

2004

**LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN
CAPITAL TERRITORY**

Human Embryo (Research) Bill 2004

EXPLANATORY STATEMENT

Circulated by the authority of the Minister for Health

Simon Corbell MLA

Human Embryo (Research) Bill 2004

EXPLANATORY STATEMENT

Overview

The object of this Bill is to give effect in this State to a nationally consistent scheme for the regulation of activities involving the use of certain human embryos created by assisted reproductive technology. For that purpose, the Bill:

- (a) applies the *Research Involving Human Embryos Act 2002* of the Commonwealth as a law of this State, and
- (b) makes provision to ensure that the Commonwealth Act and the applied laws of this State are administered on a uniform basis by the Commonwealth as if they constituted a single law of the Commonwealth.

NOTES ON CLAUSES

PART 1 PRELIMINARY

Clause 1—Name of Act

This is a formal provision that sets out the name (also called the short title) of the proposed Act.

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 Embryo (Research) Bill 2004*.

Clause 6—Object of Act

This clause states the object of the proposed Act, which is principally to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of human embryos created by assisted reproductive technology (ART).

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 human 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

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.

PART 2 REGULATION OF CERTAIN USES INVOLVING EXCESS ART EMBRYOS

DIVISION 2.1—Interpretation for pt 2

Clause 8—Definitions for part 2

This clause sets out a number of definitions for words and phrases used in Part 2 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.

confidential commercial information is defined 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.

disclose information is defined as giving or communicating the information in any way.

HREC is defined as a human research ethics committee.

licence is defined as a licence issued under section 15.

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. New guidelines could be referenced in the Commonwealth Government Gazette and therefore replace the older guidelines.

relevant Territory entity is defined as the entity notified by the Territory to the chairperson of the NHMRC licensing committee for the *Research Involving Human Embryos Act 2002* (Cwlth), part 2.

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 9—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 ART 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 9(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 2.2—Offences

Clause 10—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 10(3).

Sub-clause 10(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 10(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 11—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 12—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 2.3—Embryo research licensing committee of the NHMRC

Clause 13—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 2.4—Licensing system

Clause 14—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 15—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 15(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 15(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 16—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 Territory body (as notified by the Territory 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 Territory body.

Clause 17—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 17(2) clarifies that a licence is not in force throughout any period of suspension.

Clause 18—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 18(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 work with the excess ART embryos may commence, provided it is done 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 18(4) and (5) provide that the NHMRC Licensing Committee may impose any other conditions that are necessary and provide 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 is 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 18(6) provides that the conditions included in sub-clauses 18(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 18(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 19—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 20—Suspension or revocation of licence

This clause enables the NHMRC Licensing Committee to suspend or revoke a licence that has been issued if it believes, 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 21—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, it has completed the work involving the use of the excess ART embryos.

Clause 22—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 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 2.5—Reporting and confidentiality

Clause 23—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 23(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 24—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 8 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.

The maximum penalty under this clause is 2 years imprisonment.

DIVISION 2.6—Review provisions

Clause 25—Definitions for div 2.6

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 26—Review of decisions

Sub-clause 26(1) provides that an eligible person (as defined in clause 25) may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee:

- a decision under clause 15 not to issue a licence;
- a decision in respect of the period throughout which the licence is to be in force under clause 17;
- a decision to specify a licence condition under sub-clause 18(4);
- a decision to vary or refuse to vary a licence under clause 19; or
- a decision to suspend or revoke a licence under clause 20.

Sub-clause 26(2) provides that clause 42 has effect subject to the *Administrative Appeals Tribunal Act 1975* (Cwlth).

PART 3 MONITORING POWERS

Clause 27—Appointment of inspectors

Sub-clause 27(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 27(4)).

Sub-clause 27(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 28— Identity card

Sub-clauses 28(1) and 28(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 include a recent photograph of the inspector.

Sub-clause 28(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 28(4) requires the inspector to carry his or her identity card at all times when exercising powers or performing functions as an inspector.

Clause 29—Powers available to inspectors for monitoring compliance

Sub-clause 29(1) confers powers upon an inspector to enter any premises and to exercise any or all of the powers set out in clause 30 for the purposes of establishing whether or not the Act or regulations are being complied with.

Sub-clause 29(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 30—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 31—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 32—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 33—Consent

This clause provides that, before obtaining consent from a person to enter premises (under paragraph 29(2)(a)), the inspector must inform the person that he or she may refuse consent.

Sub-clause 33(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

Clause 34—Compensation for damage

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

In determining the amount payable, regard is to be had as 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 4 MISCELLANEOUS

Clause 35—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 36—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; and
- the acceptability of establishing a National Stem Cell Bank.

Clause 37—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 38—Approved forms

This clause allows the Minister to approve, in writing, any necessary forms. If the Minister approves a form for a particular purpose, the approved form must be used for that purpose. The approved forms must be notified under the Legislation Act 2001 as a notifiable instrument.

Clause 39—Regulation-making power

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

Clause 40—Expiry of certain provisions

This clause establishes that the provisions of sections 15(3)(b), 18(1)(c), 18(3) and this section expire on the earlier of 5 April 2005 or an earlier expiry date fixed by the Minister under subsection (3)

Clause 41—Legislation amended—sch1

This clause allows, should the *Human Embryo (Research) Bill 2004* and the *Human Cloning (Prohibition) Bill 2004* both become law, that both Acts are combined into one Act, *The Human Cloning and Embryo Research Act 2004*.

This is achieved by **Schedule 1 Amendments** which has the effect of repealing the *Human Cloning (Prohibition) Act 2004* and amending the *Human Embryo (Research) Act 2004* accordingly.

SCHEDULE 1 AMENDMENTS

The Schedule outlines the specific amendments required to amend the *Human Embryo (Research) Act 2004* to become *The Human Cloning and Embryo Research Act 2004*, including the repealing of the *Human Cloning (Prohibition) Act 2004*.

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.