

2002

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

RESEARCH INVOLVING EMBRYOS BILL 2002

REVISED EXPLANATORY MEMORANDUM

(Circulated by authority of the Prime Minister, the Hon John Howard MP)

RESEARCH INVOLVING EMBRYOS BILL 2002

OUTLINE

This Bill forms part of a national regulatory system to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos. This is to be achieved through a regulatory framework, which regulates activities that involve the use of certain human embryos created by assisted reproductive technology.

This Bill was originally introduced into Parliament as the Research Involving Embryos and Prohibition of Human Cloning Bill 2002. On 29 August 2002 the House of Representatives voted to amend the Bill by dividing it into two separate pieces of legislation – the Research Involving Embryos Bill 2002 and the Prohibition of Human Cloning Bill 2002.

Consistent with its object, the Bill:

- (a) establishes a Principal Committee within the National Health and Medical Research Council (NHMRC), the NHMRC Embryo Research Licensing Committee (the NHMRC Licensing Committee), for the purposes of performing functions and exercising powers under the Bill;
- (b) 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
- (c) provides for a centralised, publicly available database of information about all licences issued by the NHMRC Licensing Committee.

FINANCIAL IMPACT STATEMENT

In developing and implementing the Research Involving Embryos Bill 2002, the Government will incur both establishment costs and ongoing costs.

Following the passage of the legislation, costs are realistically 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, as included in the Prohibition of Human Cloning Bill 2002. There is also a variable cost, related to the number of applications received. While it is not possible to accurately predict this, the above estimate includes up to 120 applications per year, based on recent consultation with ART service providers and researchers. Establishment costs involve:

- developing administrative processes for receiving and processing applications and issuing licences;
- establishing the new NHMRC Licensing Committee;
- recruiting appropriately skilled staff;

- establishing a skilled inspectorate to ensure compliance with the Act through monitoring and inspection;
- assessment of research proposals; and
- establishment and maintenance of data systems and public reporting.

REGULATION IMPACT STATEMENT

Please refer to Attachment 1 to this Explanatory Memorandum.

RESEARCH INVOLVING EMBRYOS BILL 2002

NOTES ON CLAUSES

PART 1 - PRELIMINARY

Clause 1 – Short title

This is a formal provision that specifies the short title of the Bill as the *Research Involving Embryos Act 2002*.

Clause 2 – Commencement

Sub-clause 2(1) provides that the various provisions take effect on the date specified in the table.

Item 1 of the table provides that clauses 1 and 2 of the Bill commence on the day on which the Bill receives Royal Assent.

Item 2 of the table provides that clauses 3 to 9 will commence 28 days after the day on which the Bill receives Royal Assent. These clauses relate to the preliminary matters in the Bill and to the definitions relevant to the regulation of excess ART embryos.

Item 3 of the table provides that clauses 10 to 12 will commence 6 months after the day on which the Bill receives Royal Assent. Clause 10 provides that a person must not use an excess ART embryo unless that use is an exempt use or is authorised by a licence issued by the NHMRC Embryo Research Licensing Committee. Clause 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. Clause 12 provides that a person must comply with any conditions of a licence.

The delay of commencement for these clauses is to allow time:

- for the establishment of the new NHMRC Licensing Committee; and
- for applications for licences to be made.

During this 6 month transitional period researchers and others will continue to have to comply with existing State legislation and the NHMRC *Ethical Guidelines on ART* (1996).

Delaying the commencement of these clauses for 6 months will also allow States and Territories to introduce complementary legislation and, where necessary, repeal existing provisions of State legislation that ban the use of excess ART embryos.

Item 4 of the table provides that clauses 13 to 48 will commence 28 days after the day on which the Bill receives Royal Assent. These clauses provide, among other things, for the establishment and administration of the NHMRC Licensing Committee as well as provisions on the review of the Act and regulations to be made under the Act.

Clause 3 – Object of Act

This clause provides that the object of this Bill is to address concerns, including ethical concerns, about scientific developments in relation to the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology.

Clause 4 – Operation of Act

This clause sets out the constitutional powers on which it is proposed that the Commonwealth legislation will rely.

The Commonwealth legislation will rely on:

- the Corporations power (paragraph 51(xx) of the Constitution). This means that the Act will apply to all things done by corporations formed within the limits of the Commonwealth;
- the trade and commerce power (paragraph 51(i) of the Constitution). This means that the Act will apply to all things done in the course of trade and commerce;
- the external affairs power (paragraph 51(xxix) of the Constitution). This enables the Act to apply to matters of international concern;
- powers of the Parliament in relation to the Commonwealth (section 52 of the Constitution). This means the Act will apply to all things done by the Commonwealth and Commonwealth authorities (including Commonwealth Departments such as the Department of Health and Ageing, Commonwealth statutory authorities and Commonwealth companies);
- the census and statistics power (paragraph 51(xi) of the Constitution). This enables the Act to apply for purposes relating to the collection, compilation, analysis and dissemination of statistics (such as the provisions relating to the establishment of a database of licences issued by the NHMRC Licensing Committee); and
- incidental power (paragraph 51(xxxix) of the Constitution). This enables the establishment of the infrastructure necessary to support the regulatory system.

Clause 5 – Act to bind the Crown

Sub-clause 5(1) provides that the Bill will bind the Crown in each of its capacities.

Sub-clause 5(2) provides that the Crown may not be prosecuted for a criminal offence under this Bill.

Clause 6 – External Territories

This clause provides that the Bill will have application in every external Territory. Therefore, the legislation will cover, for example, Norfolk Island, the Indian Ocean Territories (Cocos and Christmas Islands), Macquarie and Heard Islands, the Australian Antarctic Territory and the Jervis Bay Territory.

Clause 7 – Definitions

This clause 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 8 weeks since:

- the appearance of 2 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 includes 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 1 – Interpretation

Clause 8 – Definitions

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.

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

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

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

Clause 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 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) 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 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(2).

Sub-clause 10(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);
- 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. 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.

Clause 11 – Offence – use of embryo that is not an 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.

Sub-clause 11(2) defines an “ART program” as an assisted reproductive technology program carried out in accordance with the *Code of Practice for Centres Using Assisted Reproductive Technology* issued by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia (which is used as the basis for accrediting ART clinics) or any similar code as prescribed in regulations.

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 which may, at the discretion of the Courts be supplemented by, or converted to a monetary penalty of up to \$165,000 for a corporation and \$33,000 for an individual.

Clause 12 – Offence – breaching a 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 which may, at the discretion of the Courts be supplemented by, or converted to a monetary penalty of up to \$165,000 for a corporation and \$33,000 for an individual.

DIVISION 3 – Embryo Research Licensing Committee of the NHMRC

Clause 13 – Establishment of Committee

This clause establishes the NHMRC Licensing Committee as a Principal Committee of the NHMRC. As detailed in relation to clause 14, the NHMRC Licensing Committee will be tasked with considering licence applications in relation to the use of excess ART embryos.

The *National Health and Medical Research Council Act 1992* (the NHMRC Act) establishes the NHMRC and two Principal Committees – the Research Committee and the Australian Health Ethics Committee (AHEC). The purpose of clause 13 of this Bill is to establish the new NHMRC Licensing Committee as a Principal Committee of the NHMRC. By establishing the Committee in this Bill, the Committee automatically becomes a Principal Committee of the NHMRC for the purposes of the NHMRC Act.

By establishing the NHMRC Licensing Committee as a Principal Committee for the purposes of the NHMRC Act this means that many of the provisions in the NHMRC Act that apply to Principal Committees generally will also apply to this Committee. This avoids the need to re-state all of these provisions in this Bill. The following sections of the NHMRC Act will apply in respect of the operations of the NHMRC Licensing Committee:

- section 37A - responsibilities of the Chairperson and Deputy Chairperson;
- section 38 - operating procedures;
- section 39 - working committees;
- section 40 - arrangements to assist committees;
- section 41 - remuneration and allowances;
- section 42 - leave of absence;
- section 43 - resignation;
- section 44 - termination of appointment;
- section 81 - protection from civil actions; and
- section 82(3), (4) and (5) - delegations.

Sub-clause 13(2) provides that the following clauses of the NHMRC Act will not apply to the NHMRC Licensing Committee:

- section 10 - allowing the Minister to issue certain directions to the NHMRC and other Principal Committees;
- section 35 - relating to appointment of committee members (see clause 16, below);
- section 80 - treatment of confidential commercial information; and
- subsection 82(2) of the NHMRC Act – delegations from the NHMRC to the NHMRC Licensing Committee.

Sub-clauses 13(4) and (5) provide that regulations may include disclosure of interest provisions. If such regulations are in force, these override the current NHMRC

disclosure of interest provisions which are detailed as part of NHMRC committee procedures made under paragraph 38(b)(vi) of the NHMRC Act.

Clause 14 – 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;
- 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;
- 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.

Clause 15 – Powers of Committee

This clause provides that the NHMRC Licensing Committee has power to do all things needed to be done in connection with the performance of the NHMRC Licensing Committee’s functions.

Clause 16 – Membership of Committee

This clause describes the members to be appointed to the NHMRC Licensing Committee and the means for appointing such members.

Sub-clause 16(1) provides that the NHMRC Licensing Committee will be comprised of 9 members as follows:

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

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

The members of the NHMRC Licensing Committee must be appointed by the Minister with portfolio responsibility for this Act. Before appointing any members to the NHMRC Licensing Committee the Minister must seek nominations from the organisations described in regulations accompanying this legislation. Placing the list of organisations in the regulations enables the list to be updated relatively simply as organisations change their name or as new organisations are formed that should be consulted. The 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.

Sub-clause 16(4) expressly provides that the AHEC member must not be appointed as the Chair of the NHMRC Licensing Committee. This is important because otherwise it would theoretically be possible for a member of AHEC to be both the Chair of AHEC and the Chair of the NHMRC Licensing Committee. On a practical level the workload would be considerable if an AHEC member were also the Chair of the NHMRC Licensing Committee. Further, such an arrangement could pose potential conflicts of interest.

Sub-clause 16(5) provides that before appointing the Chair of the Committee, or the person with expertise in the regulation of assisted reproductive technology, the Minister must have the majority agreement of the States and Territories.

Sub-clause 16(6) provides that in appointing members to the NHMRC Licensing Committee the Minister must also have regard to the desirability of ensuring that the Committee as a whole comprises members from different States and Territories.

Clause 17 – Terms of appointment

This clause clarifies that members of the NHMRC Licensing Committee hold office on a part-time basis and for the period specified in their instrument of appointment which must not exceed 3 years. Members may be reappointed for further terms. This is consistent with the appointment terms for the NHMRC and its other Principal Committees.

Clause 18 – Annual Report

Under section 83 of the *National Health and Medical Research Council Act 1992*, the NHMRC must prepare an Annual Report. The NHMRC is required to provide its Annual Report to the Minister as soon as practicable after the end of each calendar year and the Minister is required to table the report in Federal Parliament within 15 sitting days after receiving the Report.

This clause provides that the NHMRC Licensing Committee must provide details of its operations to the NHMRC for inclusion in the NHMRC Annual Report.

Clause 19 – Reports to Parliament

This clause enables the NHMRC Licensing Committee to make a Report to Parliament at any time should the NHMRC Licensing Committee consider this necessary. The clause provides that the NHMRC Licensing Committee must provide a copy of the report to the responsible Minister and to each State and Territory.

DIVISION 4 – Licensing System

Clause 20 – 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 21 – 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. 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 21(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 21(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 22 – 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 23 – 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 23(2) clarifies that a licence is not in force throughout any period of suspension.

Clause 24 – 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 24(1), (2) and (3) describe the conditions that all licence holders must comply with. These sub-clauses provide that before a person can commence using an excess ART embryo (under a licence issued by the NHMRC Licensing Committee), the licence holder must confirm with the NHMRC Licensing Committee (by notice in writing):

- that consent has been obtained for the use of all the embryos, in accordance with the protocol considered by the NHMRC Licensing Committee;
- any restrictions on the use of the embryos (as determined by the couples for whom the embryos were created); and
- in the case of uses of the embryos that may damage or destroy the embryos, that the embryos were created before 5 April 2002.

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

Sub-clauses 24(4) and (5) provide that the NHMRC Licensing Committee may impose any other conditions that are necessary and provides some examples of the types of conditions the NHMRC Licensing Committee may impose. For example, the NHMRC Licensing Committee may impose conditions relating to:

- (a) the persons or classes of person, 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 24(6) provides that the conditions included in sub-clauses 24(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 24(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 25 – 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.

Sub-clause 25(4) clarifies that the NHMRC Licensing Committee can not vary a licence so that the varied licence would be contrary to the requirements set out in clause 20. For example, the NHMRC Licensing Committee could not vary the licence after it has been issued so as to allow a use of embryos that have been created after 5 April 2002 that may damage or destroy the embryos (unless, that requirement ceases to have effect in three years or at an earlier time, as agreed by COAG as detailed in clause 46 of the Bill).

Clause 26 – Suspension or revocation of licence

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

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

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

Clause 27 – 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 28 – 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 or Territory body to which it notified its original decision. This ensures that State and Territory governments are kept fully informed about any variations to licences. In addition, if the change to the licence impacts on the information that is included on the publicly available database, the database must also be amended to reflect the change.

DIVISION 5 – Reporting and confidentiality

Clause 29 – 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 29(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. Under Commonwealth legislation this would be a body corporate 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*;
- (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 (refer clause 30) or any personal information that would be prohibited from disclosure under the *Privacy Act 1988*, including for example, names of individuals.

Clause 30 – 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 effect of clause 30 is that the NHMRC Licensing Committee can decide not to release certain information into the public domain (for example, by inclusion on the database established by clause 29) if the NHMRC Licensing 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 NHMRC Licensing Committee would have access to the confidential commercial information in assessing applications and could disclose such information to States and Territories (and to relevant Commonwealth agencies) but these bodies could not disclose the information to anyone else.

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 31 – Meaning of terms

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 32 – Review of decisions

Sub-clause 32(1) provides that an eligible person (as defined in clause 31) may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee:

- (a) a decision under clause 21 not to issue a licence;
- (b) a decision in respect of the period throughout which the licence is to be in force under clause 23;
- (c) a decision to specify a licence condition under sub-clause 24(4);
- (d) a decision to vary or refuse to vary a licence under clause 25; or
- (e) a decision to suspend or revoke a licence under clause 26.

Sub-clause 32(2) provides that clause 32 has effect subject to the *Administrative Appeals Tribunal Act 1975*.

PART 3 – MONITORING POWERS

Clause 33 – Appointment of inspectors

Sub-clause 33(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 are Commonwealth employees and State 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 33(3)).

Sub-clause 33(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 34 – Identity card

Sub-clauses 34(1) and 34(2) require the Chairperson of the NHMRC Licensing Committee to issue an identity card, in a form prescribed by the regulations, to every person appointed as an inspector. The identity card must have a recent photograph of the inspector.

Sub-clause 34(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.

Sub-clause 34(4) requires the inspector to carry his or her identity card at all times when exercising powers or performing functions as an inspector.

Clause 35 – Powers available to inspectors for monitoring compliance

Sub-clause 35(1) confers powers upon an inspector to enter any premises and to exercise any or all of the powers set out in clause 36 for the purposes of establishing whether or not the Act or regulations are being complied with.

Sub-clause 35(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 36 – 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 37 – 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 38 – 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 39 – Consent

This clause provides that, before obtaining consent from a person to enter premises (under paragraph 35(2)(a)), the inspector must inform the person that he or she may refuse consent.

Sub-clause 39(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

Clause 40 – Compensation for damage

This clause provides that if damage is caused to equipment or other facilities as a result of it being operated by an inspector and the damage resulted from insufficient care being

exercised by the inspector in operating the equipment, compensation is payable to the owner.

Compensation is payable out of money appropriated by the Parliament. In determining the amount payable, regard is to be had to whether the occupier (or his or her employees and agents) had provided any warning or guidance as to the operation of the equipment or facility. This is to minimise compensation in cases where, for example, there has been a deliberate programming of software to destroy or cause damage if not accessed in a particular manner, or where the occupier failed to mitigate damage by providing warning or guidance.

Clause 41 - Extended Operation of Act

This clause provides that a reference in Part 3 to the *Research Involving Embryos Act 2002* includes a reference to the *Prohibition of Human Cloning Act 2002* and a reference in Part 3 to regulations includes a reference to regulations made under the *Prohibition of Human Cloning Act 2002*. The effect of Clause 41 is that Part 3 will apply in exactly the same way to the *Prohibition of Human Cloning Act 2002* as it does to the *Research Involving Embryos Act 2002*. That is, inspectors will exercise monitoring powers under both Acts.

PART 4 – COMMONWEALTH/STATE ARRANGEMENTS

Clause 42 – Operation of State laws

This clause provides that the Act is not intended to exclude the operation of State and Territory laws except where the State or Territory laws are inconsistent with the Act and cannot operate concurrently.

One of the intended effects of this clause is that if a State has existing legislation that, for example, bans the use of excess ART embryos, such a law would not be capable of operating concurrently with the Act and as such it is intended that the Act override the State law to the extent that it is inconsistent.

By virtue of clause 2 of this Bill, clause 10 of this Bill (which provides that a person must not use an excess ART embryo unless the use is authorised by a licence from the NHMRC Licensing Committee or is an exempt use) will not commence operation for 6 months from the date that this Bill receives Royal Assent. During this time, any inconsistent State laws that ban the use of excess ART embryos will continue to operate subject to amendment by the relevant State Parliaments.

Clause 43 – Conferral of functions on Commonwealth officers and bodies

The purpose of this clause is to enable corresponding State laws to confer functions, powers and duties on the NHMRC Licensing Committee, a Commonwealth Authority and an officer 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 clause, along with clause 44, provides for the effective operation of the national scheme relating to the regulation of uses of excess ART embryos. This Commonwealth Bill is one part of the national scheme. It is anticipated that all States and Territories will implement corresponding legislation. Clauses 42 and 43 effectively enable the corresponding State laws to provide that the licensing functions exercised under a State law actually be undertaken by the NHMRC Licensing Committee. It is not intended that there be dual licensing systems in any jurisdictions. Rather, 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 whether or not they are technically organisations that come within the scope of the Commonwealth's constitutional powers or State powers.

Clause 43 also clarifies that the conferral of such functions or powers, or the imposition of duties, on the NHMRC Licensing Committee or on other Commonwealth bodies is limited by any relevant constitutional doctrines and the legislative power of the Commonwealth.

Clause 44 – When duty imposed

This clause recognises that there are constitutional doctrines that have developed on the basis of case law that restrict the duties that may be imposed on a Commonwealth officer or Commonwealth authority under State laws. Recognising these doctrines, this clause 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 clause clarifies that any duty purported to be imposed under 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 clause 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.

Clause 45 – Review of certain decisions

This clause provides the capacity for the Administrative Appeals Tribunal to review decisions made under a corresponding State law where the decision by the NHMRC Licensing Committee is actually made under State law.

Sub-clause 45(2) provides that a decision of the NHMRC Licensing Committee is a “reviewable State decision” where the State law provides for review by the Administrative Appeals Tribunal and where the decision is declared in the regulations to be a “reviewable State decision”.

Sub-clause 45(3) provides that for the purposes of this clause the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment of the Commonwealth.

PART 5 – SUNSET CLAUSE, REVIEW PROVISION AND REGULATIONS

DIVISION 1 – Repeal

Clause 46 – Repeal of paragraphs 21(3)(b) and 24(1)(c) and subsection 24(3)

This clause gives 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 – Review of Act

Clause 47 – Review of operation of Act

Sub-clause 47(1) provides that the NHMRC must cause an independent review of this Act to be undertaken commencing 2 years after the Act receives Royal Assent.

Sub-clause 47(2) provides that the review must be undertaken by persons who undertake the *Prohibition of Human Cloning Act* review and be undertaken concurrently with that review.

Sub-clause 47(3) provides that the persons conducting the review must give the Council of Australian Governments a written report of the review and the report must be accompanied by the report of the *Prohibition of Human Cloning Act* review.

Sub-clauses 47 (4), (5) and (6) describe the nature of the review and the report to be prepared as a result of the review. In summary, the review must:

- include a consideration of the scope and operation of the *Research Involving Embryos Act 2002* particularly taking into account developments in assisted reproductive technology, scientific and research developments, the potential therapeutic applications of any research and community standards;
- contain recommendations about any amendments that should be made to the Act;
- be informed by consultation with the Commonwealth, States, Territories and a broad range of stakeholders; and,

- include information about the views of the Commonwealth, States and Territories (to the extent that it is reasonably practicable to do so).

Changes in prohibited practices as a result of the review process will affect the review of the licensing scheme and vice versa. The effect of requiring the reviews of the *Research Involving Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002* to be undertaken by the same people and requiring a copy of the review of the *Prohibition of Human Cloning Act 2002* to accompany the report of the review of the other Act is to ensure that the Council of Australian Governments can consider the reports of the review of both Acts together. It should also ensure that the definitions in the Acts do not diverge, a result that would make administration of the legislation, handling of reviews and consideration of subsequent amendments to both pieces of legislation, difficult.

DIVISION 3 – Regulations

Clause 48 – Regulations

This clause empowers the Governor-General to make regulations prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

Sub-clause 48(2) clarifies that, before the Governor-General makes regulations under this Act, the Minister must be satisfied that the States and Territories have been consulted in relation to the proposed regulations and that there was regard to the views of States and Territories in the preparation of the proposed regulations.

REGULATION IMPACT STATEMENT

1. Background

On 5 April 2002 the Council of Australian Governments (COAG) agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation banning human cloning and other unacceptable practices and establishing a national regulatory framework for the use of excess assisted reproductive technology (ART) embryos. It was agreed that the National Health and Medical Research Council (NHMRC) would be the licensing and regulatory body.

This Regulation Impact Statement (RIS) focuses on the costs and benefits of the regulatory scheme for the use of excess ART embryos.

2. Issues to be addressed

The problems that currently exist in relation to the regulation of research on (and other uses of) human embryos include:

- the fundamental ethical issues posed by destruction of embryos for research and other uses and the absence of a comprehensive, nationally consistent system for the regulation of research involving human embryos;
- inconsistent regulation of research involving embryos which creates an uneven playing field for researchers, which may limit the capacity of some researchers to carry out particular work and access funding for such work. This may reduce their competitiveness relative to researchers in other jurisdictions. For example, if a national funding body identifies a particular type of research as a priority (such as embryonic stem cell research) only researchers in jurisdictions where such work is permitted would be able to carry out this research and have potential access to funding for such research; and
- the impact that the current lack of certainty or national consistency in the regulatory environment may have on Australia's international competitiveness.

3. Objectives

On 5 April 2002 COAG agreed that the Commonwealth, States and Territories would introduce nationally consistent legislation banning human cloning and other unacceptable practices and that the legislation would establish a national regulatory framework for the use of excess ART embryos, to be administered by the NHMRC as the national regulatory and licensing body.

4. Options and impact analysis

Groups likely to experience the benefits and costs

The groups likely to be affected by the regulation of uses of excess ART embryos are ART service providers, consumers of ART services, researchers, Government and the community.

ART service providers

The Australian Institute of Health and Welfare's National Perinatal Statistics Unit (NPSU) reported that there were 34 IVF units in Australia in 2000.

Consumers of ART services

Data available from the NPSU for the year 2000 showed that women underwent 27,067 treatment cycles with oocyte retrieval or embryo transfer for all techniques of assisted conception in Australia's 34 IVF units.

Researchers

Currently in Australia, research on excess ART embryos is only carried out by a limited number of organisations, predominantly ART clinics examining the effectiveness of ART techniques, particularly new methods for culturing gametes and embryos to improve infertility treatments. As destructive research on excess ART embryos has been banned in Victoria, South Australia and Western Australia for a number of years, only very limited research that is not destructive to embryos has been undertaken in these jurisdictions. It is, however, likely that if the bans are lifted there will be a number of researchers from these jurisdictions who may wish to undertake more extensive research that could be destructive to excess ART embryos particularly scientific investigations including for the derivation of new embryonic stem cell lines. Commercial companies may also have an interest in undertaking such work.

Government

This includes the Commonwealth Government, State and Territory Governments and existing regulatory authorities in Victoria, South Australia and Western Australia.

Community

Given the subject matter of the regulation, the oversight applied to the use of excess ART embryos has the potential to impact upon everyone in the community. This is not only because the use of excess ART embryos poses ethical issues that affect many but also because of the potential benefits that may flow to the community as a result of scientific advancements and medical applications developed from the study of embryos and embryonic stem cell lines.

Options and impact analysis for the scope of the regulation of uses of excess ART embryos

Options

Currently in Australia there is a lack of national consistency regarding the regulation of research using excess ART embryos. In Victoria, South Australia, and Western Australia, research that involves the destruction of an embryo (or may not otherwise leave it in an implantable condition) is not permitted under any circumstances. By contrast, in all other jurisdictions the NHMRC/AHEC *Ethical Guidelines on ART* apply and researchers may receive approval from a Human Research Ethics Committee (HREC) to undertake research that involves the destruction of an embryo under exceptional circumstances.

COAG agreed that the status quo is not acceptable and that the NHMRC would consider applications and may issue a licence for a person to use an excess embryo from an ART program for research or therapy that damages or destroys the embryo.

There are essentially two options for implementing the COAG decision. The difference between these two options is that one requires a person to have a licence for any use of an excess ART embryo (other than exempt uses) leaving the decision making about whether the work may damage or destroy the embryo with the NHMRC Licensing Committee. The other option requires a licence for uses of an excess ART embryo that may damage or destroy the embryo (other than exempt uses), with the decision making about whether the work may damage or destroy the embryo resting with the ART service provider or researcher.

Option 1: That all uses of excess ART embryos require a licence from the NHMRC (with uses that may damage or destroy the embryo subject to additional restrictions) unless the uses are exempt uses including:

- for donation of an excess ART embryo to another couple for ART treatment;
- for storage of the embryo, for removal of the embryo from storage, for transportation of the embryo, for allowing the embryo to succumb at the request of the couple for whom it was created
- for observation of the embryo; or
- for use that forms part of diagnostic investigations conducted in connection with the ART treatment of the woman for whom the excess ART embryo was created.

Option 2: That only those uses of excess ART embryos that involve research or therapy that may damage or destroy the embryos be subject to the licensing system with exemptions for:

- donation of an excess ART embryo to another couple for ART treatment;
- storage of the embryo, for removal of the embryo from storage, for transportation of the embryo, for allowing the embryo to succumb at the request of the couple for whom it was created
- observation of the embryo; or
- use that forms part of diagnostic investigations conducted in connection with the ART treatment of the woman for whom the excess ART embryo was created.

Impact analysis

Impacts of Option 1: **That all uses of excess ART embryos require a licence from the NHMRC (with uses that may harm or destroy the embryo subject to additional restrictions) unless the uses are exempt uses.**

On ART service providers: ART service providers who wish to undertake work on excess ART embryos would require a licence for such work unless the work is exempt. A licence would be required for uses that may damage or destroy the embryo (such as research, derivation of stem cells and training of clinicians in certain techniques carried out on embryos) and work that may not damage the embryo such as quality assurance testing, for example, of culture media.

The licensing system will impose costs on ART service providers, particularly those in New South Wales, Queensland, Tasmania, Northern Territory and the Australian Capital Territory where there have, to date, been no requirements for a licence to undertake such work. In Victoria, South Australia and Western Australia research involving the destruction of excess ART embryos has not previously been permitted. Should ART service providers in these States wish to undertake such research in the future it is expected that they will incur additional costs

The major cost drivers for ART service providers are expected to be associated with applying for a licence, implementing any necessary systems to enable compliance with the legislation and reporting to the NHMRC Licensing Committee. In most cases ART service providers are currently providing such information to institutional HREC and the Reproductive Technology Accreditation Committee. Any increased costs can also be minimised through streamlined administration of the legislation, particularly in relation to uses of excess ART embryos that do not damage or destroy the embryo. For example, ART service providers could apply for one licence to undertake quality assurance work using a certain number of excess ART embryos rather than having to apply each time they chose to test a different culture medium.

As the licensing requirements would apply to all uses of excess ART embryos (not just uses that damage or destroy the excess ART embryos), it is possible that this will impose additional costs on ART service providers (compared to Option 2) because licences

would be required for non-destructive work, where it is proposed that the embryo be discarded following the work. However these costs may be offset (compared to Option 2) because there will be regulatory certainty and less need to seek case by case clarification from the NHMRC Licensing Committee about whether the proposed work may damage or destroy the embryo. Further, it is expected that costs are not fully additional given that some service providers may, under Option 2, apply for licences unnecessarily, erring on the side of caution.

In relation to both Option 1 and Option 2, the inclusion of clear exemptions in the legislation means that there is greater clarity for ART service providers about the work that is part of routine ART clinical practice and does not require licensing by the NHMRC Licensing Committee.

On consumers of ART services: Couples would be assured that there is regulatory oversight for all uses of excess ART embryos and that work would not be undertaken on their ART embryo unless they have provided fully informed consent. They may also specify any conditions relating to such consent and the nature of the work that may be undertaken. Should there be increased costs to ART service providers as a result of the licensing requirements, there may be flow on costs to all consumers of ART services.

On researchers: On the basis of information available to date, it appears that most of the work proposed to be undertaken by researchers will be work that may lead to the destruction of the excess ART embryo. For example, use of excess ART embryos for the derivation of stem cells. It is therefore unlikely that this Option will have any additional impact compared with Option 2. Compared to the current situation, costs are likely to increase for all researchers proposing to undertake uses of excess ART embryos, as the result of the need to obtain, and ensure compliance with, a licence from the NHMRC to undertake research that involves destruction of the excess ART embryos. This is also the case for Option 2. The cost drivers are the same as those detailed in relation to ART service providers.

On Government: In addition to the NHMRC's cost of supporting the regulatory framework, as set out in the Financial Impact Statement, there will also be costs in relation to implementing a nationally-consistent scheme as agreed to by COAG. It is not anticipated that the costs would be substantially different under Option 2, as detailed below.

It is difficult to compare these costs to existing regulatory models because in all three States that have a licensing system, uses of embryos that may damage or destroy the embryo are banned. As such, very few research licences are issued each year and the vast majority of work undertaken by licensing authorities in those States relates to the regulation of routine ART clinical practice. However, as the authorities in Victoria, South Australia and Western Australia will no longer be required to issue licences in relation to research (as this will be done by the NHMRC Licensing Committee), it is expected that there may be a minor decrease in costs to these State agencies over time. However, in the short term there are likely to be increased costs to all States and

Territories as the result of implementing corresponding State and Territory laws. These costs are likely to be the same under Option 2.

In terms of government policy, this approach avoids “loopholes” in regulatory coverage as the NHMRC Licensing Committee will oversee all non-exempt uses of excess ART embryos and such oversight is not dependent on the researcher or ART clinic self-assessing that the work they are proposing to undertake will not damage or destroy the embryo. Further, the publicly available database of licensed uses of excess ART embryos will be much more comprehensive than under Option 2, providing greater transparency in terms of the actual work being conducted on excess ART embryos.

On the community: By regulating all uses of ART embryos, the NHMRC will be able to publicly report in a more meaningful way. By only regulating some of the uses of excess ART embryos (Option 2), the information available to the community about the number of excess ART embryos and the uses of such embryos may be incomplete. The community would also be reassured that there are no gaps in regulatory coverage and that uses of excess ART embryos are being appropriately overseen.

Impacts of Option 2: **Only those uses of excess ART embryos that involve research or therapy that may damage or destroy the embryos be subject to the regulatory system and therefore require a licence from the NHMRC (unless the uses are exempt uses).**

On ART service providers: This Option means that a more limited class of activity would be regulated and require a licence. Therefore it is expected that the costs to ART service providers would likely be less than under Option 1. However, if it is not clear to service providers whether the work on excess ART embryos is likely to cause harm or lead to the destruction of the embryos, it is likely that clinics would need to seek clarification from the NHMRC on a case by case basis and may unnecessarily apply for licences, erring on the side of caution. This may lead to increased costs comparable to those described in Option 1.

On consumers of ART services: There may be less assurance for consumers that there is government oversight of all uses (for research, quality assurance and training) of their excess ART embryos. That is, consumers would know that, should researchers self-assess their work as not being research or therapy that is harmful to an excess ART embryo, then there would be no national oversight of such work (other than internal oversight by an institutional ethics committee). While there may be increased costs to ART service providers as the result of requiring a licence for certain work, if such costs are passed on to consumers these may be less under this Option than Option 1 (as fewer licences are likely to be required). However, this may be negated by clinics passing on the costs of the possible additional burden of having to clarify, on a case by case basis with the NHMRC, the need for a licence for any work using excess ART embryos, where they are uncertain of the potential harmful impact of the work on those embryos.

On researchers: As for Option 1.

On Government: As the class of work required to be licensed is narrower under this Option than under Option 1, the costs to the Commonwealth Government as the result of administering the scheme should be lower than for Option 1. However as detailed in relation to impacts on ART service providers, the lower level of certainty on the face of the legislation may mean that in reality ART service providers and researchers seek advice from the NHMRC on a case by case basis regarding whether they need a licence, meaning that the costs to government are likely to be similar to those for Option 1. It may also be the case, that monitoring costs are higher to ensure that researchers are not undertaking work that requires a licence after self-assessing that the work does not require a licence.

On the community: The community may perceive a logical inconsistency in regulating only certain uses of excess ART embryos when all work involving excess ART embryos will involve the destruction and disposal of those embryos at some point. That is, at the completion of non-destructive quality assurance work involving excess ART embryos the excess ART embryos cannot be made available for any other work and are therefore discarded. Many people feel that the key issues of donor consent and justification for use are the same irrespective of the nature of the work and require the same level of oversight. Further, the community may have concerns about service providers and researchers deciding whether their research is likely to damage or destroy an embryo and therefore whether to seek a licence. By contrast, in Option 1, a wider range of uses must be licensed, removing the possibility for inappropriate threshold decision making by ART service providers and researchers.

Consultation

A draft of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 and accompanying RIS was provided to experts in a range of fields, for comment. In that draft of the RIS, Option 1 was different to Option 1 in this RIS. In the previous draft, Option 1 proposed regulating all uses of ART embryos unless such embryos were for use in achieving pregnancy in a woman. This approach attracted considerable criticism from ART service providers because of the uncertainty surrounding what would be required to be licensed and what could be considered to be related to “achieving pregnancy in a woman”. For example, it was not entirely clear whether licences would be required for routine ART clinical activities such as diagnostic tests on embryos intended for implantation, diagnostic investigations on chromosomally abnormal embryos and observational work. The revised Option 1 addresses these concerns by clarifying that the regulatory system only relates to excess ART embryos and does not apply to “exempt” uses such as observation of an embryo and diagnostic investigations on embryos that are unsuitable for implantation.

Notwithstanding the concerns relating to the lack of clarity with respect to the previous version of Option 1 (and therefore the potential unintended impacts on routine ART clinical practice), there was greater support for Option 1 than Option 2. In general, most

people felt that Option 2 could leave loopholes if ART service providers and researchers were self-assessing regarding whether certain work was likely to damage or destroy an embryo and therefore whether they require a licence. It was generally felt that this decision should rest with the NHMRC Licensing Committee.

One of the issues that led to considerable debate during consultations was the impact of COAG's decision that embryos not be used for research that damages or destroys an embryo unless the embryo was created before 5 April 2002. Of principal concern was that by regulating all uses of excess ART embryos, and applying the 5 April criteria to all uses of excess ART embryos, this could significantly affect the capacity of ART clinics to undertake routine training and quality assurance testing that does not damage or destroy the embryo. As a result of the consultations, Option 1 has been adjusted to better accord with the COAG decision and clarify that while all uses of excess ART embryos will be required to be licensed (except exempt uses), the NHMRC Licensing Committee will determine whether such uses are likely to damage or destroy the embryo and if so, only embryos created before 5 April 2002 may be used.

Conclusion

On balance it is considered that Option 1 provides a greater level of regulatory certainty and does not rely on researchers self-assessing in each instance regarding whether the work may harm the excess ART embryo or not. The need for case by case consideration (outside the parameters of the legislation) may, in fact, be a greater burden for both researchers and Government than a clear requirement for a licence in all cases.

While Option 1 is likely to lead to more licence applications by ART service providers, the additional burden associated with the regulatory uncertainty of Option 2, may balance the costs to ART service providers and therefore also any flow on costs to consumers. Therefore, the additional certainty and reassurance to consumers (and to the general community) under Option 1 makes it a more attractive option than Option 2.

5. Implementation and Review

As stated in the COAG communique the regulatory system will be reviewed within three years. The review will be carried out on all aspects of the legislation. It will take into account changes in technology, the potential therapeutic uses for such technology, and any changes in community standards.

Specifically, the Research Involving Embryos Bill 2002 provides for the NHMRC to ensure that an independent review of the legislation be undertaken 2 years after the legislation is enacted. In summary, the review must:

- be undertaken by the people who undertake the review of the *Prohibition of Human Cloning Act* and be undertaken concurrently with that review;

- include a consideration of the scope and operation of parts of the legislation, scientific and research developments, the potential therapeutic applications of any research and community standards;
- contain recommendations about any amendments that should be made to the legislation;
- be informed by consultation with the Commonwealth and States and a broad range of stakeholders; and,
- include information about the views of the Commonwealth and States (to the extent that it is reasonably practicable to do so).

The people who undertake the review must give COAG written report of the review. The report must accompany the report on the *Prohibition of Human Cloning Act* review.

It is also proposed that the issue of cost recovery be examined as part of the general review of the legislation in three years.

COAG also agreed that the NHMRC would report to COAG within 12 months on the adequacy of supply and distribution for research of excess ART embryos that would otherwise have been destroyed. This will allow consideration of the need to maintain the restriction on the use of embryos to those embryos created before 5 April 2002.