



Reproductive Technology Council

**POLICY ON EMBRYO STORAGE AND APPLICATIONS
TO EXTEND STORAGE BEYOND TEN YEARS.**

REPRODUCTIVE TECHNOLOGY COUNCIL

Based on recommendations from the Embryo Storage Committee.

February 2010

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GLOSSARY

ART- assisted reproductive technology/ies

Authorised storage period - see Directions under the HRT Act: Interpretation
'Authorised storage period' in respect of embryos or eggs undergoing fertilisation means the shorter of-

- a) any period of time specified in the consent to store the embryo or egg;
- b) a period of 10 years or such longer period as approved by the Council under section 24(1a) of the Act.

Council - Reproductive Technology Council of Western Australia

Directions - Directions given by the CEO of Health (Director General) under the HRT Act

Effective Consent - see section 22 of the HRT Act:

Section 22(8) For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless-

- a) it is given in writing;
- b) any condition to which it is subject is met;
- c) it has not been withdrawn;
- d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.

Embryo storage extension - an extension to an authorised storage period

FSA- Fertility Society of Australia

HRT Act- *Human Reproductive Technology Act 1991*

Initial storage period – a period of up to 10 years from the first day of storage of a human embryo or egg in the process of fertilisation, as authorised under section 24(1) of the HRT Act

IVF- in vitro fertilisation procedure as defined in section 3 of the HRT Act

NHMRC- National Health and Medical Research Council

NHMRC Ethical Guidelines - Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, June 2007

RTAC- Reproductive Technology Accreditation Committee

Stored - see section 3 of the HRT Act

In relation to human gametes, a human egg undergoing fertilisation or a human embryo a reference in this Act-

- a) to keeping, includes storing, whether by cryo-preservation or in any other way, in such a state as temporarily arrests or suspends metabolic function; and
- b) to any human gametes which are or a human egg or embryo which is, “**stored**” means kept in such a state, and “**store**” and “**storage**” shall be construed accordingly

INTRODUCTION

The process of in vitro fertilisation (IVF) involves the creation of embryos for the purpose of assisting eligible people to conceive a child or children. In Western Australia, regulation of the practice of IVF and other assisted reproductive technologies (ART) is provided by the *Human Reproductive Technology Act 1991* (the HRT Act) and Directions under the HRT Act (Directions). In addition to this, both the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia, and the National Health and Medical Research Council (NHMRC) have set out guidelines that underpin the provision of ART services in Australia.

Under the HRT Act, it is a condition of holding a licence to provide ART services that service providers be accredited by RTAC. In order to gain and retain accreditation, service providers must comply with the RTAC Code of Practice, which in turn also requires compliance with the NHMRC Ethical Guidelines. As such, the HRT Act, (including its subsidiary legislation), the RTAC Code of Practice and the NHMRC Ethical Guidelines regulate ART practice in this State. The HRT Act prevails over the RTAC Code and the NHMRC Ethical Guidelines. Compliance with provisions of the HRT Act is mandatory for licensees. Nothing in this policy document is intended to be, or should be construed as being, inconsistent with the HRT Act, RTAC Code of Practice or NHMRC Ethical Guidelines. Any reference to sections in legislation in this policy refers to sections of the HRT Act.

The HRT Act allows the creation of human embryos only for the purpose of achieving pregnancy in a woman. Most embryos are utilised in the pursuit of creating a child for individuals and couples seeking to create or expand their family. However, in some cases embryos created in vitro will not be used. Some embryos may be considered sub-optimal when an embryo is being selected for implantation in a woman, others may become excess to the IVF needs of individuals or couples if they have completed their IVF treatment. These embryos may be stored until they are used, donated or ultimately allowed to succumb.

The HRT Act permits the storage of embryos for a period of up to ten years. This storage period was increased in 2004, from an initial period of three years. To extend storage beyond ten years duration, an application for an extension of the authorised storage period must be sought from the Reproductive Technology Council (Council). Under the HRT Act, an extension to an authorised storage period beyond ten years *may be granted only if there are special reasons for doing so in a particular case*. Furthermore, the primary purpose in the consent to the storage of an embryo must relate to the probable future implantation of the embryo, or its probable future use under an NHMRC research licence. Indefinite storage of embryos is arguably not ethical, and does not assist participants, many of whom are repeat applicants, to resolve their issues concerning their stored embryos.

To this end, Council encourages participants to make a decision about how their embryos are to be dealt with well prior to expiry of the authorised storage period. Further, where this is their intention, participants are encouraged to take steps prior to expiry of the storage period to consent to donate their embryos to other eligible person/s or for research.

The 'Policy on Embryo Storage and Applications to Extend Storage Beyond Ten Years' sets out Council policy to guide decision-making regarding embryo storage extensions, and the responsibilities under the legislation of Council, licensees and participants.

ETHICAL CONSIDERATIONS OF EMBRYO STORAGE ISSUES

There are many complex ethical and emotive issues associated with embryo storage, embryo donation and allowing embryos to succumb. As an example, many people express different views as to when human life begins. For some, life begins at conception, for others it is at the time of implantation, or at the time of fetal brain development. Some people hold the view that human life begins at birth, reflecting the perspective that legal rights begin at the birth of a child. These diverse views and the experiences and outcomes of their fertility treatment will impact on how participants approach end of storage decision-making.

Council is aware that many people find it difficult to reach a definitive decision regarding their stored embryos: some participants understandably consider that they are entitled to determine how their embryos are dealt with. While this position is respected and understood by Council, to store embryos indefinitely is not considered appropriate by the legislature or by Council. Reflecting a similar position, the 2007 NHMRC Ethical Guidelines state that it is not desirable to leave embryos in storage indefinitely, and that licensees must have clear policies that limit the duration of storage of embryos.

In addition, under the HRT Act, the prospective welfare of any child born as a result of an IVF or ART procedure must also be properly taken into consideration. This influences policy on matters such as on-donation of embryos created using donor gametes. In on-donation the potential for genetic confusion and the psychosocial impact on children that may be born following donation has to be weighed up against the potential gift that a donor embryo may represent. This and many other factors underpin the legislation, policy, and decision-making about end of storage issues for embryos.

A summary of the legal and ethical principles determining this Embryo Storage Policy follows.

1.0 EMBRYO STORAGE POLICY – DETERMINING FACTORS

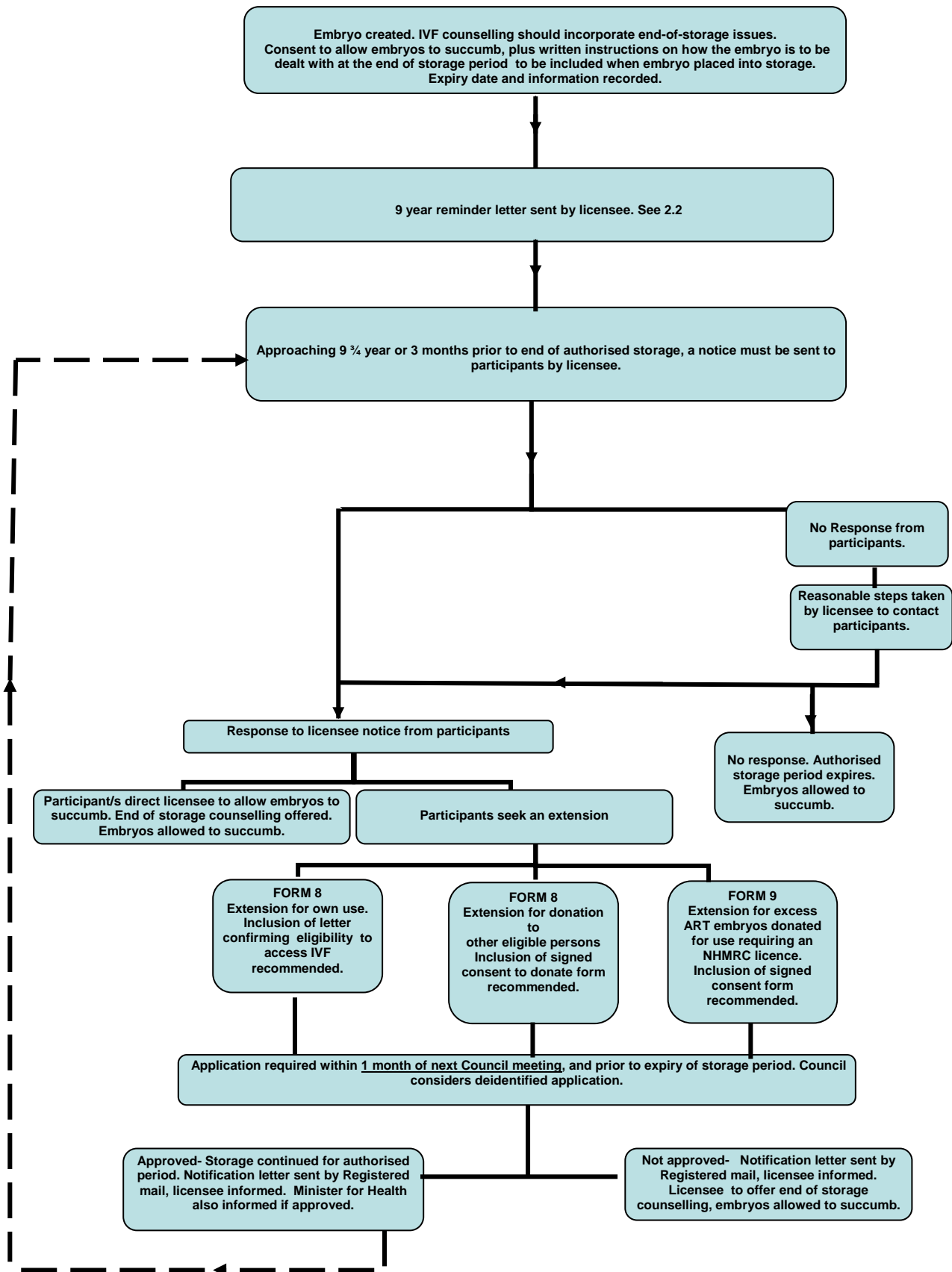
The primary legal and ethical principles underpinning the Embryo Storage Policy follow:

- 1.1 In WA an embryo must not be stored for more than ten years except where this has been approved by Council (s24(1)).
- 1.2 An embryo storage extension beyond a ten year period may be granted by Council only if it considers there are special reasons for doing so in a particular case (s24 (1a)).
- 1.3 The primary purpose of storage of an embryo must relate either to its probable future implantation or its probable future use under an NHMRC licence (s24(1)(a)).
- 1.4 Where storage is for probable future implantation, compliance with the IVF eligibility requirements of the HRT Act (s23) will be taken into consideration.
- 1.5 The options for embryos in storage include:
 - future use by the participants;
 - donation to other eligible participants;
 - donation to research as an excess ART embryo; and
 - being allowed to succumb.

Indefinite storage is not an option.

- 1.6 Any extension to storage must only be in accordance with consent given by those with a right to consent (s22).
- 1.7 To facilitate participant decision-making about their embryos, ongoing communication between licensees and participants during the initial storage period outlining options and responsibilities will be important. Licensees will be required to undertake this communication, and ensure clinic policies incorporate counselling on embryo storage.
- 1.8 The HRT Act provides that where the initial storage period comes to an end and no application has been made to extend the storage period, the licensee (having taken reasonable steps to notify participants of the impending expiry in accordance with s24(3)) may allow the embryo to succumb and will not be liable for doing so. In such circumstances, at the end of an authorised storage period, an embryo must be removed from storage and allowed to succumb (s24(4), s33(3)(d), Direction 6.11). The RTAC Code of Practice and NHMRC Ethical Guidelines also support this practice.
- 1.9 The prospective welfare of any future child must be taken into consideration in matters associated with reproductive technology, including embryo storage (s4(1)(d) iv)).
- 1.10 Consideration of the welfare of the persons requesting an extension to the storage period should be given and their decisions respected, subject to compliance with the Act.
- 1.11 Any decision to extend storage must take into account equity, welfare and general standards prevailing in the community.

EMBRYO STORAGE - FLOW CHART FOR INITIAL STORAGE PERIOD (MAXIMUM TEN YEARS) AND ONGOING APPLICATIONS



2.0 LICENSEE INFORMATION

2.1 LICENSEE EMBRYO STORAGE POLICY AND PROTOCOLS

The provision of regular information regarding embryo storage issues is considered vital to ensure participants are well prepared to make decisions about their stored embryos.

2.1.1 Licensees must develop a protocol that covers their methods for informing participants about embryo storage, consent renewal, options for the future of embryos and the process for situations where there are difficulties notifying participants.

2.1.2 Licensees should incorporate embryo storage issues in their counselling policy.

2.2 TIME-LINE FOR LICENSEE INFORMATION FOR INITIAL STORAGE PERIOD (MAXIMUM TEN YEARS)

As set out in the Flowchart, the provision of written information by licensees after 9 years of storage is recommended *in addition* to the required notification of expiry 3 months prior to the expiry date. It may be licensee practice to send additional information to participants during an authorised embryo storage period, for example, some licensees send biannual invoices for storage. In this case, the recommended reminder letter below may be included at an appropriate time convenient to clinic practice. Example letters from the Council have been included in Appendix 5. Clinics may opt to send these, or develop their own reminders. The importance of participants providing updated contact details should also be included with reminders.

2.2.1 Information on embryos storage matters to be provided with initial IVF counselling. Storage payment fee letters should include reminders about responsibility to update contact details for both participants.

2.2.2 9 years of storage- reminder letter should be sent.

This aims to encourage participants that may be approaching the completion of their ART treatment to consider all options for their embryos. For those who may have difficulties in allowing any unused embryos to succumb, the options of donation to other eligible participants or as excess ART embryos for research should be considered, so that the donation process can be underway before the initial storage period has expired. Counselling may be beneficial for participants who remain uncertain of their intended actions. An Embryo Storage Brochure has been developed by Council, and aims to assist in the provision of relevant information. See Appendix 4.

2.2.3 9 3/4 years storage or 3 months prior to expiry - Notice to be sent.

Three months before the expiry of the authorised storage period, the licensee must take reasonable steps to notify participants of the impending expiry. This action is required by legislation (s24(3), d6.12), and aims to notify participants:

- a) of the impending expiry of the authorised storage period
- b) that further instructions are being sought from the participants on how the embryo/s is to be dealt with
- c) that the licensee is unable to keep an embryo for a period longer than the authorised storage period
- d) where the authorised storage period was less than ten years, that effective consent to continue storage will be required
- e) where the authorised storage period was for ten years and it is a 9 3/4 year notice, that participants are aware that they may apply to Council for an extension (Form 8), and that such an application

must be received by the Council at least one month before the Council meeting that precedes expiry of the storage period; the due date (one month before the relevant Council meeting) should be included in this notification. This may be calculated from Council meeting dates available on the RTC website www.rtc.org.au/

- f) that the licensee is required to provide assistance with completion of the Form 8 if necessary
- g) that an extension to an embryo storage period may be granted where Council considers there are *special reasons* for doing so
- h) that supporting documentation (such as the inclusion of signed consent forms to donate) will assist Council in determining that the basis for approval meets this criterion (g)
- i) that Council is unable to approve an extension to the storage period once the authorised storage period has expired
- j) that if approval for a storage extension by Council is not received, it is a legislative requirement that the embryos be allowed to succumb

2.2.4 An End of Storage Information Sheet (to be developed by Council) aims to assist participants who are unable to use, or who do not intend to use or donate their embryos, but who find it *difficult* to allow their embryos to succumb. It will set out options for the process of allowing embryos to succumb; for example, when a ceremony may be of benefit to participants. It also will encourage participants to undertake counselling.

2.3 CONSENT ISSUES AND PATIENT INFORMATION

To avoid difficulties near the end of an authorised storage period, it is important that licensees inform participants of their legislative requirements at the outset and throughout storage. Where the authorised storage period was for a period less than ten years, renewed effective consent to continue storage will be required from participants. NB: When Council approval to extend the authorised storage period beyond ten years has been granted, renewed effective consent to continue storage will also be required.

2.3.1 The patient information provided to participants at the time of giving consent to store embryos -

- a) should advise that participants may only consent to a maximum of ten years for embryo storage
- b) should advise that embryos cannot be stored indefinitely
- c) should advise that consent must be renewed for storage beyond ten years and that Council may only approve an application by an eligible person for a longer embryo storage period where it considers there are special reasons for doing so
- d) should advise that Council is unable to approve an extension after expiry of the authorised storage period
- e) should advise that after expiry of the authorised storage period an embryo must be removed from storage and allowed to succumb, and that consent for this must be given at the time of consenting to store (see 2.3.2 (d), direction 3.6).

2.3.2 The patient consent forms to store embryos -

- a) must specify the maximum period of storage, being the initial storage period of up to ten years;
- b) must state the storage period required by the participants or determined by the licensee (which may be less than ten years) See 2.3.3

- c) must state that the primary purpose of storage relates to the probable future implantation of the embryo, or its use under an NHMRC research licence (s24(1)(a))
- d) must include consent to allow embryos to succumb at the end of the authorised storage period (Direction 3.6)
- e) should indicate that 3 months prior to expiry of the authorised storage period reasonable steps will be taken to notify the participants. An application to extend an authorised storage period beyond ten years may only be approved by Council where there are special reasons for doing so (s24(3), Direction 6.12)
- f) should seek written instructions on how embryos are to be dealt with at the end of authorised storage
- g) must seek instructions on what is to be done with an embryo in storage if one or both parties die or are unable by reasons of incapacity to vary the terms of the consent or to withdraw this. The consent may specify conditions upon which the embryos are to remain in storage (s22 (6)(b))
- h) should inform participants in advance of their terms regarding any storage fees and any conditions that apply in the event of ongoing unpaid storage fees, in particular where the licensee has lost contact with or is otherwise unable to obtain any further instructions from the participants.

2.3.3 Licensees are to notify each person for whom the embryos are being stored 3 months prior to the expiry of the authorised storage period in accordance with s24 (3), even though that storage period may be less than 10 years.

2.3.4 Consent to donate embryos to other recipients or for research must be effective consent (see glossary) under the HRT Act. The licensee must ensure that prior to donation of an embryo-

- a) effective consent to the donation is given by the person for whom the embryo was developed and
- b) any person who donated gametes to create the embryo and the spouse or de-facto partner of the gamete provider (if any) have given their effective consent to the use at the time donation was made (though see 3.3.7 re on-donation)

2.3.5 Each person on whose behalf an embryo was developed (or is being kept or is to be kept) has the right to decide, during the authorised storage period, how the embryo is dealt with, or disposed of.

2.3.6 The donors of an embryo may withdraw consent or vary consent up to the commencement of implantation of an embryo in the woman receiving the embryo (s26(1)).

2.3.7 Counselling requirements for donation of embryos where the recipient is known to the donor are set out in the Schedule 4, Part 2 of the Directions. These requirements include a minimum of 3 hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together. There is then a requirement for a minimum *3 month cooling off period*, before the embryos may be used in an artificial fertilisation procedure.

2.3.8 Counselling is also strongly encouraged prior to donation of embryos where the recipient is not known to the donor (Direction 5.7).

2.3.9 For couples seeking embryo storage extensions, any *one* member of the participant couple may apply for an extension. For donation or a directive for embryos to be allowed to succumb before the expiry of the authorised storage period, *both* members of the participating couple must give consent (see 4.1.3).

2.4 NON-RESPONSE BY PARTICIPANTS TO LICENSEE CONTACT

Regular contact with participants by a licensee during the course of the authorised storage period (including issuance of embryo storage fees, and through the reminder at 9 years and notice at 9 $\frac{3}{4}$ years) aims to remind participants of their responsibility to provide updated contact information and to make a decision about their embryos in storage.

However, when participants do not respond to reminders or licensee prompts regarding decision-making for their embryos in storage, it may eventuate that an authorised storage period for these embryos may expire *without* the participants directing licensees to allow their embryos to succumb. Licensee responsibilities in these circumstances are set out below:

2.4.1 Under s24 (3) of the HRT Act, three months before the end of an embryo storage period, licensees are required to take reasonable steps to notify each person for whom the embryo is being stored that the storage period is due to expire.

2.4.2 The note to Direction 6.10 sets out that “reasonable steps” may include-

- a) writing to the person at the last known address
- b) writing to the person at an address obtained from an electoral roll search
- c) telephoning or contacting the person’s general practitioner
- d) telephoning or contacting any other suitable third party.

2.4.3. Where embryos have been donated to a recipient/s, in the event that the recipient/s does not respond despite licensee reminders about impending storage expiry and where reasonable steps to contact have been made, the licensee may then take reasonable steps to contact the donor/s to give them the opportunity to vary or withdraw the consent given, or apply for an extension of storage prior to the expiry of the authorised storage period.

2.4.4 Under s24(4) of the HRT Act, if a period of storage comes to an end, no application has been made for the extension of the storage period, AND the requirements under s24(3) above have been met, licensees may allow the embryos to succumb and will not be liable to anyone for so doing.

2.4.5 Direction 6.11 states that the licensee must ensure that at the expiry of the authorised storage period for an embryo or egg undergoing fertilisation, the embryo or egg is removed from storage and allowed to succumb. Compliance with s24(3) should be ensured and documented *before* the step to allow an embryo or embryos to succumb is taken. Documentation demonstrating compliance with s24(3) may be taken into account in determining whether the requirements have been met.

2.4.6 Council is unable to approve an embryo storage extension after the expiry of an authorised storage period.

3.0 EMBRYO STORAGE EXTENSIONS

3.1 GENERAL MATTERS

- 3.1.1** Council approval for the extension of an embryo storage period beyond ten years is required under s24(1) of the HRT Act.
- 3.1.2** Where an embryo is intended for use in an IVF procedure an eligible person may apply for an extension to the storage period on a Form 8: 'Application for extension of frozen embryo storage period for use in IVF procedure'. A Form 8 application may be made by -
- a) a person/s for whom the embryo was developed, or
 - b) the recipient/s, if this responsibility has been passed on to a recipient/s following donation (see 2.4.3)
- 3.1.3** Where an embryo is intended for use in research an eligible person may apply for an extension to the storage period on a Form 9: 'Application for extension of permitted storage where excess ART embryos have been donated for a use requiring a licence from the NHMRC'. A Form 9 application may be made by -
- a) the participant/s for whom the embryo was developed
 - b) the storage licensee or
 - c) a person with an exemption to a storage licence issued under s28A.
- 3.1.4** Council will only consider an extension to an authorised storage period if it considers there are "special reasons for doing so in a particular case". Part B of Form 8 requests participants to briefly explain their reasons for seeking an extension. Some examples of circumstances that may, and may not be considered by Council as warranting an extension are set out in 3.2 and 3.3.
- 3.1.5** De-identification: Forms containing participant information received by the Executive Officer of the Council will be de-identified before being presented to Council for consideration, in order to comply with confidentiality obligations under the HRT Act.
- 3.1.6** In general, extensions will be initially considered by the Embryo Storage Committee of Council, and a recommendation regarding the application will be then made to Council.
- 3.1.7** The length of any approved extended storage period will be at the discretion of Council. An application should demonstrate the need for an extension and, if a specific time period is requested, the reason for this specified extension period.
- 3.1.8** Supporting documentation such as medical confirmation of eligibility to use the embryos and 'consent to donate' forms will assist Council to determine whether the basis for an extension can be considered a "special reason". Accordingly, such documentation, where appropriate, should be included with the extension application.
- 3.1.9** Section 24(1) states that the primary purpose of storage must relate to the probable future implantation of that embryo, or its probable future use under an NHMRC licence. Applications made for "own treatment at a later time" therefore are underpinned by participant eligibility for IVF under s23 of the HRT Act. Section 23(d) requires that the reason for infertility is not age. In cases where participant age may raise uncertainty about eligibility, medical

confirmation that a participant is not infertile by reason of age (that is, not post menopausal at the usual time) will be required.

- 3.1.10** Where there appears to be insufficient grounds on which to grant an extension, participants may be requested to supply further information to support their application. In this event, the request from Council will be sent by registered mail, and set out the date by which the participants must respond in order for their embryo storage extension application to be considered. As per Part B of Form 8: if a participant consents, the Executive Officer may use phone contact if further information is required in a short time frame.

3.2 WHEN APPROVAL MAY BE CONSIDERED.

An application to extend an authorised storage period may be considered by Council if there are *special reasons* for doing so. The following may assist Council in making a decision as to the special reasons for the application-

- 3.2.1** Participant/s stated intent to continue with infertility treatment in an attempt to conceive a child. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).
- 3.2.2** Participant/s have one or more live births as a result of treatment, and wish to have additional children. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).
- 3.2.3** Participants or (following donation and consent) recipient/s may have an existing child from the use of embryos formed with donor gametes and wish to have further children with the same genetic background. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).
- 3.2.4** Participant/s have stored embryo/s for later use where a serious medical condition and/or its treatment may make the person infertile at a later date. Where practicable, medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).
- 3.2.5** Participant/s wish to pursue a surrogacy arrangement in an attempt to conceive a child. Medical confirmation should be provided in support of the person/s eligibility to access IVF under the HRT Act (see 3.1.9) and/or evidence of the surrogacy arrangement being in progress.
- 3.2.6** Participant/s state their intent to donate their embryo to an eligible recipient/s. Either a 'consent to donate' form signed by all responsible persons or licensee confirmation that pre-donation counselling for donation has been initiated should be attached with the application for an extension for donation. This is to assist Council in the decision making process. Suitable recipients may have already been selected to receive the donor embryos, but this is not necessary for approval.
- 3.2.7** Participant/s state their intent to donate their embryos for research purposes or other purposes authorised under the Act. Section 24(1) states that the primary purpose of storage must relate to the probable future implantation of that embryo, or its probable future use under an NHMRC licence. A Consent to Donate Embryos for Research under an NHMRC Licence Form, signed by all responsible persons, should accompany the application to assist Council

to determine that the primary purpose of storage will relate to the probable future use under an NHMRC licence.

3.3 WHEN APPROVAL WILL NOT BE CONSIDERED

The following circumstances will not generally be considered by Council as “special reasons” to extend an authorised storage period beyond ten years.

- 3.3.1** The authorised storage period has expired and no extension has been sought. In this event, Council is unable to approve an embryo extension.
- 3.3.2** Participants cannot be located after reasonable steps have been taken by a licensee, and the authorised storage period has expired. In this event, Council is unable to approve an embryo extension.
- 3.3.3** Participants, who are no longer eligible for IVF treatment, remain undecided about their intended use of an embryo. (This does not rule out a brief extension approved by Council to allow the participants to access counselling etc where they are having difficulty in making a decision).
- 3.3.4** Where an embryo in storage has been donated by a couple, and that couple withdraw their consent to the donation/use (see 2.3). (This does not preclude an application being made by the donor couple for an extension and Council may give approval where there are special reasons for seeking an extension).
- 3.3.5** Participant/s wish to keep an embryo in storage indefinitely, or wish to be buried with the embryo.
- 3.3.6** Participant/s wish to keep an embryo in storage where the basis for the application is a proposed use that is not authorised under the HRT Act. This (under current legislation) includes future use as a source of stem cells.
- 3.3.7** In general, where recipient/s of a donated embryo (or an embryo created using a donated gamete or gametes) are applying for a storage extension in order to donate the embryo (on-donation) to another eligible person/s, Council approval will not be given: NHMRC Ethical Guideline 7.2 states that clinics should not facilitate on-donation as this may increase difficulties in tracing genetic parents and have possible effects on the long-term psychosocial welfare of persons born from embryos that have undergone serial donations.

In addition, at the present time it is likely that the gamete donor will not have consented to the provision of identifying information to any child born when they reach 16 years of age. For embryos created before December 2004, Direction 8.5 requires licensees to take reasonable efforts to contact any gamete donor involved in the creation of an embryo to obtain his or her consent to the provision of identifying information before using an embryo created with donor gametes in an artificial fertilisation procedure.

The inclusion of a copy of a signed consent form (verifying that the gamete donor agrees to the provision of identifying information) with the application may be considered by Council as a *special reason* by which to consider an embryo storage extension for on-donation.

4.0 DONATION OF EMBRYOS

4.1 DONATION TO OTHER ELIGIBLE PERSONS FOR PROBABLE FUTURE IMPLANTATION.

4.1.1 Donation to unknown recipient/s: where participant/s have decided to donate an embryo/s to anonymous recipient/s (where a cooling off period is not a requirement)

- a) a copy of a Consent to Donate Embryos for Treatment form signed by all responsible persons, or
- b) licensee confirmation that pre-donation counselling for donation has been initiated

attached with the application for an extension to the authorised storage period will assist Council in the approval process.

4.1.2 Donation to known recipients: where participant/s have decided to donate an embryo/s to known recipient/s (where a cooling off period is a requirement),

- a) a copy of a 'consent to donate' form signed by all responsible persons, or
- b) licensee confirmation that pre-donation counselling for donation has been initiated

attached with the application for an extension to the authorised storage period, will assist Council with the approval process.

4.1.3 An application for a storage extension can be made by one member of an eligible couple. However, consent to donate an embryo to other participant/s must include the effective consent of -

- a) any person on whose behalf the embryo was developed;
- b) any person who donated gametes used to develop the embryo (see 3.3.7) and
- c) the spouse or de facto partner of the gamete provider.

4.1.4 Where an intention to donate is indicated, a 'consent to donate' form attached with an application for extension to storage, or evidence that pre-donation counselling has been initiated, will assist Council in the approval process. Where no 'consent to donate' form is included with the application, it is recommended that both participants (male and female) complete and sign the application for an embryo storage extension.

4.1.5 Licensees must maintain a clear procedure for the transfer of responsibility for an embryo at each stage (NHMRC Ethical Guideline 7.3)

4.1.6 If an embryo donor has not specified a recipient for the embryo, licensees should keep or place the embryo in storage until a suitable recipient/s is found (subject to the authorised storage period). Any application to extend an authorised storage period must still be made by the donating participants on a Form 8 and cannot be made by the licensee.

4.1.7 Where recipient/s of a donor embryo/s apply for an extension to the storage period for probable future implantation, the Form 8 application should provide that these embryos are donated, and specify what, if any, specified time period is requested for the purpose of the recipient/s undergoing IVF treatment and that the recipients are eligible for IVF under the HRT Act.

4.1.8 See 3.3.7 regarding extension of storage periods and donation of embryos created using donor material, or donation of donor embryos.

4.2 COUNSELLING

- 4.2.1** A licensee must ensure that all IVF participants have access to an approved counsellor, and that cost of one counselling session is included in each IVF cycle that is begun. Licensees should ensure participants who may not have utilised this paid-for session are informed that they may be able to access this counselling session to discuss end-of storage issues.
- 4.2.2** If embryos are to be donated to an unknown recipient/s, counselling should be offered and information regarding donation be provided as set out in the HRT Act (see Directions 4.1, 4.2 and 5.7).
- 4.2.3** If embryos are to be donated to a known recipient/s, psychosocial counselling (with cooling off period) and information must be provided, as set out in the HRT Act (see Schedule 4, Part 2, directions 4.1, 4.2 and 5.8).

4.3 DONATION OF EXCESS ART EMBRYOS FOR RESEARCH

Participants may donate their embryos for the purpose of research. Section 53T(2) of the HRT Act provides that each relevant person may determine in writing that an embryo is excess to their needs and give written authority for use of an embryo for a purpose other than relating to their ART treatment. However, the embryo may only be used for a purpose authorised under WA legislation, which will therefore be limited to research permitted under the HRT Act. This may also have implications for embryos intended to be exported for research outside of Western Australia, as embryos must not be exported for a use not allowed under the HRT Act (see 8.5, Direction 6.4).

For excess ART embryos donated for research under an NHMRC licence, NHMRC Ethical Guidelines require the researcher to obtain consent to donate for research under an NHMRC licence and also consent to the specific proposed research. This is set out in NHMRC Ethical Guidelines 15.7, 17.10 and 17.17.

NB: At present as the licensing system for excess ART embryo research is inoperative under the HRT Act and such, a licence may only be issued to certain entities under the Commonwealth *Research Involving Human Embryos Act 2002*.

Use of embryos declared to be excess ART embryos may be an “exempt use” (that is, exempt from requiring an NHMRC licence) if the use consists only of-

- a) storage
- b) removal from storage
- c) transport
- d) observation
- e) allowing the embryo to succumb,
- f) diagnostic investigations for the benefit of the woman for whom the embryo was created, and that the embryo is not fit for implantation. In this case, Council approval for the diagnostic investigation must be granted. (See p2 of the Policy on Approval of Diagnostic Procedures involving Embryos, Council website, www.rtc.org.au/)
- g) use by a licensee for the purpose of achieving pregnancy in a woman other than the woman for whom it was created.
See s 53W (2)

5.0 WHERE PARTICIPANTS DISAGREE

- 5.1 When an embryo developed on behalf of a person or on whose behalf the embryo is being kept or is to be kept in storage, each such person has the right to decide how the embryo is dealt with, or how it may be disposed of (s26(1)), and may review, vary or withdraw consent for storage.
- 5.2 If a couple in whom the rights to an embryo are vested disagree about the embryo's use or continued storage, a member of the couple can apply to the CEO of Health (Director General), to direct the licensee to continue storage. On receiving such an application, the CEO of Health must direct the storage licensee to ensure that storage is continued. This will be subject to the storage fees being paid, any limitation on the storage period under s24(1)(b) of the Act, and any order made by a Court of relevant jurisdiction.

6.0 DEATH OF PERSON/S WITH RIGHTS TO AN EMBRYO

- 6.1 In the event of the death of one member of a couple in whom the rights to an embryo are vested, the responsibility and right to decide how an embryo is dealt with or disposed of remains with the surviving member (s26(1)(b)).
- 6.2 In the event that both members of a couple (who have provided gametes to create an embryo) die, the licensee should act in accordance with any written consent of the couple as to how the embryo is to be dealt with. There is no prohibition on the posthumous use of *embryos*, provided that it is a use otherwise permitted under the HRT Act. NHMRC Ethical Guideline 8.7.2 also provides that in such circumstances any reasonable, clearly expressed and witnessed directive from the couple should be followed. NB. As at Jan 2010 Direction 8.9 prohibits a licensee from knowingly using or authorising the use of *gametes*, but not embryos, in an artificial fertilisation after the death of the gamete provider).
- 6.3 With regard to 6.2, a directive may include a lawful donation to another couple, or use in research.
- 6.4 In the absence of a reasonable or lawful directive for the future of any embryos stored for a participant couple who have died, licensees should arrange for the disposal of the embryo/s (NHMRC Ethical Guideline 8.7.2).

7.0 ALLOWING EMBRYOS TO SUCCUMB

- 7.1 The HRT Act requires that embryos be allowed to succumb on the premises licensed under the HRT Act. Participants are not able to take their live embryos home to succumb.
- 7.2 NHMRC Ethical Guidelines 8.5 and 8.9 outline that licensees must provide information about the removal of embryos from storage to participants, and have protocols in place for the respectful disposal of embryos.
- 7.3 The HRT Act does not appear to expressly prohibit a person (in whom rights to an embryo were formerly vested) taking an embryo that has been allowed to succumb off the licensed premises for disposal. However, other regulation

(of biological materials etc) may apply. For this reason, licensees should seek their own legal advice upon receiving such a request.

- 7.4** Participants may wish to consider providing consent to the use of their embryos for training purposes, once the embryos have been allowed to succumb. The use of non-living embryos for licensee training does not require an NHMRC licence, although licensees must receive general Council approval to use non-living embryos for training or research purposes (s20(2)).

8.0 IMPORT AND EXPORT OF EMBRYOS

- 8.1** Where a licensee seeks to import embryos created from donated human reproductive material from outside of Western Australia, information about the donor embryo/s required for the Reproductive Technology Registers must be available to the licensee, or waived by Council (Direction 6.2).
- 8.2** If the information (including donor identifying information) is not available, Council may waive this requirement on application, based on compassionate grounds (Direction 6.3).
- 8.3** A licensee must not permit or facilitate the export of a donated embryo or an embryo created from donated gametes from Western Australia without the prior approval of Council (Direction 6.5).
- 8.4** The approval to export a donated embryo is dependant on the recipient of the embryo/s undertaking to provide the WA licensee with information required for the RT Registers. Form 10 sets out this requirement (Appendix 3).
- 8.5** The export of embryos for a use that is prohibited in Western Australia is not permitted (Direction 6.4).
- 8.6** A licensee accepting an embryo from another person for storage is responsible for the reporting requirements for that embryo (Direction 2.12).

9.0 ENQUIRIES REGARDING EMBRYO STORAGE MATTERS

Form 8 and Form 9 applications should be marked 'Confidential' and returned to the 'Executive Officer, Reproductive Technology Council, PO Box 8172, Perth Business Centre, Perth WA 6849.

When an application is received by the Executive Officer directly from participants, the Executive Officer or Deputy Executive Officer will notify the licensee storing the embryos that an application has been received. Following a decision by Council, participants will be notified of Council's decision by registered mail. Licensees will be informed and the Minister for Health notified as per s24(1d).

Licensee enquiries regarding embryo storage may be directed to the Executive Officer or Deputy Executive Officer by email, or telephone. Current contact details are available on the RTC website www.rtc.org.au, or by telephoning the Department of Health on (08) 9222 4222. Queries may also be sent to the above postal address.

APPENDICES

Appendix 1: FORM 8

Appendix 2: FORM 9

Appendix 3: FORM 10

Appendix 4: EMBRYO STORAGE BROCHURE

Appendix 5: EXAMPLE LETTERS TO PATIENTS FOR 9 AND 9 ³/₄ YEARS

Appendix 6: RELEVANT LEGISLATION AND GUIDELINES

CONFIDENTIAL

PART B

Eligible Participant(s) to complete:

Date of Application
day month year

Eligible Participant Name: **Female** **Partner (if any)**
name: **Family name** _____ **Family name** _____
Given name _____ **Given name** _____

Signature: _____

Address: _____

Postcode: **Phone Number:** _____

You will be contacted by mail for notification of the outcome of your application or should we require further information in order to process your application. Your phone number will only be used to contact you if further information is required within a short time frame, we do not anticipate this happening in the majority of cases. Should we attempt to contact you discretion will be used and we will only speak to the participant or their partner.

Please indicate if there are any restrictions to the way in which you would like us to contact you.

1. Who is applying?:
- (a) Both members of the eligible couple.
 - (b) One member only of the eligible couple.
 - (c) Eligible single person.

2. Are you seeking an extension with the intention of:
- (a) Using the embryos for your own treatment at a later time.
 - (b) Donating the embryos to an eligible recipient/s.
 - (c) Other

3. Briefly explain your reasons for seeking an extension:

4. When do you plan to use or dispose of your embryos?

5. Signature of applicant(s) _____

FORM 10 - UNDERTAKING

EXPORT OF DONATED HUMAN REPRODUCTIVE MATERIAL FROM WESTERN AUSTRALIA (WA):

Formal undertaking between a person seeking the approval of the Reproductive Technology Council to receive this material and the WA licensee who is to export the donated human reproductive material.

This is to certify that I,

.....
(full name, title and occupation)

of
(full address)

do undertake:

1. To provide the WA licensee

.....
(Full name of licensee who is to provide the material)

within a reasonable time, with all the information that would be required if any assisted fertilisation procedure that I carry out or authorise with the donated human reproductive material were carried out in Western Australia (ie recipient code, type of treatment, date of treatment and outcome at 8 weeks after the procedure);

2. To provide to the WA Donor Register, when requested by Register staff, recipient identifying information as required under the Act;
3. To provide the recipient and their spouse/partner with all relevant information, especially regarding the Registers which have been established, prior to obtaining their consent to the procedure as set out under the Act.

I understand that if I fail to provide the required information to the licensee or the Register within a reasonable time and without good cause, the approval of Reproductive Technology Council for me to receive further material from the licensee may be withdrawn.

..... (Date)
(Signature of applicant)

TO OBTAIN APPROVAL THE APPLICANT FOR APPROVAL SHOULD RETURN THE SIGNED ORIGINAL OF THIS UNDERTAKING TO THE RELEVANT WA LICENSEE. THE LICENSEE SHOULD THEN CONTACT THE REPRODUCTIVE TECHNOLOGY COUNCIL SEEKING ITS APPROVAL, IN WRITING, TO EXPORT THE MATERIAL TO THE APPLICANT, ENCLOSING A COPY OF THIS UNDERTAKING.

suggested that you include a medical report supporting that you are still eligible to access IVF.

- If your intention is to donate your embryos for use by another person or couple or to the clinic for research, it will help the application process to include documents supporting this intention to donate. This may include a signed 'consent to donate embryos' form, or verification that you have started the counselling process prior to donation.

The law requires that the Council receives any embryo storage extension at least one month before it is due to meet next. In addition to this, your embryo storage period must still be valid at the time the Council meets to discuss this matter. For this reason, it is important that you have given some consideration to your situation and what you wish to do with your embryos- it can be very difficult to have to make a hurried decision.

If you wish to seek an extension of your embryo storage period, your clinic can provide help to ensure that your application meets the requirements under the HRT Act.

Who has the responsibility to apply for an extension?

If you intend to store your embryos for your own use at a later date, or if you are intending to donate your embryos but a recipient has not yet been selected, you will need to apply for an

extension. Your clinic is not able to do this on your behalf.

If you have donated them to another person or couple, you may have agreed to give this person or couple the responsibility of applying to the Council for any ongoing storage extensions.

Clinics can only apply for embryo storage extensions if you have declared your embryos to be excess to your needs (they are then considered "excess ART embryos") and have donated your embryos to the clinic for approved NHMRC research purposes.

What happens if I don't apply for an extension?

It is illegal for clinics to continue to store your embryos beyond ten years unless you are granted a storage period extension. If you have *not* made an application to extend the storage time to the Council and the authorised storage period expires, your clinic will have to allow these embryos to succumb. Under the law, Council is unable to approve an embryo storage extension once the authorised storage period has expired.

What if we can't decide what to do with our embryos?

Some people find it very difficult to reach a decision regarding their stored embryos. Every

person or couple needs to consider their particular situation.

People facing these decisions are encouraged to have counselling with an 'Approved Counsellor' to discuss their options and to assist with decision-making. Counselling will be required if you wish to donate your embryos to someone you know, but also can benefit anyone who is considering what to do with their embryos in storage. Talking about these issues with other couples who have undergone IVF has also helped many people facing this difficult decision.

What if we can't agree, or our circumstances change?

In the situation where a couple is in disagreement, one of the couple must apply, before the end of the storage period, to the Director General of the Department of Health WA. The Director General may instruct the clinic to store the embryos until resolution of the disagreement, or a Court order is issued regarding this matter.

Where do I get more information about embryo storage?

Your clinic is able to provide you with assistance in completing an application and discussing your embryo storage issues. You can also visit the **RTC website** <http://www.rtc.org.au> for further information, or contact the RTC Executive Officer, on rtc@health.wa.gov.au



Reproductive Technology Council

Storage of embryos at *Fertility clinic*

Dear IVF participant

This letter serves as a reminder that the embryos created from your in vitro fertilisation (IVF) treatment at _____ have now been in storage for more than nine years.

You may be aware that in 2004, the maximum time for embryos to remain in storage in Western Australia was increased from three years to ten years. This increase aimed to provide enough time, in general, for people to complete their fertility treatment. Embryos may be stored beyond ten years. However, this requires an application to the WA Reproductive Technology Council (Council). In order to grant an extension under the *Human Reproductive Technology Act 1991*, the Council must consider that your application is for a *special reason*.

At this point in time, you may be still undergoing fertility treatment at your clinic and wish to keep your embryos in storage for this purpose. If the embryos are to be used for your own treatment, you must still be eligible to undertake IVF treatment- your clinic can assist you with this. However, if you are reaching completion of your treatment, or no longer wish to use your embryos for your own treatment, you are encouraged to give some consideration to your future options.

Many people will choose to allow their embryos to succumb when they no longer wish to keep them for their own treatment. Another option is to donate embryos to another person or couple, or donate embryos for research purposes. Donation to other people who are seeking infertility treatment can be a very generous act, though there are important issues that will require consideration. For this reason, if you are considering donation, you will be asked to see a clinic counsellor before consenting to this. If your embryos were created using donated gametes, it may not be possible to on-donate your embryos- this matter can also be discussed with your clinic or counsellor.

Your clinic is required to take reasonable steps to contact you three months before the end of the authorised storage period to notify you that your embryo storage period is coming to an end. The law does not allow Council to consider applications once the authorised storage period ends. For this reason, it is important that you keep your clinic updated with any changes to your contact details, and that you respond promptly to the clinic notification in the event that you do wish to apply for an embryo storage extension.

If you would like further information on embryo storage matters, please contact your clinic. Information is also available on the Reproductive Technology Council website <http://www.rtc.org.au/>. If you are uncertain about your future intentions or have any other issues of concern, discussing these issues with a clinic counsellor before the ten year end of storage approaches can also be very beneficial.

Yours faithfully

Ms Jenny O'Callaghan
Executive Officer
Reproductive Technology Council



Reproductive Technology Council

Storage of embryos at *Fertility clinic*

Dear IVF participant

This letter is to remind you that the ten year authorised storage period for the embryos created through your in vitro fertilisation (IVF) treatment at _____ is soon to expire. Your clinic is required to inform you that if you wish to keep your embryos in storage beyond this time, you will need to apply to the Reproductive Technology Council (Council) to extend your embryo storage period.

Under the *Human Reproductive Technology Act 1991* (HRT Act), Council is able to approve such an extension to an authorised storage period. However, the HRT Act requires that Council consider that there are *special reasons* for approving an extension. Another requirement of the law is that the future use of an embryo must relate to the probable future implantation of the embryo, or its probable future use under a national research licence.

At this point in time, you may be still undergoing fertility treatment at your clinic and wish to keep your embryos in storage for this purpose. If the embryos are to be used for your own treatment, you must still be eligible to undertake IVF treatment.. Eligibility for IVF requires that the reason for infertility is *not* age, and therefore women who have undergone menopause (where it is not considered a premature menopause) are unfortunately no longer eligible for IVF. Written support from your IVF specialist that you are still eligible for IVF (which includes the embryo transfer process) will assist your application.

If you have completed your treatment, or no longer wish or are able to use your embryos for your own treatment, it is hoped that you have given some consideration to the other options available to you.

If you have decided to donate your remaining embryos to another person or couple, or for research, then the inclusion of supporting documents with your embryo storage application will assist your application for an embryo storage extension. For example, including a copy of the completed 'consent to donate' form with your application will enable Council to consider that the extension is for a *special reason*, and that the storage of the embryos is for probable implantation or for research purposes. Alternatively your clinic may be able to verify that you have started the counselling process as an indication of your intention to donate.

Donation of embryos can be considered to be a generous act, but it is not for everybody. If your embryos were created using donated gametes, it may not be possible to on-donate your embryos- this matter can also be discussed with your clinic or counsellor.

Many people will choose to allow their embryos to succumb when they no longer wish to keep them for their own treatment. This is a very personal decision - if you are uncertain about your future intentions or have any other issues of concern, discussing these issues with a clinic counsellor before the ten year end of storage approaches can be very beneficial.

Whatever your intention, the law does *not* allow embryos to be stored indefinitely, and you will need to take action before the expiry of your embryo storage period if you do not wish your embryos to succumb at the end of this period as the HRT Act does not allow Council to consider applications once the authorised storage period ends. Your clinic can assist you with the application, but cannot undertake the extension application for you unless embryos have been donated for research to the clinic.

The law also requires the application to be received one month before the next Council meeting. **For this reason, it is important that you keep your clinic updated with any changes to your contact details, and that you respond promptly to the clinic notification in the event that you do wish to apply for an embryo storage extension.**

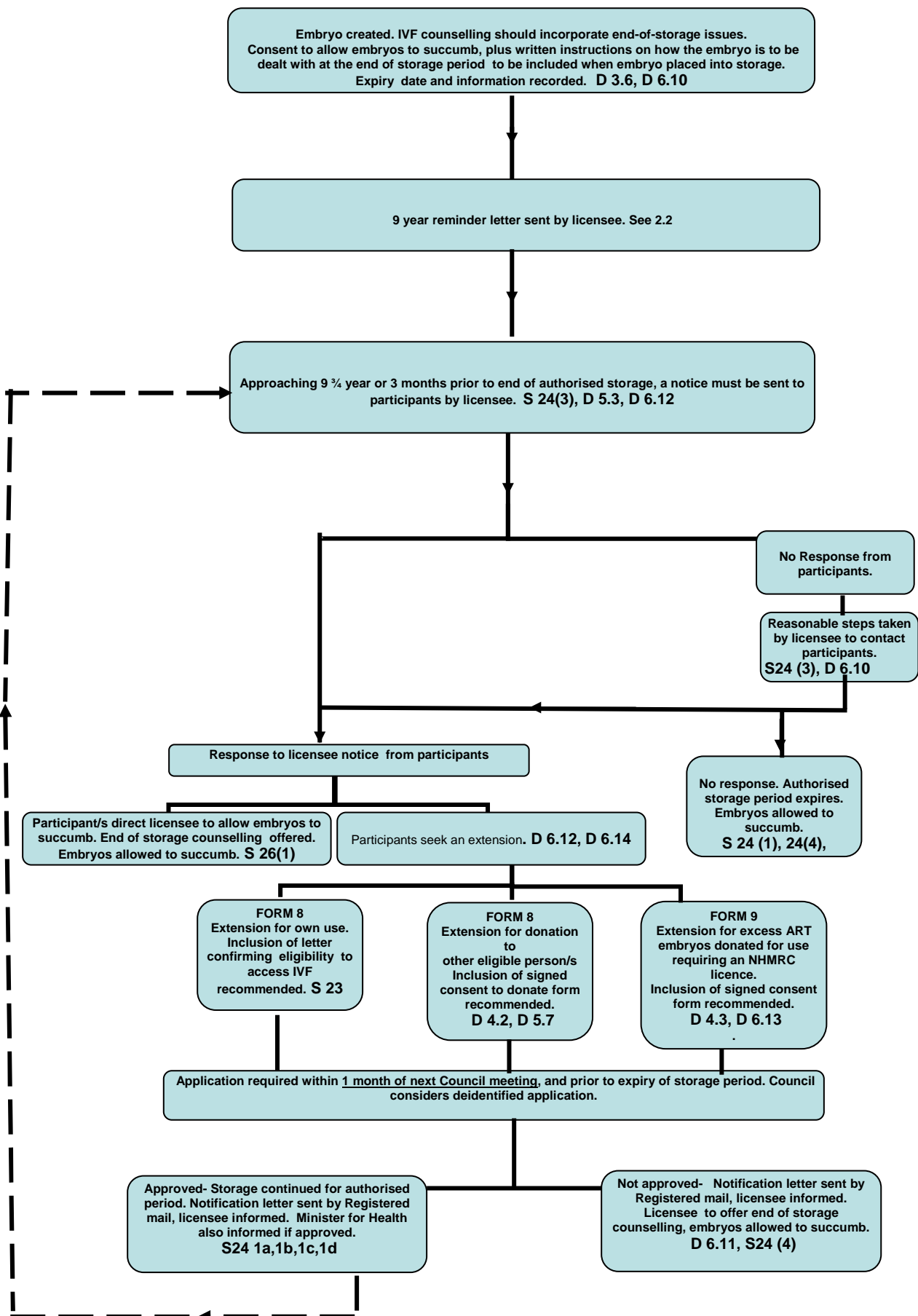
You will be notified of the outcome of your embryo storage extension application. If you would like further information on embryo storage matters, please contact your clinic. Information is also available on the Reproductive Technology Council website <http://www.rtc.org.au/>.

Yours faithfully



Ms Jenny O'Callaghan
Executive Officer
Reproductive Technology Council

APPENDIX 6- RELEVANT LEGISLATION AND GUIDELINES



EXCERPTS FROM LEGISLATION CONCERNING EMBRYO STORAGE

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

3A. Meaning of “human embryo”

- (1) In this Act —
 “**human embryo**” means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.
- (2) For the purposes of the definition of “human embryo” in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

6. Unlicensed practices

- (1) No person shall cause or permit —
 - (a) any procedure to be carried out related to the storage of —
 - (i) a human egg intended for use in an in vitro fertilisation procedure;
 - (ii) a human egg undergoing fertilisation; or
 - (iii) a human embryo;
 - (b) human sperm, having been obtained from different men, to be kept;
 - (c) an artificial fertilisation procedure, other than an artificial insemination to which section 28(3) applies, to be carried out; or
 - (d) any other use, outside the body of a woman, of a human embryo, if the use is not for a purpose relating to the reproductive technology treatment of the woman,except pursuant to a licence or exemption by which it is authorised under this Act.
- (2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.
Summary conviction penalty: Imprisonment for one year.

7. Offences relating to reproductive technology

- (1) A person, whether or not a licensee, must not cause or permit —
 - (a) research to be conducted upon or with a human egg undergoing fertilisation, or any embryo, not being research in respect of which the Council has already granted relevant approval or all requisite specific prior approvals have been sought and obtained under section 20; or
 - (b) a diagnostic procedure to be carried out upon or with a human egg undergoing fertilisation, or any embryo, not being a procedure which is —
 - (i) authorised by the Code; or
 - (ii) specifically approved by the Council.
- (2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.
Summary conviction penalty: Imprisonment for one year.

[(3), (4) repealed]

(5) A person who —

- (a) being a licensee, keeps or uses human gametes, a human egg undergoing fertilisation or a human embryo in contravention of this Act; or
- (b) being a person to whom a licence applies or applied, fails to comply with a direction given for the purpose of section 30(4)(a),

commits an offence.

Penalty: 2 years imprisonment.

14. Functions of the Council

(2a) The Council must not grant approval to any research being conducted upon or with a human embryo unless —

- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman; or
- (b) the research consists of a use referred to in section 53W(2)(b) or (f).

(2b) The Council must not grant approval to any diagnostic procedure to be carried out upon or with a human embryo unless —

- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that —
 - (i) the diagnostic procedure is unlikely to leave the embryo unfit to be implanted in the body of a woman; and
 - (ii) where the diagnostic procedure is for the genetic testing of the embryo, there is a significant risk of a serious genetic abnormality or disease being present in the embryo;

or

- (b) the diagnostic procedure consists of a use referred to in section 53W(2)(d) or (f).

20. Principles applicable to projects of research

(1) A licence shall not be capable of authorising any research contravening the condition referred to in subsection (3).

(2) No licensee shall carry out, or authorise or facilitate or become involved in the carrying out of, any project of research —

(a) upon or with —

- (i) human gametes obtained in the course of an in vitro fertilisation procedure or intended for use in an artificial fertilisation procedure; or
- (ii) a human egg undergoing fertilisation or a human embryo whether or not live;

or

(b) involving any person who is a participant in an artificial fertilisation procedure,

unless general or specific approval relevant to that project has already been granted by the Council, or unless specific prior approval from the Council for that particular project

of research is sought for in such manner as may be required by the Code or directions, and if the Council so requires is also sought from a specific Institutional Ethics Committee recognised by the Council, and is obtained.

- (2a) Subsection (2)(a)(ii) does not apply in relation to an excess ART embryo except in relation to a use of such an embryo that is an exempt use as defined in section 53W(2).

22. Consents, generally

- (1) For the purposes of the licence condition referred to in section 33(2)(e) —

(d) where the development of an egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure it shall not be kept in storage unless —

- (i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the storage; and
 - (ii) the egg or embryo is stored in accordance with that consent;
- (e) where the development of a human egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure, it shall not be used for any purpose, or for such a purpose be received by a licensee or participant, unless —

- (i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the use for that purpose;
- (ia) in the case of a use outside the body of a woman, there is an effective consent to the use for that purpose by the woman on whose behalf it is being developed and her spouse or de facto partner, if any;

(2) Where a consent is given in general terms to the use or storage of human gametes separately, whether human eggs or human sperm, that consent shall be taken to relate to the use or storage of any of those eggs or sperm, and also to any human egg undergoing fertilisation or human embryo derived from the use of the human gametes, for any purpose, save that —

- (a) any such consent may be given subject to specific conditions in its terms; and
- (b) notwithstanding subsection (4) or that a human egg undergoing fertilisation or a human embryo, may have developed which is derived from the use of human gametes the subject of any particular consent, in so far as it relates to any human egg or human sperm that has not been used that consent may be varied or withdrawn,
but where a human egg in the process of fertilisation, or a human embryo, has been developed from any human gametes the consent thereafter to be required is not a consent to the use of those human gametes but a specific consent relating to that particular egg undergoing fertilisation or embryo only.

(6) A consent to the keeping of any human gametes, a human egg undergoing fertilisation or a human embryo must —

- (a) specify the maximum period of storage, if that is to be less than such limit as may be prescribed or may be determined in accordance with section 24(1)(b); and
- (b) give instructions as to what is, subject to this Act, to be done with the gametes, the egg or the embryo if the person who gave the consent is unable by reason of incapacity or otherwise to vary the terms of the consent or to withdraw it,

and may specify conditions subject to which the gametes, or the egg or embryo, shall or shall not remain in storage.

- (7) Before a licensee gives effect to a consent given for the purposes of this Act the licensee shall ensure that each participant has been provided with a suitable opportunity to receive —
- (a) proper counselling about the implications of the proposed procedures; and
 - (b) such other relevant and suitable information as is proper or as may be specifically required by the Code or directions, including an explanation of the effect of subsection (3) and subsection (4).
- (8) For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless —
- (a) it is given in writing;
 - (b) any condition to which it is subject is met;
 - (c) it has not been withdrawn; and
 - (d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.

23. When procedures may be carried out

An in vitro fertilisation procedure may be carried out where —

- (a) it would be likely to benefit —
 - (i) persons who, as a couple, are unable to conceive a child due to medical reasons;
 - (ia) a woman who is unable to conceive a child due to medical reasons; or
 - (ii) a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or a disease;
- (b) each of the participants required to do so has given an effective consent;
- (c) the persons seeking to be treated as members of a couple are —
 - (i) married to each other; or
 - (ii) in a de facto relationship with each other and are of the opposite sex to each other;
- (d) the reason for infertility is not age or some other cause prescribed for the purpose of this paragraph; and
- (e) consideration has been given to the welfare and interests of —
 - (i) the participants; and
 - (ii) any child likely to be born as a result of the procedure,and in the opinion of the licensee that consideration does not show any cause why the procedure should not be carried out,

but not otherwise.

24. Storage

- (1) In relation to the storage of any human gametes, human egg undergoing fertilisation or human embryo —

- (a) the primary purpose stated in any consent to the storage of a human embryo must relate to the probable future implantation of that embryo or its probable future use under an NHMRC licence; and
- (b) the Code may make provision as to what, in particular circumstances, constitutes an excessive time for the storage of —
 - (i) human gametes;
 - (ii) a human egg undergoing fertilisation; or
 - (iii) a human embryo,

but no human egg undergoing fertilisation or human embryo shall be stored for a period in excess of 10 years except with the approval of the Council under subsection (1a).

- (1a) The Council may, on an application by an eligible person, approve in writing a longer storage period for a human egg undergoing fertilisation or a human embryo if it considers that there are special reasons for doing so in a particular case.
- (1b) An approval under subsection (1a) may be subject to conditions and is to specify the date on which the longer storage period ends.
- (1c) An approval under subsection (1a) can only be given before the end of 10 years, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.
- (1d) The Council is to inform the Minister of each approval given under subsection (1a), but in such a manner that the identity of the biological parents cannot be ascertained from the approval.
- (2) In subsection (1a) —
 - “**eligible person**”, in relation to a human egg undergoing fertilisation or a human embryo, means —
 - (a) a person who is or is to be a participant in an artificial fertilisation procedure in which the egg or embryo is to be used;
 - (b) a person for whom the egg or embryo was developed; or
 - (c) in the case of an excess ART embryo, except in relation to the use of such an embryo referred to in section 10(2)(e) of the Commonwealth Human Embryo Act, the licensee.
- (3) Three months before the end of a period of storage permitted under this section the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored.
- (4) If a period of storage permitted under this section comes to an end and no application has been made for the extension of the storage period, the licensee may, if the licensee has complied with subsection (3), allow the human egg undergoing fertilisation or the human embryo to succumb and will not be liable to anyone for so doing.

[Section 24 amended by No. 1 of 1996 s. 5 and 6; No. 3 of 2002 s. 75; No. 17 of 2004 s. 18.]

26. Control, dealing and disposal in relation to an egg in the process of fertilisation or an embryo

- (1a) This section does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).

- (1) Subject to section 24(4), in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside the body of a woman —
 - (a) each person on whose behalf it is developed or is being or is to be, kept has, subject to section 53Q, the right to decide how a human egg undergoing fertilisation or a human embryo is to be dealt with or disposed of, so that —
 - (i) such a person shall have, while storage continues, the right to review the decision to store from time to time and may withdraw consent or vary the terms of any consent; and
 - (ii) any question as to the nature or extent of the respective rights or powers may, subject to subsection (2), be referred to a court of competent jurisdiction;
 - (b) in the event of the death of one member of a couple in whom the rights are vested, those rights vest solely in the survivor;
 - (c) where from any human gametes, a human egg undergoing fertilisation or a human embryo is developed, whether or not with effective consent, the individual rights of a human gamete provider or person to whom the human gametes were provided and of a licensee cease at the moment fertilisation begins and the rights thereafter vest jointly in the couple on whose behalf that egg or embryo was developed, or vest in the woman on whose behalf that egg or embryo was developed;
 - (d) where a human egg undergoing fertilisation or a human embryo has been developed on behalf of a couple or a woman and is no longer required for that purpose, the egg may be used if all the participants in a proposed procedure give an effective consent; and
 - (e) on the commencement of an implantation procedure the rights in a human egg undergoing fertilisation or a human embryo vest in the woman receiving it, whether or not —
 - (i) that recipient was eligible to undergo the procedure; or
 - (ii) any consent required was given or, if given, was effective.
- (2) Where rights in relation to a human egg undergoing fertilisation or a human embryo are vested in a couple and the couple disagree about its use or continued storage, the CEO shall, on application by a member of that couple, direct the licensee storing the egg or embryo to ensure that the storage is maintained subject to —
 - (a) payment of the proper charges of the licensee for the storage;
 - (b) any limitation as to the time of storage prescribed or determined in accordance with section 24(1)(b); and
 - (c) any order made by a court of competent jurisdiction which otherwise requires.

[Section 26 amended by No. 3 of 2002 s. 76; No. 17 of 2004 s. 20; No. 18 of 2004 s. 7; No. 28 of 2006 s. 270(1).]

27. Licences, and the person responsible

- (2) In accordance with its terms a storage licence may authorise the licensee to carry out any procedure related to —
 - (a) the storage of —
 - (i) any human egg intended for use in an in vitro fertilisation procedure;
 - (ii) any human embryo; or
 - (iii) any human egg undergoing fertilisation;

- (b) the keeping of human sperm, having been obtained from different men; and
- (c) any project of research related to such storage and approved under section 20.

33. Conditions applicable to all licences and exemptions

- (3) Every storage licence is subject to the conditions —
- (a) that human gametes, a human egg undergoing fertilisation or a human embryo shall be stored only if received or acquired from —
 - (i) a person to whom a licence applies; or
 - (ii) a person who satisfies the licensee that they can give an effective consent to that storage;
 - (b) that a human egg undergoing fertilisation or a human embryo the development of which was brought about by an in vitro fertilisation procedure, otherwise than under the authorisation conferred by a practice licence held by the same licensee, shall be stored only if received or acquired from —
 - (i) another person to whom a licence applies; or
 - (ii) a person who satisfies the licensee that they can give an effective consent to that storage;
 - (c) that human gametes, human eggs undergoing fertilisation or human embryos which are or have been stored shall not be supplied to a person unless that person is a person to whom a licence or an exemption applies, or the supply has been otherwise authorised under this Act; and
 - (d) that no human gametes, human egg undergoing fertilisation or human embryo shall be stored for longer than this Act authorises.

49. Confidentiality

- (1) A person shall not divulge, or communicate to any other person, any information disclosed or obtained by reason of this Act respecting the identity of —
- (a) a donor of human gametes, a human egg undergoing fertilisation or a human embryo;
 - (b) a participant in any procedure involving reproductive technology; or
 - (c) a child born as a result of any artificial fertilisation procedure,
- unless subsection (2) applies.
- (2) Information to which subsection (1) applies may be divulged or communicated —
- (a) for a purpose necessary to the carrying out of any procedure, or the conduct of any research, to which this Act applies;
 - (b) for the purposes of and in the course of the administration of this Act, or pursuant to a request of the Minister made for the purposes of section 5;
 - (c) as may be authorised or required by the Code or the regulations;
 - (d) subject to subsections (2a) to (2c), with the consent of each donor, participant or child in question or other person whose identity may be disclosed in so far as it does not identify any person who was a participant in the relevant procedure and who has not given such consent; or
 - (e) under an authorisation conferred by another written law.

51. Supervision

(2) It shall be the duty of the licence supervisor to secure —

(c) that proper arrangements are made for the keeping of human gametes, human eggs undergoing fertilisation and human embryos and for the disposal of any such gametes, eggs or embryos that succumb;

53Q. Offence — commercial trading in human eggs, human sperm or human embryos

(1) A person commits a crime if the person gives or offers valuable consideration to another person for the supply of a human egg, human sperm or a human embryo.

(2) A person commits a crime if the person receives, or offers to receive, valuable consideration from another person for the supply of a human egg, human sperm or a human embryo.

(3) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

(4) In this section —

“reasonable expenses” —

(a) in relation to the supply of a human egg or human sperm includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and

(b) in relation to the supply of a human embryo —

(i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and

(ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo;

“valuable consideration”, in relation to the supply of a human egg, human sperm or a human embryo by a person, includes any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply.

[Section 53Q inserted by No. 18 of 2004 s. 8.]

53T. Definitions

“excess ART embryo” means a human embryo that —

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

(b) is excess to the needs of —

(i) the woman for whom it was created; and

(ii) her spouse or de facto partner (if any) at the time the embryo was created;

“proper consent”, in relation to the use of an excess ART embryo, means —

(a) consent obtained in accordance with the *Ethical Guidelines on Assisted Reproductive Technology* (1996) issued by the NHMRC;

- (b) if other guidelines are issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of paragraph (b) of the definition of “proper consent” in section 8 of the Commonwealth Human Embryo Act — consent obtained in accordance with those other guidelines, rather than the guidelines mentioned in paragraph (a); or
- (c) where an intended use is to provide a human embryonic stem cell line, the uses to which the human embryonic stem cell line may be put must have been disclosed and explained;

“**responsible person**”, in relation to an excess ART embryo, means —

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

“**State**” includes the Australian Capital Territory and the Northern Territory.

- (2) For the purposes of paragraph (b) of the definition of “excess ART embryo”, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if —
 - (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
 - (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

53W. Offence — use of excess ART embryo

- (1) A person commits a crime if the person uses an excess ART embryo, unless —
 - (a) the use by the person is authorised by a licence; or
 - (b) the use by the person is an exempt use as defined in subsection (2).

Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.

Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.

- (2) A use of an excess ART embryo by a person is an “**exempt use**” for the purposes of subsection (1) if —
 - (a) the use consists only of —
 - (i) storage of the excess ART embryo;
 - (ii) removal of the excess ART embryo from storage; or
 - (iii) transport of the excess ART embryo;
 or
 - (b) the use consists only of observation of the excess ART embryo;
 - (c) the use consists only of allowing the excess ART embryo to succumb;

- (d) the use is carried out by a licensed ART centre, and —
 - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
 - (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created;
- (e) the use is carried out by a licensed ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
- (f) the use is of a kind prescribed by the Commonwealth Human Embryo regulations for the purposes of section 10(2)(f) of the Commonwealth Human Embryo Act.

53ZE. Licence is subject to conditions

- (1) A licence is subject to the condition that before an excess ART embryo is used as authorised by the licence —
 - (a) each responsible person in relation to the excess ART embryo must have given proper consent to that use;

Directions under the *Human Reproductive Technology Act 1991*

***2.12 Transfer of responsibility to report to the Commissioner of Health**

A licensee, including the holder of an exemption under section 28A of the Act, who accepts gametes or an embryo from another person for storage, is responsible for the provision of any report required in respect of those gametes or that embryo.

2.15 Reporting on excess ART embryos donated for research

A storage licensee must provide to the Commissioner of Health for inclusion in the registers, information set out in Part 3 of the Data Structure in Schedule 2 that is relevant to each excess ART embryo that has been donated for research.

2.16 Copies of reports to NHMRC Licensing Committee to be provided to Council

A licensee, including the holder of an exemption under section 28A, must provide the Council with a copy of any report provided to the NHMRC Licensing Committee in connection with an NHMRC licence held by the licensee.

1.6 Standards for an exemption for storage of excess ART embryos (holder of an exemption under section 28A of the Act)

The holder of an exemption from the requirement to hold a storage licence authorising the storage of an excess ART embryo under section 28A of the Act must ensure that.

- (a) as a minimum, standards for practice, equipment, staff and facilities comply with good laboratory practice;
- (b) any relevant conditions of the NHMRC licence are complied with; and
- (c) any requirements established under the Act are complied with.

1.7 Application for renewal of a licence

A licensee who is the holder of a storage or practice licence must apply for renewal of a licence no later than 3 months before its expiry.

1.8 Renewal in relation to an exemption under section 28A of the Act

The holder of an exemption under section 28A of the Act must apply for a new exemption in relation to each NHMRC licence held.

1.9 Notification in relation to an exemption under section 28A of the Act

The holder of an exemption under section 28A of the Act must notify the Commission of Health of any change to the NHMRC licence for which the excess ART embryos are being stored.

3.4 Consent to use of embryo or egg undergoing fertilisation

Prior to the donation of an embryo or egg undergoing fertilisation for use in an artificial fertilisation procedure, any person to whom the licence applies must ensure that.

- (a) effective consent to the donation and use is given by the person(s) for whom the embryo or egg was developed; and
- (b) any person who donated gametes used to develop the embryo or egg, and the spouse or defacto partner of the gamete provider (if any) gave effective consent to the use at the time the donation was made.

3.5 Donors and recipients of gametes, embryos and eggs undergoing fertilisation to be aware of *Artificial Conception Act 1985

Any person to whom the licence applies, including an exempt practitioner, who proposes to use donated gametes, embryos or eggs undergoing fertilisation in an artificial fertilisation procedure must ensure that the donor(s) and recipient(s) are aware of the impact of the *Artificial Conception Act 1985* on the legal parentage of a child born as a result of the procedure.

3.6 Consent to allow an embryo to succumb

The licensee must ensure that any consent to storage of an embryo or egg undergoing fertilisation includes consent to remove the embryo or egg from storage and allow it to succumb at the end of any authorised storage period.

3.8 Consent for the use of excess ART embryos

The licensee supervisor must ensure that no embryo is provided for use in connection with an NHMRC licence unless.

- (a) the embryo has been declared to be an excess ART embryo by the woman for whom it was created and her spouse or de facto partner (if any); and
- (b) proper consent to the use of the embryo for the purposes authorised under the NHMRC licence has been given by each responsible person.

3.9 Donors of excess ART embryos for research to be informed that further, specific consent may be required

The licensee must ensure that donors of excess ART embryos for research are informed that further specific consent for use of the embryo in a particular project may be required in the future and that they may refuse to give such consent.

3.10 Donors of excess ART embryos for research to be informed of eligibility to apply for an extension of storage period

The licensee must ensure that donors of excess ART embryos for use in providing treatment to another person or couple are informed that they may be eligible to apply for an extension of the storage period of an embryo that has not yet been used. The donors should be given the option of indicating whether they want to be contacted in accordance with the provisions in section 24(3) of the Act if the embryo is still in storage.

***4.2 Additional information to be given in relation to the use of donated reproductive material**

The licensee must ensure that, prior to consent being given for the donation or use of donated human reproductive material in an artificial fertilisation procedure, all donors and recipients are given oral explanations, supported by relevant written information in a form approved by Council, including information about:

- (a) the effect of the *Artificial Conception Act 1985*;
- (b) information that is included on the registers in relation to the donated material, its use and the biological parentage of any child born as a result of the use;
- (c) rights of donors, participants and children born as a result of the donation to access identifying and non-identifying information in accordance with the Act;
- (d) the medical and social implications in relation to donation and for children born as a result of the donation;
- (e) the need to refrain from unprotected sexual intercourse during the course of treatment to avoid confusion about the biological parentage of any child born;
- (f) limitations on the storage periods permitted for the reproductive material and requirements of the Act in relation to seeking extension of the storage period.

4.3 Information to be given in relation to the use of donated embryos for a use requiring an NHMRC licence

The licensee must ensure that, prior to consent being given, persons wishing to donate excess ART embryos for a use which requires an NHMRC licence are given oral explanations, supported by relevant written information in a form approved by Council, including information about:

- (a) procedures under Part 4B of the Act and the *Research Involving Human Embryos Act 2002* (Cth) for obtaining consent to the use of an excess ART embryo for a specific NHMRC licence, including advice that consent for a specific use may be requested at some future date and that the person has the right to refuse to give that consent;
- (b) rights to place conditions on the uses to which the embryo may be put;
- (c) rights to withdraw consent prior to use of the embryos; and
- (d) limitations on the storage period for embryos, including advice that the licensee may apply for approval to extend the storage of an embryo unless the person who is donating the embryo has advised that they wish the embryo to be removed from storage at a specified time.

5.3 Cost of treatment to include time with approved counsellor

The licensee must ensure that the overall cost of treatment includes the cost of at least one consultation with an approved counsellor for each IVF cycle begun. The licensee must not provide a discount to a participant on the basis that the participant chooses not to use the counselling included in the overall cost of treatment.

5.5 IVF participants must be provided with information as to counselling entitlements

The licensee must ensure that participant/s proposing to undergo an IVF procedure is/are provided with information about their entitlements to counselling and the options that available in relation to how and when and if to take up the entitlement and that they are strongly encouraged to undertake such counselling.

5.7 Information about counselling to be provided to donors of eggs, embryos or eggs undergoing fertilisation where recipient is unknown to the donor

The licensee must ensure that where the recipient is unknown to the donor, the donors of eggs, embryos or eggs undergoing fertilisation, are provided with adequate information, in a form approved by the Council, that:

- (a) strongly encourages the donor to seek assistance with decision making and counselling from an approved counsellor and provides a list of approved counsellors;
- (b) sets out the availability of and entitlement to, counselling through the licensed practice; and

(c) provides information about the possible impacts of becoming a donor, including medical, social, secrecy and disclosure implications of donation.

6.10 Records of period of storage of embryos and eggs undergoing fertilisation

The licensee must ensure that.

(a) records are maintained to accurately reflect the expiry date of the authorised storage period for each embryo and egg undergoing fertilisation; and

(b) a system is in place to identify embryos or eggs undergoing fertilisation that are nearing the expiry of the authorised storage period and to notify persons on whose behalf those embryos or eggs are being stored.

Note: The licensee has a potential liability to the persons for whom the embryo or egg undergoing fertilisation is stored if the notification requirements in section 24(3) of the Act have not been complied with before the embryo is removed from storage. To avoid such liability it is in the interests of the licensee to ensure that the steps they have taken to notify the persons of the expiry of the storage period are reasonable. Such steps may include writing to the person at the last known address, writing to the person at an address obtained from an electoral roll search, or telephoning or contacting the person's general practitioner or any other suitable third party.

6.11 Embryo or egg undergoing fertilisation must be allowed to succumb

The licensee must ensure that at the expiry of the authorised storage period for an embryo or egg undergoing fertilisation, the embryo or egg is removed from storage and allowed to succumb.

6.12 Extension of storage period for embryos and eggs undergoing fertilisation for use in an artificial fertilisation procedure

Note: The licensee cannot apply for an extension of the storage period for an embryo or egg undergoing fertilisation that is to be used in an artificial fertilisation procedure.

The licensee must ensure that.

(a) information is provided to persons on whose behalf an embryo or egg undergoing fertilisation is being stored for use in an artificial fertilisation procedure, about the possibility that the person may apply to the Council, using Form 8 in Schedule 1, for an extension of the storage period, and that such an application must be received by the Council at least one month before the Council meeting that precedes the expiry of the storage period;

(b) if required, assistance with completion of Form 8 is provided to a person who wishes to seek an extension to the authorised storage period.

6.13 Extension of storage period for excess ART embryos donated for research

The licensee or the person(s) for whom the embryo was developed may apply to the Council using Form 9 in Schedule 1 for approval to extend the storage of an excess ART embryos that have been donated for a use requiring an NHMRC licence.

6.14 Time for applications for approval to extend storage period of excess ART embryo

The licensee must ensure that an application for approval to extend the storage period of an excess ART embryo that has been donated for research is received by the Council at least one month prior to the meeting of the Council that precedes the expiry of the storage period.

***8.5 Restrictions on use of reproductive material donated prior to 1 December 2004**

A licensee must ensure that reproductive material donated before the commencement date of the *Human Reproductive Technology Amendment Act 2004* (1 December 2004) is not used in an artificial fertilisation procedure unless.

(a) each donor has been given information about the changes to the Act in relation to the rights of donor offspring who has reached 16 years of age to be given identifying information about the donor, and the donor has given consent after 1 December 2004 to the use of the donation in an artificial fertilisation procedure; or

(b) donated gametes are stored for a woman who wishes to have a full sibling for an existing donor child, and.

(i) the licence supervisor has not been able to contact the donor(s) to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or

(ii) the donor(s) has been asked to consent to the provision of identifying information to a future donor offspring who has reached 16 years of age and has refused;

or

(c) an embryo was created before 1 December 2004, and.

(i) the licence supervisor has not been able to contact each person who provided gametes used in the creation of the embryo to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or

(ii) each person who provided gametes used in the creation of the embryo donor(s) has been asked to consent to the provision of identifying information to a future donor offspring

who has reached 16 years of age and has refused;

or

(d) the conditions set out in section 49(2e)(b)(ii) of the Act have been complied with in respect of the donation.

SCHEDULE 5.PROTOCOL MANUALS

PART 1 REQUIREMENTS FOR PROTOCOL MANUALS

4.2 Protocols relating to data collection and reporting, including.

Protocols for maintenance of clinic Database/reporting to RTAC/RT Register and Annual Reporting requirements;

Protocols for database of gamete and embryo storage/ for managing embryo extensions