



Reproductive Technology Council

POLICY ON EMBRYO STORAGE AND APPLICATIONS TO EXTEND STORAGE BEYOND 10 YEARS

Reproductive Technology Council

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GLOSSARY

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| ART | Assisted reproductive technology/ies |
| Authorised storage period | Authorised storage period in respect of embryos or eggs undergoing fertilisation means the shorter of - <ul style="list-style-type: none"> 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 |
| Counsellor | A person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors' Association (ANZICA); |
| Directions | Directions given by the CEO of Health (Director General) under the HRT Act |
| Effective Consent | A consent; <ul style="list-style-type: none"> a) that is given in writing; b) where any condition to which it is subject is met; c) that has not been withdrawn; d) where the gametes are, or that egg or embryo is, kept and used in accordance with the consent (section 22(8) of the HRT Act) |
| Embryo storage extension | An extension to an authorised storage period |
| FSA | Fertility Society of Australia |
| HRT Act | <i>Human Reproductive Technology Act 1991</i> |
| 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 |
| IVF Procedure | 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, 2017 |
| RTAC | Reproductive Technology Accreditation Committee |
| Stored | In relation to human gametes, a human egg undergoing fertilisation or a human embryo a reference in this Act <ul style="list-style-type: none"> 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 conception. 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 (including Directions), 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, some 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 10 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 section 24(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”. 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.

To this end, Council encourages participants to make a decision about how their embryos are to be dealt with prior to expiry of the authorised storage period. 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 if this is their intention.

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, while others hold the view that human life begins at birth. 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 consider that they are entitled to determine how their embryos are dealt with. While this position is respected by Council, to store embryos indefinitely is not considered appropriate by the legislation.

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

1. LEGISLATIVE REQUIREMENTS OF EMBRYO STORAGE POLICY

Licensees must provide participants considering embryo storage access to counselling (s22(7) NHMRC 8.2.2). 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.

Any decision to extend storage must take into account equity, welfare and general standards prevailing in the community.

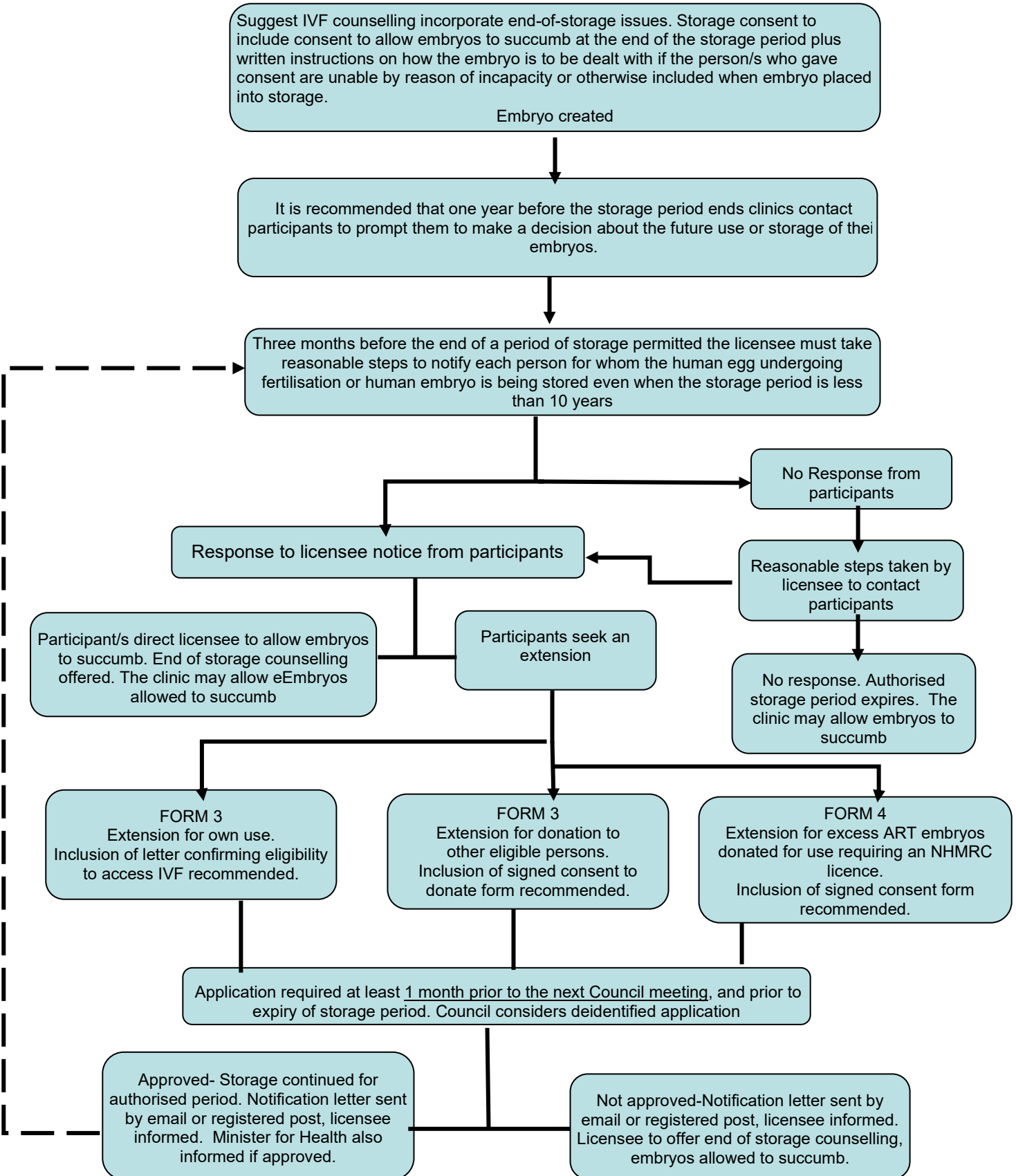
Options for embryos in storage include:

- future use by the participants;
- donation to other eligible participants;
- donation to research as an excess ART embryo; and
- being allowed to succumb.

The legislative requirements underpinning the Embryo Storage Policy are as follows:

- 1.1 In WA an embryo must not be stored for more than 10 years except where this has been approved by Council (s24(1)).
- 1.2 An embryo storage extension beyond a 10-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 Any extension to storage must only be in accordance with consent given by those with a right to consent (s22).
- 1.6 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.
- 1.7 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) and s231(e)).
- 1.8 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 HRT Act (s23 (1)(e)).

EMBRYO STORAGE - FLOW CHART TO GUIDE LICENSEES



2. LICENSEE INFORMATION

2.1. Licensee Embryo Storage Policy and Protocols

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 (HRT Directions 2021 Schedule 4 s4.2).

2.2. Timeline for Licensees - maximum 10 years

As set out in the Flowchart, the provision of written information by licensees after nine years of storage is recommended in addition to the required notification of expiry three months prior to the expiry date.

2.2.1. Three 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 (HRT Act s24(3), Direction 6.10), 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 10 years, that effective consent to continue storage will be required
- e. where the authorised storage period was for 10 years this is the three month prior to expiry notice, that participants are aware that they may apply to Council for an extension (Form 3), 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 3 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. Council can only approve an extension if the request is received before the end of the storage period. If a period of approved storage comes to an end and no application has been made to extend storage, the licensee may allow the embryos to succumb as long as all the relevant actions the licensee is required to take under the Act have been completed.

2.2.2. Fact Sheet

The fact sheet “Embryos Remaining in Storage” aims to assist participants to make a decision about their remaining embryos and encourages them 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 10 years, renewed effective consent to continue storage will be required from participants. NB: When Council approval to extend the authorised storage period beyond 10 years has been granted, renewed effective consent to continue storage will also be required.

2.3.1. Patient Information

The patient information provided to participants at the time of giving consent to store embryos should:

- a. advise that participants may only consent to a maximum of 10 years for embryo storage
- b. advise that embryos cannot be stored indefinitely
- c. should advise that consent must be renewed for storage beyond 10 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. advise that Council can only approve an extension if the request is received before the end of the storage period
- e. advise that after expiry of the authorised storage period an embryo may 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 3.5).

2.3.2. Patient Consent Forms

The patient consent forms to store embryos

- a. must state that the maximum initial storage period is 10 years
- b. must state the storage period required by the participants or determined by the licensee (which may be less than 10 years) See 2.3.3
- c. must state that the primary purpose of storage relates to the probable future implantation of the embryo (own use or donation), 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 3.5)
- e. should indicate that three 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 10 years may only be approved by Council where there are special reasons for doing so (s24(3), Direction 6.10)
- 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, particularly where the licensee has lost contact with or is otherwise unable to obtain any further instructions from the participants.

2.3.3. Notifying Each Person

Licensees are to notify each person for whom the embryos are being stored three 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

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 (s22(1)(e)); 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 (Direction 3.6).

2.3.5. Right to Decide

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 (s26(1)).

2.3.6. Withdrawal of Consent

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 for Donation of Embryos

Counselling requirements for donation of embryos where the recipient is known to the donor are set out in Schedule 3 of the Directions. These requirements include a minimum of three 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 three month cooling off period, before the embryos may be used in an artificial fertilisation procedure.

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

2.3.8. Consent Conditions

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 is recommended 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. Reasonable Steps

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. Direction 6.8

The note to Direction 6.8 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. Donated Embryos – Contact with Recipient

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. Succumb

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 doing so.

2.4.5. Direction 6.9

Direction 6.9 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. Expiry of Authorised Storage Period

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

3. EMBRYO STORAGE EXTENSION

3.1. General Matters

Council approval for the extension of an embryo storage period beyond 10 years is required under s24(1) of the HRT Act.

3.1.1. Use in an IVF Procedure

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 3: 'Application for extension of frozen embryo storage period for use in IVF procedure'. A Form 3 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).

3.1.2. Use in Research

Where an embryo is intended for use in research an eligible person may apply for an extension to the storage period on a Form 4: 'Application for extension of permitted storage where excess ART embryos have been donated for a use requiring a licence from the NHMRC'. A Form 4 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.

3.1.3. Special Reasons

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 3 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.

3.1.4. De-identification

De-identification: Forms containing participant information received by the Executive Officer of the Council will be de-identified/redacted before being presented to Council for consideration to comply with confidentiality obligations under the HRT Act.

3.1.5. Length of Storage Extension Approval

Approval of storage extension and 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.

3.1.6. Supporting Documentation

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.

3.1.7. Section 24(1) of the HRT 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. 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.

3.1.8. Requests for Further Information

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 secure email or 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 3: if a participant consents, the Executive Officer may use phone contact if further information is required in a short timeframe.

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:

- 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 3.1.8).
- 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 3.1.8).
- Participants (or 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 3.1.8).
- 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 3.1.8).
- 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 3.1.8).
- 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 10 years:

- The authorised storage period has expired, and no extension has been sought. In this event, Council is unable to approve an embryo extension (s 24(1c)).
- 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 (s 24(1c)).
- 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) (s 23(1)(d)).
- 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).
- Participant/s wish to keep an embryo in storage indefinitely or wish to be buried with the embryo (s24(1)(a)).
- 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 (s24(1)(a)).
- Where the gamete donor has not 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. DONATION OF EMBRYOS

4.1. Donation to Other Eligible Persons for Probable Future Implantation

Licensees must maintain a clear procedure for the transfer of responsibility for an embryo at each stage (NHMRC Ethical Guideline 6.2)

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.

An application for a storage extension can be made by one member of an eligible couple. However, if the application is for the intention to donate the 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 prior to December 2004 to the release of their identifying information or evidence of compliance with Direction 8.5.

When neither a 'consent to donate' form nor evidence that pre-donation counselling has been initiated is included with an application with the intent of donation, then it is recommended that both participants complete and sign the application for an embryo storage extension.

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 3 and cannot be made by the licensee.

Where recipient/s of donated embryo/s apply for an extension to the storage period for probable future implantation, the Form 3 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.

4.2. Counselling

It is recommended licensees ensure that all IVF participants have access to a counsellor to discuss end-of storage issues.

If embryos are to be donated to an unknown recipient/s, counselling is required under the RTAC Code of Practice and information regarding donation be provided as set out in the HRT Act (see Directions 4.1, 4.2 and 5.7).

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 3, 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 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 sections 11,12 and 13.

NB: At present as the licensing system for excess ART embryo research is inoperative under the HRT Act, 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 page 2 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 s53W(2).

5. WHERE PARTICIPANTS DISAGREE

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.

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. DEATH OF PERSON/S WITH RIGHTS TO AN EMBRYO

6.1. Death of One Member of a Couple

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. Death of Both Members of a Couple

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 8.22 also provides that in such circumstances any reasonable, clearly expressed and witnessed directive from the couple should be followed.

A directive may include a lawful donation to another person/couple, or for use in research.

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??8.22).

7. ALLOWING EMBRYOS TO SUCCUMB

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.

NHMRC Ethical Guidelines 3.9, 4.1.2, 4.1.3, 4.6.4 and 7.6.1 outline that licensees must provide information about the removal of embryos from storage to participants and have protocols in place for the disposal of embryos.

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.

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. ENQUIRIES REGARDING EMBRYO STORAGE MATTERS

Electronic Form 3 and Form 4 applications may be emailed to Embryo.Storage@health.wa.gov.au for prompt processing.

Form 3 and Form 4 applications may also be sent via mail and 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 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 email or registered mail. Licensees will be informed via email.

The Minister for Health will be notified as per s24(1d).

Licensee enquiries regarding embryo storage may be directed to the Executive Officer by email at Embryo.Storage@health.wa.gov.au or telephone. Current contact details are available on the RTC website www.rtc.org.au, or by telephoning the Department of Health on (08) 6373 2236.

Appendix 1 Form 3

CONFIDENTIAL

FORM 3: APPLICATION FOR EXTENSION OF FROZEN EMBRYO STORAGE PERIOD FOR USE IN IVF PROCEDURE

Direction 6.10

INSTRUCTIONS

- Application can only be made by eligible participants ie those for whom the embryo was developed or, if consent for receipt after donation has been completed, the recipient(s).
- Both Part A and Part B of the application should be completed.
- Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.
- Approval for extension of storage cannot be granted if the storage period has already expired. Embryos are required to be removed from storage if the storage period expires and no extension has been granted.
- Please mark your envelope 'Confidential' and return this application to: the Executive Officer, Reproductive Technology Council, Health Dept of WA, 189 Royal Street, East Perth WA 6004 email: embryo.storage@health.wa.gov.au

PART A

Clinic to complete:

1. Have these embryos been granted a previous extension? yes no

2. Storage details:

Date of expiry of current storage period 10 years from date embryos placed in storage in WA, or date of expiry of any later current extension

Date of Completion by Clinic Licensee number

3. Treatment cycle details:

Participant ID Code Female Partner (if any)

Treatment unit ID

Treatment cycle codes: Cycle ID Fertilisation F

Date cycle commenced

Date of embryo storage in WA

Female DOB: Partner DOB:

Number of embryos affected by this expiry:

Also indicate Participant ID codes of donor/s here if applicable:

Female Partner (if any)

Health Department use only:

Application Number - Code

Date of Expiry of Extended Storage Period

Chairperson, RTC

CONFIDENTIAL

PART B

Eligible Participant(s) to complete:

Date of Application
day month year

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

Appendix 2 Form 4

CONFIDENTIAL

FORM 4: APPLICATION FOR EXTENSION OF PERMITTED STORAGE PERIOD WHERE EXCESS ART EMBRYOS HAVE BEEN DONATED FOR A USE REQUIRING A LICENCE FROM THE NHMRC

Direction 6.12

INSTRUCTIONS

- Application may be made by:
 - The participant(s) for whom the embryo was developed
 - Storage licensee
 - Holder of an exemption under section 28A of the *Human Reproductive Technology Act 1991* (HRT Act)
 - Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.
 - Approval for extension of storage cannot be granted if the storage period has already expired.
 - Embryos are required to be removed from storage if the storage period expires and no extension has been granted.
- Please mark 'Confidential' and return to Executive Officer, Reproductive Technology Council, Health Dept of WA 189 Royal Street, East Perth WA 6004 embryo.storage@health.wa.gov.au

1. Who is applying?

- (a) Participant(s) for whom the embryo is being stored
- (b) Licensee
- (c) Holder of exemption under section 28A of the HRT Act

2. Have these embryos been granted a previous extension? yes no

3. Storage details:

Date of expiry of current storage period 10 years from date embryos placed in storage in WA, or date of expiry of any later current extension

Licensee

4. Treatment cycle details:

Participant ID Code Partner (if any)

Treatment unit ID

Treatment cycle codes: Cycle ID Fertilisation

Date cycle commenced

Date of embryo storage in WA

Female DOB: Partner

Number of embryos affected by this expiry:

5. Briefly explain reasons for seeking extension.

Signature of applicant(s)

Health Department use only:

Application Number

9-200

-

Code

Date of Expiry of Extended Storage Period

day

month

year

Chairperson, RTC

Appendix 3 Form 5

FORM 5

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 the licensee with recipient identifying information as required by the licensee to meet its obligations under the *Human Reproductive Technology Act 1991*;

3.To provide the recipient and their spouse/partner with all relevant information, especially regarding the Registers which have been established under section 45 of the Act, 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.

Appendix 4 – Relevant Legislation & Guidelines
RELEVANT LEGISLATION & GUIDELINES

Suggest IVF counselling incorporate end-of-storage issues. Storage consent to include consent to allow embryos to succumb at the end of the storage period plus written instructions on how the embryo is to be dealt with if the person/s who gave consent are unable by reason of incapacity or otherwise included when embryo placed into storage D 3.5 and (s.22(6))
 Embryo created (D 3.5, 6.8)

It is recommended that one year before the storage period ends clinics contact participants to prompt them to make a decision about the future use or storage of the embryos. (See 2.2)

Three months before the end of a period of storage permitted the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored even when the storage period is less than 10 years (s.24(3)), D5.3, D6.12

No Response from participants

Response to licensee notice from participants

Reasonable steps taken by licensee to contact participants

Participant/s direct licensee to allow embryos to succumb. End of storage counselling offered. Embryos may be allowed to succumb.

Participants seek an extension s24(1a) D 6.10, D 6.12

No response. Authorised storage period expires. Embryos may be allowed to succumb S 24 (1), 24(4), 33(3)(d)

FORM 3
 Extension for own use. Inclusion of letter confirming eligibility to access IVF recommended. s23

FORM 3
 Extension for donation to other eligible persons. Inclusion of signed consent to donate form recommended.

FORM 4
 Extension for excess ART embryos donated for use requiring an NHMRC license. Inclusion of signed consent form recommended. D 4.3, D 6.11

Application required at least **1 month prior to the next Council meeting**, and prior to expiry of storage period. Council considers deidentified application (D 6.10).

Approved- Storage continued for authorised period. Notification letter sent by email or registered post, licensee informed. Minister for Health also informed if approved. s24 (1a),(1b),(1c),(1d)

Not approved-Notification letter sent by email or registered post, licensee informed. Licensee to offer end of storage counselling, embryos allowed to succumb. D6.9, s24 (4)

Review

These guidelines are to be reviewed within three years of release.

| Version | Effective from | Effective to | Amendment(s) |
|---------|----------------|--------------|---|
| 1.2 | May 2022 | Current | <p>Pg. 6 Simplified wording in paragraph one and two.</p> <p>1.6 Removed final sentence.</p> <p>Updated wording on flowchart to match 1.6</p> <p>2.2.1 (i) Updated to reflect change to 1.6 (j) removed</p> <p>2.3.1 (d) Simplified wording</p> <p>2.3.2 Simplified wording</p> <p>3.2 Removed evidence of surrogacy arrangement, and 'consent to donate'</p> |
| 1.1 | June 2021 | | Alignment with amendments to HRT Directions 2021 and Surrogacy Regulations 2021 |
| 1.0 | Feb 2010 | | |