The identity card must have a recent photograph of the inspector.

Sub-clause 44(3) provides that it is an offence for a person who ceases to be appointed as an inspector to fail to return his or her identity card, as soon as practicable, to the Chairperson of the NHMRC Licensing Committee. The offence attracts a maximum penalty of 1 penalty unit.

Sub-clause 44(4) requires the inspector to carry his or her identity card at all times when exercising powers or performing functions as an inspector.

Clause 45—Powers available to inspectors for monitoring compliance

Sub-clause 45(1) confers powers upon an inspector to enter any premises and to exercise any or all of the powers set out in clause 46 for the purposes of establishing whether or not the Act or regulations are being complied with.

Sub-clause 45(2) provides that an inspector may only enter premises under this clause if he or she has the consent of the occupier of the premises or if

the occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

Clause 46—Monitoring Powers

This clause describes the monitoring powers that an inspector may exercise for the purposes of finding out whether the Act or regulations have been complied with.

Clause 47—Power to secure

This clause provides that if an inspector, during the course of inspecting premises, finds something that may be evidence in relation to an offence committed under the Act, the inspector may secure the thing pending the obtaining of a warrant to seize it.

Clause 48—Inspector must produce identity card on request

This clause provides that an inspector cannot exercise any of the powers under this Part in relation to premises unless he or she produces his or her identity card upon being requested to do so by the occupier of those premises.

Clause 49—Consent

This clause provides that, before obtaining consent from a person to enter premises (under paragraph 45(2)(a), the inspector must inform the person that he or she may refuse consent.

Sub-clause 49(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

Clause 50—Compensation for damage

This clause provides that if damage is caused to equipment or other facilities as a result of it being operated by an inspector and the damage resulted from insufficient care being exercised by the inspector in operating the equipment, compensation is payable to the owner.

In determining the amount payable, regard is to be had to whether the occupier (or his or her employees and agents) had provided any warning or guidance as to the operation of the equipment or facility. This is to minimise compensation in cases where, for example, there has been a deliberate

programming of software to destroy or cause damage if not accessed in a particular manner, or where the occupier failed to mitigate damage by providing warning or guidance.

PART 5 MISCELLANEOUS

Clause 51—Reports to Legislative Assembly

This clause provides that once the Minister receives a copy of the report from the NHMRC licensing committee, a copy of that report must be presented to the Legislative Assembly.

Clause 52—Review of operation of Act

This clause requires that the Minister review the operation of the Act as soon as practicable 2 years after the Act commences. In considering and reporting on the scope of the Act the review must take in account the following:

- developments in technology in relation to ART
- developments in medical and scientific research and the potential application of such research
- community standards
- the acceptability of establishing a National Stem Cell Bank.

Clause 53—Determination of fees

This clause allows the Minister to determine any necessary fees. The fees must be presented to the Legislative Assembly as a disallowable instrument.

Clause 54—Approved forms

Clause 54 allows the Minister to approve, in writing, any necessary forms. The approved form must be used for the purpose it was approved for. The approved forms must be notified under the *Legislation Act 2001* as a notifiable instrument.

Clause 55—Regulations

Clause 55 provides the Executive with the power to make necessary regulations for this Bill. The regulations must be presented to the Legislative Assembly.

Clause 56—Expiry of certain provisions

Clause 56 provides for the expiry of certain provisions in relation to embryo research licensing that expire on a date to be notified under the *Legislation Act 2001* by the Minister as a notifiable instrument.

Dictionary

The dictionary at the end of the Bill defines key words and phrases that are used in the Bill and is part of the Bill. These definitions determine the meaning that is to be attributed to certain words or phrases whenever they are used in the Bill or regulations.