# RESEARCH INVOLVING HUMAN EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2003

## EXPLANATORY NOTES

### GENERAL OUTLINE

### Objectives of the Legislation

The objectives of the *Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003* are to address ethical and safety concerns about scientific developments associated with reproductive technology by –

- prohibiting human cloning;
- prohibiting certain other practices associated with reproductive technology; and
- regulating the use of excess assisted reproductive technology (ART) embryos for research and other activities.

The policy objectives of the Bill are to form part of a national scheme to be established by State, Territory and Commonwealth legislation.

### Reasons for and means of achieving the Policy objectives

At international, national and state levels, creation of human clones is widely regarded as unacceptable and contrary to human dignity. The United Nations Educational, Scientific and Cultural Organisation (UNESCO) and the World Health Organisation have condemned the use of cloning for replication of humans as unacceptable. In Australia, the National Health and Medical Research Council (NHMRC), Fertility Society of Australia and the Australian Academy of Science regard human reproductive cloning as unacceptable. The *Code of Ethical Practice for Biotechnology in Queensland* (the Code) commits government biotechnology organisations and others that subscribe to the Code to not undertake human reproductive cloning.

*COAG Communique of 5 April 2002*

On 5 April 2002, the Council of Australian Governments (COAG) agreed the Commonwealth, States and Territories would introduce nationally consistent legislation banning human cloning and other unacceptable practices associated with reproductive technology. COAG also agreed on the establishment of a national regulatory framework for the use of excess assisted reproductive technology (ART) embryos to enable Australia to remain at the forefront of research that may lead to medical breakthroughs in the treatment of disease. COAG agreed the regulatory regime for licensing of research involving excess ART embryos would be administered by the National Health and Medical Research Council (the NHMRC).

*Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (Cth)*

On 27 June 2002, the Prime Minister introduced the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (the Commonwealth Bill) to the Commonwealth House of Representatives. During the House of Representatives debate on 29 August 2002, the Commonwealth Bill was split into two Bills – The *Prohibition of Human Cloning Bill 2002* (Cth) and the *Research Involving Embryos Bill 2002* (Cth). Amendments were made in Parliament to both Bills. The *Prohibition of Human Cloning Act 2002* (Cth) and the now *Research Involving Human Embryos Act 2002* (Cth) were both passed by Commonwealth Parliament on 11 December 2002. The Commonwealth Bills received Royal Assent on 19 December 2002.

*Research Involving Human Embryos and Prohibition of Human Cloning Bill 2003 (Qld)*

*Human cloning*

COAG agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation to ban human cloning. This Bill implements that agreement in Queensland by prohibiting creation and implantation of human embryo clones. This legislative approach is considered to be necessary and appropriate because it applies a prohibition on human cloning rather than relying on voluntary compliance with existing guidelines and codes.

*Other unacceptable practices associated with reproductive technology*

Consistent with the COAG agreement of 5 April 2002, the Bill prohibits a range of other practices associated with reproductive technology including –

- creation of a human embryo for research purposes;
- creation or implantation of chimeric or animal/human hybrid embryos;
- creation of a human embryo that contains genetic material provided by more than two people; and
- commercial trading in human eggs, human sperm or human embryos.

At present, the practices prohibited by the Bill are considered unacceptable for ethical and safety reasons.

*Use of embryos*

Consistent with its object, and as complementary legislation to a national regulatory scheme, the Bill –

- supports prohibition of the creation, importation, exportation or implantation of certain other embryos for ethical and safety reasons under the Commonwealth *Prohibition of Human Cloning Act 2002*;
- supports establishment of a principal committee of the National Health and Medical Research Council (NHMRC), the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee). Its purpose is to perform functions and exercise powers under the national regulatory scheme outlined in the Commonwealth *Research Involving Human Embryos Act 2002;*
- establishes a scheme for the assessment and licensing of certain activities involving the use of excess embryos created by assisted reproductive technology (excess ART embryos); and
- provides for a centralised, publicly available database of information about all licences issued by the NHMRC Licensing Committee.

Scientific research associated with reproductive technology is evolving at a rapid rate around the world. Given the dynamic nature of this field, it is considered necessary to monitor developments and assess the operation of the regulatory framework. COAG has agreed that the legislation should be

reviewed in three years. On that basis, the Bill requires the review to take into account –

- developments in technology;
- the potential therapeutic uses for such technology;
- any changes in community standards; and
- the applicability of establishing a National Stem Cell Bank.

## Alternatives to the Bill

The Commonwealth introduced the *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (the Commonwealth Bill) to the Commonwealth House of Representatives on 27 June 2002. In the House of Representatives' debate on 29 August 2002, the Commonwealth Bill was split into two Bills – the *Prohibition of Human Cloning Bill 2002* (Cth) and the *Research Involving Embryos Bill 2002* (Cth).

Amendments were made in Parliament to both Bills. The *Prohibition of Human Cloning Act 2002* (Cth) and the now *Research Involving Human Embryos Act 2002* (Cth) were both passed by Commonwealth Parliament on 11 December 2002. The Commonwealth Bills received Royal Assent on 19 December 2002.

Due to Constitutional limitations, the Commonwealth Acts do not provide full regulatory coverage for ethical medical research involving embryos (eg. they do not cover the activities of State Government agencies, individuals or higher education institutions). Therefore, both State and Commonwealth legislation is required to provide full regulatory coverage.

The two Commonwealth Acts share a single inspection and monitoring regime for the proposed national regulatory scheme and contain provisions for concurrent review of the Acts. One Queensland Bill has been prepared.

There are no alternatives considered appropriate for achieving these policy objectives.

## Estimated Costs of Government Implementation

*Commonwealth Government*

The Commonwealth Government will incur establishment costs and ongoing costs associated with the Commonwealth Acts, including support

for the NHMRC Licensing Committee and monitoring the compliance with the legislation.

Costs to the Commonwealth Government are expected to be approximately $3m per annum, with an upper maximum of $6m. This involves a fixed cost to support the NHMRC Licensing Committee and provide for ongoing compliance monitoring related to the prohibited practices. There is also a variable cost, which will relate to the number of licence applications received. While it is not possible to accurately predict these variable costs, the cost estimate assumes up to 120 licence applications per year, based on Commonwealth consultation with ART service providers and researchers.

Commonwealth establishment costs involve –

- developing administrative processes for receiving and processing applications and issuing licences;
- establishing the NHMRC Licensing Committee;
- recruiting appropriately skilled staff;
- establishing a skilled inspectorate to ensure compliance with the Act through monitoring and inspection;
- developing assessment frameworks for research proposals; and
- establishment and maintenance of data systems and public reporting.

*Queensland Government*

The Commonwealth *Research Involving Human Embryos Act 2002* provides for a "relevant State body" to be nominated for Queensland. The role of the relevant State body will be to receive information regarding licence applications under the scheme and assist in inspection and monitoring of the legislation. This is expected to generate minimal costs, which would be met from existing resources.

Other issues associated with the cost to the Queensland Government of administering the national legislative scheme will be addressed in an Inter-governmental Agreement between all jurisdictions. This will be supported by a bi-lateral agreement between the Commonwealth of Australia and the State of Queensland.

## Consistency with Fundamental Legislative Principles

The Bill forms part of a regulatory regime to provide for a nationally consistent approach to ban human cloning and other unacceptable practices and to regulate research involving embryos within a strict framework. To ensure national consistency, it is necessary to replicate some provisions of the Commonwealth Acts in the Bill, which may raise fundamental legislative principle issues. Aspects of the Bill which raise possible fundamental legislative principle issues are outlined below.

*Regulation making powers*

The definitions of "hybrid embryo"; and "chimeric embryo" in the Schedule of the Bill, the definition of "accredited ART centre" in clause 21; and the exempt uses of an excess ART embryo in sub-clause 23(2)(f) all include a regulation-making capacity to further define the relevant terms.

The power to further prescribe these definitions and to prescribe additional exempt uses of an excess ART embryo in regulations is considered necessary to respond quickly to regulate changing technology and unforeseen advances in scientific methods. Timely government response to technological changes is expected to be necessary to achieve the objects of the national regulatory scheme.

*Powers of entry*

Inspectors are appointed under the Commonwealth *Research Involving Human Embryos Act 2002* to monitor and inspect activities relevant to that Act and the Commonwealth *Prohibition of Human Cloning Act 2002*. It is intended that the inspectors would also inspect and monitor compliance with complementary State and Territory legislation as part of the national regulatory regime. This Bill supports this arrangement.

Clause 43 of the Bill provides that inspectors may enter premises without a warrant, where the occupier is carrying out activities authorised by a licence, and the entry is at a reasonable time. Under clause 44, the inspector may exercise specified monitoring powers at the premises. Clause 45 also provides that, if an inspector believes on reasonable grounds that there is evidence of the commission of an offence, the monitoring powers include securing the evidence pending the obtaining of a warrant to seize it.

The consequences associated with human cloning, other prohibited practices and with non-compliance with requirements of the legislation or licence conditions for research involving embryos, are potentially serious.

The power to enter research premises at a reasonable time is considered necessary to enable adequate monitoring of research practices. The powers of entry allow inspectors under the national scheme to respond promptly in monitoring of compliance with the regulatory regime.

## Consultation

This Bill is complementary to the Commonwealth Acts, which in turn were largely based on recommendations of the *Report on Human Cloning, Assisted Reproductive Technology and Related Matters* provided by Health Ministers to COAG on 5 April 2002. This report was informed by consultation with –

- experts in ethics, law and medical sciences identified by States and Territories;
- representatives from the health department in each jurisdiction and departments of the Prime Minister, premiers and chief ministers; and
- the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC.

In May and June 2002, Commonwealth officials engaged in further national consultation with experts in ART clinical practice, medical research, consumer issues, ethics and law. A confidential exposure draft of the Commonwealth legislation and an accompanying explanatory guide were provided to these parties for consideration and comment. Targeted consultation was undertaken in Brisbane in May 2002. As this is a national scheme involving complementary legislation to ensure consistency, the national consultative process has informed the development of this Bill. Representatives of key church groups were consulted on a draft of this Bill.

## Approach to drafting the complementary Queensland Bill

This Bill replicates the relevant provisions of the Commonwealth Acts to form part of the national regulatory regime. Where it is not appropriate, the Commonwealth provisions have not been included in the Bill. Instead, references are made in these Explanatory Notes to the heading and content of those provisions of the Commonwealth Acts which are not replicated, to assist understanding of the proposed national scheme.

# NOTES ON PROVISIONS

## PART 1 – PRELIMINARY

*Clause 1 – Short Title*

This is a formal provision that specifies the short title of the Act as the *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003.*

*Clause 2 – Commencement*

Clause 2 allows for different parts of the Act to commence at different times.

Sub-clause 2(1) provides for the Act, other than Part 6 division 1, to commence on a date to be proclaimed.

Sub-clause 2(2) provides for Part 6, division 1 to commence on 5 April 2005 or on an earlier day if COAG declares the earlier day by notice in the Gazette.

*Commencement of the Commonwealth Acts*

Commencement of provisions of the Commonwealth Acts is structured so that the various provisions take effect on the date specified in the schedules of the Commonwealth Acts.

*The Prohibition of Human Cloning Act 2003*

The Commonwealth *Prohibition of Human Cloning Act 2002* provides that the title of the Act and its commencement schedule commenced on the date of Royal Assent. The Act received Royal Assent on 19 December 2002. The rest of the Act (clauses 3 to 26 and Schedule 1) commenced 28 days after the day on which the Bill received Royal Assent. This gave effect to the Commonwealth's prohibition of human cloning and other unacceptable practices.

Schedule 1 repealed certain sections of the *Gene Technology Act 2000 (*Cth) that were replaced by sections of the Commonwealth legislation.

*The Research Involving Human Embryos Act 2002*

Sections 13 to 48 of the Commonwealth *Research Involving Human Embryos Act 2002* commenced on 16 January 2003. These sections provide, among other things, for the establishment and administration of the NHMRC Licensing Committee, review of both Commonwealth Acts and regulations to be made under the Act.

The Commonwealth *Research Involving Human Embryos Act 2002* sections 10 to 12 are intended to commence on 19 June 2003, six months after the day on which that Bill received Royal Assent. Section 10 provides that a person must not intentionally use an excess assisted reproductive technology (ART) embryo unless that use is an exempt use or is authorised by a licence issued by the NHMRC Licensing Committee.

Section 11 provides that a person must not use a non-excess ART embryo unless it is part of an ART program carried out by an accredited ART centre. Section 12 provides that a person must comply with any conditions of a licence.

The commencement of these provisions in June 2003 is to allow time for the establishment of the NHMRC Licensing Committee and for applications for licences to be made.

During this transitional period, researchers and others will continue to be required to comply with the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996).

The delayed commencement of these provisions of the Commonwealth *Research Involving Human Embryos Act 2002* for six months, is also intended to allow States and Territories time to introduce complementary legislation.

*Clause 3 – Object of the 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 –

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

*Operation of the Act*

The Commonwealth Acts include provisions about the scope for the operation of each Commonwealth Act. No clause has been included in this Bill as the provisions in the Commonwealth Acts are used only to establish the constitutionality of each Act.

*Clause 4 – Act binds all persons*

Sub-clause 4(1) provides that the Act will bind the Crown in each of its capacities, as far as the Parliament permits.

Sub-clause 4(2) provides that the Crown may not be prosecuted for a criminal offence against this Act.

*External Territories*

A clause to extend the Act to all external territories is included in the Commonwealth Acts. No clause has been included in this Bill.

*Clause 5 – Definitions*

Sub-clause 5(1) states that particular words used in the legislation are defined in the dictionary in the Schedule.

Sub-clause 5(2) clarifies matters relating to the term "human embryo clone".

First, 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. Second, the copy of the genes does not have to be an identical genetic copy. Therefore, the human embryo clone does not have to be genetically identical to the human who was cloned. This ensures that a "human embryo clone" includes one where –

- there is DNA outside the nucleus (ie mitochondrial DNA) that is not identical to the living or dead human from whom the nuclear DNA was taken;
- spontaneous changes to the nuclear DNA have occurred during the development of the human embryo clone;
- there has been deliberate alteration of the DNA with the intention 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 issue is also addressed in the definition of "human embryo", which includes an embryo that has an altered human

genome. An embryo that is a clone of another human and has had its genome deliberately altered will still be regarded as a human embryo. As its original genome was copied, it will also fall within the definition of a "human embryo clone".

Sub-clause 5(3) clarifies that any period when the development of a human embryo is suspended, for example when the embryo is frozen, is excluded when working out the length of period of development of the embryo. For example, if an embryo is placed in storage and its development suspended two days after fertilisation and is stored for 10 weeks, it is still considered to be a two-day embryo in terms of its development.

Sub-clause 5(4) clarifies that for the purpose of the definition of "human embryo clone", a human embryo created by the technological process known as embryo splitting is a human embryo clone. Embryo splitting is a term used to describe a micro-surgical technique carried out on an embryo created by in-vitro fertilisation. This technique can be used to divide an embryo in the early stages of development to produce two or more identical embryos. This clause provides that an embryo created through embryo splitting is not to be regarded as an embryo created by a process of fertilisation of a human egg by human sperm. The Bill does not intend to include natural embryo splitting in the definition of "human embryo clone".

Sub-clause 5(5) clarifies that the definition of "spouse" used in the Bill applies, instead of the definition of "spouse" in the *Acts Interpretation Act 1954*. The definition of "spouse" is used in clause 21 to define responsible persons required to provide consent under the scheme. This applies for the purpose of clauses 22 and 24 to determine whether an ART embryo is excess, and may be used for research purposes.

This is consistent with the definition of "spouse" in the Commonwealth legislation and ensures operational consistency for the national consent regime for donation of an excess ART embryo for research purposes.

*Clause 6 – Meaning of "reckless'*

This definition, which is based on that provided in the Commonwealth Criminal Code has been included to reflect the national nature of the regulatory scheme. As the scheme establishes criminal offences under the Commonwealth Acts and this Bill, it necessarily requires the interaction of State and Commonwealth Criminal Codes.

The Commonwealth Acts include the term "reckless" in the creation of offences. Recognising that the term is commonly used, this definition provides that a person is "reckless" if they are aware of, and take an unjustifiable risk. The definition has been included to ensure prosecutions are carried out in a nationally consistent manner.

# PART 2 – PROHIBITED PRACTICES

## DIVISION 1 – Human Cloning

*Clause 7 – 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 technological 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). The definition in the Schedule clarifies that identical twins (created by the fertilisation of a human egg by human sperm) are not "human embryo clones".

The maximum penalty for creating a human embryo clone is 15 years' imprisonment, both in this Bill and the Commonwealth *Prohibition of Human Cloning Act 2002*. The constitutional jurisdiction issues underpinning the national scheme mean that the facts of a case will determine whether an alleged offence is prosecuted under the Commonwealth Act or the Queensland Act. An alleged offence will not be prosecuted under both.

If an alleged offence is prosecuted under Commonwealth jurisdiction, a court may at its discretion supplement the imprisonment term with a monetary penalty or convert the imprisonment term to a monetary penalty of up to $495,000 for a corporation and $99,000 for an individual.

If an alleged offence is prosecuted under Queensland jurisdiction, the equivalent financial penalty for an individual convicted in the District Court is restricted to a maximum of approximately $313,125 (4,175 penalty units). The Supreme Court may issue an unlimited financial penalty.

*Clause 8 – Offence – placing a human embryo clone in the human body or the body of an 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. This clause is intended to cover, for example, the circumstance where, a human embryo clone has been illegally created in Australia, or imported into Australia, and is subsequently implanted in a human body or the body of an animal.

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 both in this Bill and in the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 7.

*Offence – importing or exporting a human embryo clone*

The Commonwealth *Prohibition of Human Cloning Act 2002* makes it an offence to intentionally import a human embryo clone into Australia or intentionally export a human embryo clone from Australia. This ensures that all avenues for obtaining a human embryo clone in Australia are unlawful, while ensuring that a person cannot export a human embryo clone that has been illegally created or obtained.

No clause has been included in the Bill as it is beyond the competence of the State to create import and export offences.

The maximum penalty that may be applied for importing or exporting a human embryo clone under the Commonwealth Act is 15 years' imprisonment. The potential for financial penalties to be incurred is outlined under clause 7.

*Clause 9 – No defence that clone could not survive*

This clause provides that any human embryo clone that is intentionally created or implanted does not have to survive to the point of live birth in order for an offence to be established under clauses 7 or 8. This would include, but is not necessarily limited to situations where –

- an unsuccessful attempt is made to create a human embryo clone;
- a human embryo clone is created and then allowed to die;
- a human embryo clone is created and deliberately destroyed without attempting implantation;
- 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
- a human embryo clone is successfully implanted, develops to full term but is stillborn.

The corresponding Commonwealth Act also excludes the non-survival of a human embryo clone as a defence to importation and exportation offences.

## DIVISION 2 – Other prohibited practices

*Clause 10 – Offence – creating a human embryo other than by fertilisation, or developing such an embryo*

This clause is intended to ensure that a human embryo is not intentionally created outside the body of a woman by any means other than by the fertilisation of a human egg by human sperm. This means 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.

This clause is also intended to ensure that, if such an embryo was imported into Australia (an offence under clause 22 of the Commonwealth *Prohibition of Human Cloning Act 2002)*, it could not be developed by the person who imported it or any other person without an offence being committed.

In conjunction with the definition of sperm in the Schedule, clause 10 does not make it unlawful to create a human embryo by fertilising a human egg with human spermatids. Spermatids are one of the precursor cells of sperm and can be used in assisted reproductive treatment to create an

embryo through the procedure known as intracytoplasmic sperm injection (ICSI), where a man may be unable to produce functional sperm cells.

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 under both this Bill and the corresponding Commonwealth Act. The constitutional jurisdiction issues underpinning the national scheme mean that the facts of a case will determine whether an alleged offence is prosecuted under the Commonwealth Act or the Queensland Act. An alleged offence will not be prosecuted under both.

If an alleged offence is prosecuted under Commonwealth jurisdiction, a court may at its discretion supplement the imprisonment term with a monetary penalty or convert the imprisonment term to a monetary penalty of up to $330,000 for a corporation and $66,000 for an individual.

If an alleged offence is prosecuted under Queensland jurisdiction, the equivalent financial penalty for an individual convicted in the District Court is restricted to a maximum of approximately $313,125 (4,175 penalty units). The Supreme Court may issue an unlimited financial penalty.

*Clause 11 – Offence – creating a human embryo for a purpose other than achieving pregnancy in a woman*

Sub-clause 11(1) provides that a person can only create a human embryo outside the body of a woman if it is intended, at the time of creation, to attempt to achieve pregnancy in a particular woman.

It is an offence to create human embryos specifically for other purposes such as research or to derive embryonic stem cells. 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. ART clinical practice is subject to a national system of industry accreditation carried out by the Reproductive Technology Accreditation Committee (of the Fertility Society of

Australia), and to the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996); or

- prevent the circumstance whereby a human embryo created in an ART clinic, originally intended for implantation into a woman, may be found to be unsuitable for implantation, or may at some point not be required by the woman for whom it was originally created. In these situations, it is possible that such embryos could become excess ART embryos and at that point they may be used for purposes other than to attempt to achieve pregnancy in a woman subject to the system of regulatory oversight described in Part 3 of the Bill.

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 under this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

Sub-clause 11(2) has the effect that, despite subsection 13.3(3) of the Commonwealth Criminal Code, a defendant does not bear an evidential burden in relation to the offence in subsection (1) of this section. The prosecution must establish the case in relation to all of the offences detailed in this Bill; however, as this clause is worded slightly differently to the other clauses, it could be interpreted to be reversing the burden of proof. This clause is not required by, nor relevant to the Queensland Criminal Code but has been included to provide consistency with the Commonwealth *Prohibition of Human Cloning Act 2002* and to add maximum clarity to ensure prosecutions are carried out in a nationally consistent manner.

*Clause 12 – Offence – creating or developing a human embryo containing genetic material provided by more than two persons*

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

One of the effects of this clause is to ban a relatively new ART technique of 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 problems in achieving pregnancy related to the cytoplasm. It has been reported that this procedure may be particularly valuable in achieving pregnancy in older women.

Both safety and ethical concerns have been raised about cytoplasmic transfer. Firstly, the technique is new and its safety with respect to children born following the use of the technique is yet to be established. Additionally, any live-born child may have DNA from three separate people, which poses 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 clear at this stage.

The wording of this clause avoids explicit reference to cytoplasmic transfer and instead prohibits the creation of human embryos with genetic material from more than two people. In this way, the prohibition applies broadly to include other techniques, current or future, that may 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 by more than two persons is 10 years' imprisonment under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 13 – Offence – developing a human embryo outside the body of a woman for more than 14 days*

This clause makes it an offence to intentionally develop a human embryo created outside the body of a woman beyond 14 days. This does not include any time that the embryo's development is suspended whilst in storage (eg. while the embryo is frozen).

In practice, this means that human embryos created by assisted reproductive technology must be implanted, stored or allowed to succumb (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 10 that bans the creation of a human embryo by a 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, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 14 – Offence – using precursor cells from a human embryo or a human foetus to create a human embryo, or developing such an embryo*

This clause prohibits the creation of a human embryo with cells 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 that has been created with precursor cells of eggs or sperm taken from an embryo or foetus.

The practice is prohibited, as it would result in the birth of children who have had no 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, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 15 – 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 an 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 under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 16 – Offence – collecting a viable human embryo from the body of a woman*

This clause prohibits the removal of a viable human embryo 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, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 17 – Offence – creating a chimeric or hybrid embryo*

This clause makes it an offence to intentionally create a chimeric embryo or to intentionally create a hybrid embryo. These terms are defined in the Schedule, and are intended to include embryos created using combinations of animal and human reproductive materials.

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* (Cth) and the *Gene Technology Act 2001* (Qld).

The maximum penalty for creating, or developing, a hybrid or chimeric embryo is 10 years' imprisonment, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 18 – Offence – placing of an embryo*

This clause makes it an offence to place –

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

It may be possible in the future for a human embryo to be developed into a foetus outside the body of a woman. This would be prevented by clause 13 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, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 19 – Offence – placing a prohibited embryo*

This clause prevents the intentional placement of any embryo prohibited by clauses 10 to 17 inclusive, in the body of a woman.

The Commonwealth *Prohibition of Human Cloning Act 2002* includes both this prohibition on placement and an additional prohibition on importation of these same prohibited embryos. This is to remove the possibility that one person would 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 forming the national regulatory scheme. Including exportation of a prohibited embryo as an offence under the Commonwealth Act ensures that a person cannot import a prohibited embryo that has been illegally created or obtained.

Under this national regulatory regime, the practice of importing or exporting embryos (that have been created by fertilisation of a human egg by human sperm) for the ART treatment of a particular couple, will be permitted to continue, subject to other legislation such as the *Quarantine Act 1908* (Cth) or the *Customs Act 1901* (Cth). This may occur, for example, where a couple have had embryos created for the purposes of ART in another country, subsequently move to Australia, and wish to continue their ART treatment program in Australia.

However, the Commonwealth Government has undertaken to address concerns discussed during the Senate debate of the *Research Involving Embryos Bill 2002*, by making amendments to the:

- *Customs (Prohibited Export) Regulation 1958* (Cth) to prohibit the export of all human embryos for a period of 12 months. During this 12 month period the Government will assess appropriate regulation of this area; and
- *Customs (Prohibited Import) Regulations 1958* to prohibit the import of certain materials derived from human embryo clones created overseas.

When these amendments are made, they may impact on Queensland patients of ART clinics who wish to export their embryos to continue their fertility treatment in another country.

The maximum penalty for importing, exporting or placing in the body of a woman a prohibited embryo is 10 years' imprisonment, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

*Clause 20 – Offence – commercial trading in human eggs, human sperm or human embryos*

This clause makes it an offence to trade commercially in human eggs, sperm and embryos. Both the person who sells the egg, sperm or embryo, and the person who purchases the egg, sperm or embryo, would commit an offence. 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. Similarly, if a woman is to be treated with donated eggs, it would not be unlawful for her to pay for the cost of egg retrieval from another woman.

Subclause 20(3) This clause provides that 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. Therefore, if a person wishes to donate embryos that are excess to their needs, they cannot have the costs of their ART treatment reimbursed by the person receiving the donated embryos.

The maximum penalty for trading in human embryos, sperm or eggs is 10 years' imprisonment, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 10.

## PART 3 – REGULATION OF CERTAIN USES INVOLVING EXCESS ART EMBRYOS

### DIVISION 1 – Interpretation

*Clause 21 – Definitions*

This clause sets out a number of definitions for words and phrases used in Part 3 of the Bill. Key definitions include:

***accredited ART centre –*** this is defined to mean a person or body accredited to carry out assisted reproductive technology by an accreditation body prescribed under a regulation.

The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia currently oversees a system of industry-based accreditation for ART clinics, and sets 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. It is anticipated that RTAC would be prescribed in the initial regulation made under this section.

***proper consent*** is defined in relation to the use of an excess ART embryo. It means consent that is obtained in accordance with the current NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) or any other guidelines issued under the *National Health and Medical Research Council Act 1992* and prescribed under a regulation. The power to prescribe alternative or additional guidelines in a regulation 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 under review and it is likely that new guidelines will be issued during 2003. These new guidelines could be prescribed in a regulation to replace the current guidelines.

***responsible person***, in relation to an excess ART embryo, is defined to mean each person who donated egg or sperm from which the embryo was created (and their spouse – if they had one at the time of the donation) and the woman for whom the embryo was created, for the purpose of achieving her pregnancy (and her spouse – if she had one at the time the embryo was created). This definition sets out each person required to have given consent for an excess ART embryo to be used for research, before a researcher may commence activities for which they have a licence.

*Clause 22 – Meaning of excess ART embryo*

Sub-clause 22(1) defines what is meant by an "excess ART embryo", which are those embryos which may be available for research.

To be excess it is necessary 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 her spouse (if she had one at the time the embryo was created).

Sub-clause 22(2) additionally 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) have 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 – Offences

*Clause 23 – Offence – use of excess ART embryo*

Sub-clause 23(1) essentially describes the scope of the regulatory scheme for excess ART embryos. It creates an offence to intentionally use an excess ART embryo without a licence. 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 23(2).

Sub-clause 23(2) 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);
- transportation 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 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 this instance, the suitability of the embryo for implantation must be determined on the basis of its biological fitness for implantation. The procedure must also be undertaken on the embryo for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it 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 treatment techniques);
- to train clinical and laboratory staff 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 effect of sub-clause 23(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 five years' imprisonment, under both this Bill and the Commonwealth *Research Involving Human Embryos Act 2002*.

There are complex issues of constitutional jurisdiction underpinning the national scheme, which mean that the facts of a case will determine

whether an alleged offence is prosecuted under the Commonwealth Act or the Queensland Act. An alleged offence will not be prosecuted under both.

If an alleged offence is prosecuted under Commonwealth jurisdiction, a court may, at its discretion, supplement the imprisonment term with a monetary penalty or convert the imprisonment term to a monetary penalty of up to $165,000 for a corporation and $33,000 for an individual.

If an alleged offence is prosecuted under Queensland jurisdiction, the equivalent financial penalty for an individual convicted in the District Court is restricted to a maximum of approximately $313,125 (4,176 penalty units). The Supreme Court may issue an unlimited financial penalty.

Sub-clause 23(3) provides that, despite sub-section 13.3(3) of the Commonwealth Criminal Code, a defendant does not bear an evidential burden in relation to any matter in sub-section (1) of this section. This subclause clarifies that the burden of proof is not reversed.

This clause is not required by, nor relevant to, the Queensland Criminal Code but has been included to provide consistency with the Commonwealth *Research Involving Human Embryos Act 2002* and to ensure prosecutions are carried out in a nationally consistent manner.

*Clause 24 – Offence – use of embryo that is not an excess embryo*

This clause provides that it is an offence to intentionally use a non-excess ART embryo unless the use is part of assisted reproductive technology treatment 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.

Currently, ART programs are accredited with the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. Adherence to the RTAC *Code of Practice for Centres Using Assisted Reproductive Technology*, is the basis for accreditation of ART clinics. It is anticipated that RTAC would be prescribed in a regulation.

The maximum penalty for an offence under this clause is five years' imprisonment, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 23.

*Clause 25 – Offence – breaching a licence condition*

Clause 25 provides that a person commits 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. If a person is reckless as to whether or not the act or omission will contravene a condition of licence, they have also committed an offence.

The maximum penalty for breaching a condition of licence is 5 year's imprisonment, under both this Bill and the corresponding Commonwealth Act. The potential for financial penalties to be incurred is outlined under clause 23.

## DIVISION 3 – Embryo Research Licensing Committee of the NHMRC

*Establishment of Committee*

The Commonwealth *Research Involving Human Embryos Act 2002* establishes the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee) as a Principal Committee of the NHMRC.

The NHMRC Licensing Committee will be tasked with considering licence applications under this Bill and the Commonwealth Act in relation to the use of excess ART embryos.

The *National Health and Medical Research Council Act 1992* (Cth) (the NHMRC Act) establishes the NHMRC and two Principal Committees – the Research Committee and the Australian Health Ethics Committee (AHEC). The purpose of the provision in the Commonwealth Act is to establish the new NHMRC Licensing Committee as a Principal Committee of the NHMRC. By establishing the Committee in that Bill, the Committee automatically becomes a Principal Committee of the NHMRC for the purposes of the NHMRC Act.

*Clause 26 – Functions of Committee*

This clause provides that the NHMRC Licensing Committee will carry out the following functions –

- considering licence applications;
- refusing licences or granting licences including subject to conditions;
- notifying relevant people of the Committee's decision about an 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 activity involving excess ART embryos that has been licensed by the Committee;
- monitoring compliance with the legislation (the NHMRC Licensing Committee may also delegate this function to a Commonwealth or State officer) and taking any necessary enforcement action; and
- providing information about the Committee's functions for inclusion in the NHMRC annual report and reporting to Parliament.

The effect of this clause is to confer powers on the NHMRC Licensing Committee to carry out these functions for this Act.

*Clause 27 – Powers of Committee*

This clause provides for the NHMRC Licensing Committee to have the power necessary to carry out the functions and duties assigned to the Committee under this Bill.

*Membership of Committee*

The Commonwealth *Research Involving Human Embryos Act 2002* prescribes members to be appointed to the NHMRC Licensing Committee and the terms of their appointment.

Section 16 of the Commonwealth Act provides that the NHMRC Licensing Committee will comprise nine members as follows –

- a member of AHEC;
- a person with expertise in research ethics;
- a person with expertise in a relevant area of research;
- a person with expertise in assisted reproductive technology;
- a person with expertise in a relevant area of law;
- a person with expertise in consumer health issues as they relate to disability and disease;

- a person with expertise in consumer issues relating to assisted reproductive technology;
- a person with expertise in the regulation of assisted reproductive technology; and
- a person with expertise in embryology.

The members of the NHMRC Licensing Committee must be appointed by the Commonwealth Minister with responsibility for the *Research Involving Human Embryos Act 2002* (Cth). Before appointing any members to the NHMRC Licensing Committee, the Commonwealth Minister must seek nominations from the organisations prescribed in regulation under that Act. The Commonwealth Minister must also seek nominations from all States and Territories, consult the States and Territories on proposed appointments and have regard to the views expressed by the States and Territories. The Commonwealth Minister must ensure that before any appointment is made, the proposed member does not have a direct or indirect pecuniary interest which would conflict with the proper performance of their function as a member of the NHMRC Licensing Committee.

The Commonwealth Minister must appoint one of these members as Chairperson. The Commonwealth *Research Involving Human Embryos Act 2002* expressly provides that the AHEC member must not be appointed as the Chairperson of the NHMRC Licensing Committee. This is important because otherwise it would theoretically be possible for a member of AHEC to be both the Chairperson of AHEC and the Chairperson of the NHMRC Licensing Committee. On a practical level, the workload would be considerable if an AHEC member were also the Chairperson of the NHMRC Licensing Committee. Further, such an arrangement could pose potential conflicts of interest.

In appointing members to the NHMRC Licensing Committee, the Commonwealth Act also requires the Commonwealth Minister to have regard to the desirability of ensuring that the Committee as a whole comprises members from different States and Territories.

*Terms of appointment*

The Commonwealth Act provides that members of the NHMRC Licensing Committee hold office on a part-time basis and for a period specified, which must not exceed three years. Members may be reappointed for further terms. This is consistent with the appointment terms for the NHMRC and its other Principal Committees.

*Annual Report*

Under section 83 of the *National Health and Medical Research Council Act 1992*, the NHMRC must prepare an annual report and provide it to the responsible Commonwealth Minister. The Minister is required to table the report in Commonwealth Parliament. The Commonwealth legislation requires the NHMRC Licensing Committee to provide details of its operations for inclusion in the annual report.

*Reports to Parliament*

The Commonwealth Act provides for the NHMRC Licensing Committee to cause a report to Commonwealth Parliament at any time should the NHMRC Licensing Committee consider this necessary. The NHMRC Licensing Committee must provide a copy of the report to the responsible Commonwealth Minister and to each State and Territory.

The NHMRC Licensing Committee is also required to provide reports on the operation of the scheme and licences issued under the scheme every six months to either House of Commonwealth Parliament.

## DIVISION 4 – Licensing system

*Clause 28 – Person may apply for licence*

This clause provides that a person may apply to the NHMRC Licensing Committee for a licence under this Act. 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 information that should be included in any application.

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

*Clause 29 – Determination of application by Committee*

This clause describes the matters that must be considered by the NHMRC Licensing Committee when deciding whether or not to issue a licence.

Sub-clause 29(3) provides that the NHMRC Licensing Committee must not issue a 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 activity (should the licence be approved) have been created before 5 April 2002; and

- the proposed research 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 29(4) provides that, in deciding whether to issue a licence, the NHMRC Licensing Committee must have regard to the following –

- restricting the number of excess ART embryos to that 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, under the NHMRC Act and prescribed under a regulation. For example, the NHMRC 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

- any additional matters prescribed by a regulation.

*Clause 30 – 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 31 – Period of licence*

Clause 31 provides that a licence comes into force on the day specified in the licence or, if no date is specified, the day that the licence is issued and continues until the day specified in the licence unless it is suspended, revoked or surrendered before that day. The clause clarifies that a licence is not in force throughout any period of suspension.

*Clause 32 – Licence is subject to conditions*

This clause confers powers on the NHMRC Licensing Committee to impose conditions on licences issued under this Act.

Sub-clauses 32(1), (2) and (3) describe the conditions with which all licence holders must comply. Before a person can commence using an excess ART embryo under a licence issued by the NHMRC Licensing Committee, the licence holder must provide written notice to the NHMRC Licensing Committee-

- that consent has been obtained for the use of all the embryos, in accordance with the protocol considered by the NHMRC Licensing Committee; and
- of any restrictions on the use of the embryos (as determined by the responsible persons); and
- in the case of uses 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 responsible persons. 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 32(4) and (5) confer powers on the NHMRC Licensing Committee to impose any other conditions that are necessary, and provide

examples of the types of conditions the NHMRC Licensing Committee may impose. For example, the NHMRC Licensing Committee may impose conditions relating to-

- the persons or classes of person, authorised by the licence to use the excess ART embryos;
- the number of excess ART embryos in respect of which use is authorised by the licence;
- reporting;
- monitoring; and
- information to be given by the licence holder to persons authorised by the licence to use excess ART embryos.

Sub-clause 32(6) provides that the conditions included in sub-clauses 32(1), (2) and (3) are applicable to all people who are authorised by the licence to use excess ART embryos.

Sub-clause 32(7) provides that licence conditions are applicable to the licence holder and to any other people who are authorised by the licence to use excess ART embryos as specified in the licence.

*Clause 33 – Variation of licence*

This clause confers powers on the NHMRC Licensing Committee to vary a licence issued under this Act. 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, the NHMRC Licensing Committee may wish to add conditions, change the wording of existing conditions or delete existing conditions of a licence.

Sub-clause 33(4) clarifies that the NHMRC Licensing Committee can not vary a licence so that the varied licence would be contrary to the requirements for a licence. For example, the NHMRC Licensing Committee could not vary the licence after it has been issued so as to allow a use of embryos without proper consent having been obtained.

*Clause 34 – Suspension or revocation of licence*

This clause confers power on 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 issued under this Act has been breached. The NHMRC Licensing Committee must also revoke each licence held by a licence holder convicted of an offence under this Act.

This clause provides an important safeguard because it enables the NHMRC Licensing Committee to take immediate action in the event of apparent non-compliance. By suspending or revoking a licence the work can no longer continue.

The NHMRC Licensing Committee has the power to reinstate 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 a 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.

*Clause 35 – 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 36 – Notification 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 body to which it notified its original decision. This ensures that the State Government is 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 5 – Reporting and confidentiality

*Clause 37 – 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 under this Act. The clause allows for the database information under this Act to be kept as part of a broader national database.

Sub-clause 37(1) provides that the database must include the following information in relation to each licence-

- the name of the person to whom the licence was issued. Under Commonwealth legislation this would be a corporation or other legal entity. The names of individual people will not be included on the database without the express consent of the person in accordance with the *Privacy Act 1988* (Cth);
- 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;
- the conditions of licence;
- 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 requirements to report on the number of embryos 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;
- the date on which the licence was issued; and
- 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.

*Clause 38 – 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 21 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 effect of clause 38 is that the NHMRC Licensing Committee can decide not to release certain information in the public domain (for example, by inclusion on the database established by clause 37) if the Committee is satisfied that the information is commercial information or other information (such as research findings) that has a value that would be, or could reasonably be expected to be, destroyed or diminished as the result of disclosure.

The Commonwealth *Research Involving Human Embryos Act 2002* provides that the NHMRC Licensing Committee, which has access to confidential commercial information provided in licence applications, may only disclose the information to States, Territories and to relevant Commonwealth agencies. The State would only be allowed to disclose confidential commercial information obtained in administering this Act to the Commonwealth and other States.

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 6 – Review provisions

*Clause 39 – Meaning of terms*

This clause provides for persons who are able to seek review of 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 not to issue a licence; and
- the licence holder in relation to –
    - a decision relating to the period of a licence;

- a condition of licence imposed; and
- a decision to vary, refuse to vary, suspend or revoke a licence.

*Clause 40 – Review of decisions*

Sub-clause 40(1) provides that an eligible person (as defined in clause 39) may apply to the Commonwealth Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee made under this Act –

- a decision under clause 29 not to issue a licence;
- a decision in respect of the period throughout which the licence is to be in force under clause 31;
- a decision to specify a licence condition under sub-clause 32(4);
- a decision to vary or refuse to vary a licence under clause 33; or
- a decision to suspend or revoke a licence under clause 34.

If the Commonwealth declares decisions made under this Act to be "reviewable State decisions", then a decision of the NHMRC Licensing Committee can by reviewed by the Commonwealth Administrative Appeals Tribunal.

Sub-clause 40(2) provides that clause 40 has effect subject to the *Administrative Appeals Tribunal Act 1975* (Cth). This clause provides the capacity for the Administrative Appeals Tribunal to review decisions made under this Act where the decision by the NHMRC Licensing Committee is actually made under this Act.

Sub-clause 40(4) provides that for the purposes of this clause the *Administrative Appeals Tribunal Act 1975* (Cth) has effect as if this Act were an enactment of the Commonwealth.

## PART 4 – MONITORING POWERS

*Clause 41 – Appointment of inspectors*

Sub-clause 41(1) confers powers on the Chairperson of the NHMRC Licensing Committee to appoint inspectors for the purposes of exercising all the powers under this Part of this Bill. The Chairperson of the NHMRC

Licensing Committee may appoint Commonwealth or State employees as inspectors. The Chairperson of the Licensing Committee must also ensure that each person appointed as an inspector has appropriate skills and experience (sub-clause 41(3)).

Sub-clause 41(2) requires a person appointed as an inspector under this Act to comply with any directions of the Chairperson of the NHMRC Licensing Committee when exercising powers or performing functions in that capacity.

*Clause 42 – Identity card*

Sub-clauses 42(1) and 42(2) require the Chairperson of the NHMRC Licensing Committee to issue an identity card, in a form prescribed by the Commonwealth regulations, to every person appointed as an inspector. The identity card must have a recent photograph of the inspector.

Sub-clause 42(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, which is equivalent to $110 under the Commonwealth jurisdiction and $75 under the Queensland jurisdiction.

Sub-clause 42(4) requires the inspector to carry his or her identity card at all times when exercising powers or performing functions as an inspector.

*Clause 43 – Powers available to inspectors for monitoring compliance*

Sub-clause 43(1) provides that an inspector may enter any premises and exercise any or all of the powers set out in clause 44 for the purposes of establishing whether or not the Act or regulations are being complied with. However, sub-clause 43(2) provides that an inspector may only enter premises 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 44 – 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 45 – 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 46 – 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 47 – Consent*

Sub-clause 47(1) provides that, before obtaining consent from a person to enter premises under paragraph 43(2)(a), the inspector must inform the person that he or she may refuse consent.

Sub-clause 47(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

*Clause 48 – 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 acting under this Act, and the damage resulted from insufficient care being exercised by the inspector in operating the equipment, compensation is payable to the owner.

*Sections of the Commonwealth Act on Commonwealth/State Arrangements*

*Operation of State laws*

The Commonwealth Acts both provide that the Commonwealth Acts are not intended to exclude the operation of State and Territory laws except where the State or Territory laws are inconsistent with the Commonwealth Acts and cannot operate concurrently. It is beyond the competence of the State to include that clause in this Bill.

*Conferral of functions on Commonwealth officers and bodies*

The Commonwealth *Research Involving Human Embryos Act 2002* enables the responsible Commonwealth Minister to declare a corresponding State law which may confer functions, powers and duties on

the NHMRC Licensing Committee, a Commonwealth authority and an office of the Commonwealth or a Commonwealth authority and to empower a person or body on whom a function, power, or duty is conferred, to perform the function or duty, or exercise the power.

This, combined with provisions in this Bill, provides for the effective operation of the national scheme relating to the regulation of uses of excess ART embryos. It is anticipated that all States and Territories will implement legislation which will be dealared to be a corresponding law. The Commonwealth *Research Involving Human Embryos Act 2002* effectively enables this Bill, as a corresponding State law, to provide that the licensing functions exercised under a State law will actually be undertaken by the NHMRC Licensing Committee. It is not intended that there be dual licensing systems in any jurisdictions. Rather, this national regulatory scheme means that anyone wishing to undertake work using excess ART embryos (other than exempt uses), would need to apply for a licence from the NHMRC Licensing Committee. This applies whether or not they are organisations that come within the scope of the Commonwealth's constitutional powers or State powers under this Bill.

*When duty imposed*

The Commonwealth *Research Involving Human Embryos Act 2002* recognises that there are constitutional doctrines that restrict the duties that may be imposed on a Commonwealth officer or Commonwealth authority by State laws. Recognising these doctrines, the Commonwealth Act clarifies that the extent to which duties may be imposed on the NHMRC Licensing Committee, Commonwealth authorities or Commonwealth officers, by corresponding State laws, is limited by such doctrines.

The Commonwealth Act clarifies that any duty purported to be imposed by a State law is taken to be imposed by force of a State law where State legislative power is sufficient to support that duty. Where such power does not exist, to ensure the validity of the duty's imposition, reliance is then to be placed on Commonwealth legislative power if it is sufficient to support the duty.

The Commonwealth *Research Involving Human Embryos Act 2002* also clarifies that, if the imposition of a duty on a Commonwealth officer or authority under applied State law contravenes a relevant constitutional doctrine or exceeds the legislative power of both the State and the Commonwealth, the State law is not taken to confer a duty on the Commonwealth officer or authority.

# PART 5 – MISCELLANEOUS

## DIVISION 1 – Review of Act

*Repeal of paragraphs 36(3)(b) and 39(1)(c) and subsection 39(3)*

The Commonwealth *Research Involving Human Embryos Act 2002* gives effect to the Council of Australian Governments' decision that the restriction on the use of excess ART embryos created after 5 April 2002 will cease to have effect on 5 April 2005, unless an earlier time is agreed by the Council of Australian Governments.

In this Bill, the same decision is given effect through provisions in Part 6 Division 1 and the commencement provision in clause 2(2).

*Clause 49 – Review of operation of Act*

Sub-clause 49(1) provides that the Queensland Minister responsible for this Act must cause a review of this Act to start two years after this section is commenced.

Sub-clause 49(2) describes the nature and scope of the review, particularly taking into account developments in assisted reproductive technology, scientific and research developments, the potential therapeutic applications of any research and community standards. The review must also take into account the applicability of establishing a National Stem Cell Bank.

Sub-clause 49(3) provides that a review of this Act may be undertaken as part of the reviews of the Commonwealth *Research Involving Human Embryos Act 2002* and the Commonwealth *Prohibition on Human Cloning Act 2002*.

The Commonwealth *Research Involving Human Embryos Act 2002* contains other clauses regarding the nature of the review to be carried out by the Commonwealth of that Act, concurrently with the review of the Commonwealth *Prohibition of Human Cloning Act 2002*. It also notes that States and Territories must be consulted in that review process.

This clause of the Bill has been drafted to take into account the importance of national consistency and allow for the Queensland Act to be reviewed in conjunction with the Commonwealth Acts as part of a consistent national regulatory regime.

## DIVISION 2 – Matters about offences

*Clause 50 – Attempts to commit offences against this Act*

This clause clarifies that an attempt to commit an offence carries the same maximum penalty as if the offence were committed. It has been included here to provide national consistency. As the scheme establishes criminal offences under both Commonwealth Acts and this Bill, it necessarily requires the interaction of State and Commonwealth Criminal Codes. The Commonwealth Criminal Code provides that an attempt to commit a criminal offence attracts the same maximum penalty as if the offence had been committed. The Queensland Criminal Code provides that an attempt to commit a criminal offence attracts a lesser maximum penalty. Therefore, the creation of criminal offences under the Commonwealth Acts include attempts to commit the offence. This clause of the Bill has been included to ensure prosecutions are carried out in a nationally consistent manner.

*Clause 51 – Crimes and summary offences*

This clause specifies which offences in the Bill are crimes and which are summary offences. This clause also provides that an offender cannot be arrested without a warrant.

*Clause 52 – Limitation on time for starting summary proceedings*

This clause places a limit on commencing proceedings for summary offences to one year after the offence occurred, or within six months of the offence coming to the complainant's knowledge, but within two years after the offence has been committed.

## DIVISION 3 – Regulations

*Clause 53 – Regulation-making power*

This clause empowers the Governor in Council to make regulations.

# PART 6 – AMENDMENT OF ACTS

## DIVISION 1 – Amendment of this Act

*Clauses 54 and 55 – Amendment of various sections*

These clauses, in conjunction with clause 2(2) give effect to the Council of Australian Governments' decision that the regulation restricting the use of excess ART embryos created after 5 April 2002 will cease to have effect on 5 April 2005, unless an earlier time is agreed by the Council of Australian Governments.

## Division 2 – Amendment of the *Gene Technology Act 2001*

*Clauses 56, 57, 58 and 59 – Amendments to sections of the Gene Technology Act 2001*

These clauses amend notes contained in the *Gene Technology Act 2001* (Qld) that make reference to the recently repealed equivalent provisions of the Commonwealth *Gene Technology Act 2000*, which banned human cloning, certain experiments involving animal eggs and certain experiments involving putting human and animal cells into a human uterus.

## SCHEDULE – Dictionary

The Schedule sets out a number of definitions for words and phrases used in 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. Key definitions which are essential to defining the scope of the legislation and describing how it will be administered, include the following:

***human embryo*** which is defined to mean a live embryo that has a human genome or an altered human genome, that has been developing for less than eight weeks since-

- the appearance of two pro-nuclei; or
- the initiation of development by other means.

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 as there may be other ways that the development of an embryo may be initiated.

Sub-clause 5(3) 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 any embryo is placed in storage two days after fertilisation and is held in storage for 10 weeks, it is still considered to be a two-day embryo in terms of its development.

***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.

Sub-clause 5(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 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.

Sub-clause 5(4) 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.