**Applications for extension of storage of gametes and embryos**

**Guidance note**

**July 2021**

*This Guidance Note has been prepared to assist applicants and assisted reproductive treatment (ART) providers in the preparation of applications to the Patient Review Panel for approval of extensions of storage periods for gametes and embryos under the* Assisted Reproductive Treatment Act 2008 (Victoria)*.*

*This Guidance Note does not constitute legal advice, nor does it pre-judge any decision that the Patient Review Panel might make in relation to any particular application.*

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| **NOTE:**  **In response to the COVID-19 pandemic, from 24 March 2020 until further notice:**   * **all applications to the Patient Review Panel must be made via email:**[**prp@dhhs.vic.gov.au**](mailto:prp@dhhs.vic.gov.au) * **all enquiries should be made via email:**[**prp@dhhs.vic.gov.au**](mailto:prp@dhhs.vic.gov.au) * **hearings will continue and will be held via videoconference** * **applicants will be advised of the process for videoconference hearings once a date for the hearing of their application has been fixed** * **applicants should provide copies of their applications to their assisted reproductive treatment (ART) clinics** |

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# Glossary/Definitions

The Victorian *Assisted Reproductive Treatment Act 2008* (the ART Act) provides definitions for a number of terms that will be used within this Guidance Note.

* **assisted reproductive treatment** **(ART)** means medical treatment or a procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes—
  + in-vitro fertilisation; and
  + gamete intrafallopian transfer; and
  + any related treatment or procedure prescribed by the regulations[[1]](#footnote-2);
* **child** means a person who is less than 18 years of age;
* **doctor** means a person registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);
* **embryo** means a discrete entity that has arisen from either—
  + the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
  + any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears—
    - and has not yet reached 8 weeks of development since the first mitotic division;
* **gametes** mean sperm or an oocyte;
* **oocyte** means an ovum (egg) from a woman;
* **registered ART provider** means a person who is registered under Part 8 of the ART Act as a registered ART provider;
* **store** means
  + to freeze an oocyte, embryo or sperm; or
  + to otherwise preserve an oocyte, embryo or sperm by a prescribed method;
* **treatment procedure** means—
  + artificial insemination, other than self-insemination; or
  + assisted reproductive treatment.

# Restrictions on storage of gametes and embryos

The ART Act regulates the length of time gametes and embryos may be stored for treatment and the circumstances in which the storage periods can be extended. The regulation of storage of gametes and embryos is intended to ensure that gametes and embryos do not remain in storage without the consent of the persons who provided the gametes and to prevent build-up of unwanted stores of gametes and embryos.[[2]](#footnote-3)

# What are the restrictions on storing gametes?

Section 31(1) of the ART Act provides that gametes must not be stored for more than 10 years, except where:

* the gametes have been produced by a child or a person who has been certified, at the time of producing the gametes, at reasonable risk of becoming prematurely infertile because of a medical condition or procedure, in which case the gametes may be stored for 20 years; OR
* the person who has produced the gametes has given written approval for a specified longer storage period and the Patient Review Panel (the Panel) has approved that longer or further storage period.

Unless an extension has been approved by the Panel, the storage facility must remove the gametes from storage and dispose of them within 3 months from the date of the expiration of the storage period. This must occur irrespective of whether or not the person who stored the gametes has consented to the disposal.

# What are the restrictions on storing embryos?

Section 32 of the ART Act prohibits the storage of an embryo unless:

* the embryo is stored by an assisted reproductive treatment (ART) provider, AND
* it is intended to transfer the stored embryo to a woman in a treatment procedure; AND
* the persons who produced the gametes from which the embryo has been formed have consented to its storage for the purposes of later transfer.

Section 33 provides that the ART provider must not permit the embryos to remain in storage beyond either:

* 5 years after the day the embryo was placed in storage (or a lesser period as defined in the consents of either of the persons who produced the gametes from which the embryo is formed);[[3]](#footnote-4) OR
* where the persons who produced the gametes from which the embryo was formed consent to storage for up to 5 years in addition to the 5 years after the day the embryo was placed in storage – meaning up to 10 years after the day when the embryo was first placed in storage;[[4]](#footnote-5) OR
* the Panel has approved a longer or further storage period.

This means that storage of embryos for more than 10 years after the embryo was first placed in storage (5+5 years as described above) must be approved by the Panel.

Following the expiration of the statutory storage period, or a period approved by the Panel, the ART provider must remove the embryos from storage and dispose of them within 3 months from the date of the expiration of the storage period. This must occur irrespective of whether the persons who produced the gametes from which the embryos are formed, and the persons for whom the embryos are stored, have consented to the disposal or not.

# Penalties

Section 31(1) imposes a penalty of 240 penalty units or 2 years imprisonment or both where a storage facility has permitted gametes to remain in storage beyond the statutory period or where it is known that the person who produced the gametes has asked for those gametes to be removed from storage.

Section 33 imposes a penalty of 240 penalty units or 2 years imprisonment or both where an ART provider has permitted embryos to remain in storage beyond the statutory period or a further period approved by the Panel.

# What is the Patient Review Panel?

The Patient Review Panel (the Panel) is an independent body established under the ART Act to consider different types of applications involving ART, including applications for further or longer periods of storage of gametes or embryos. Its members have specialist skills and are appointed by the Governor in Council, on the recommendation of the Minister for Health.

# What is the Patient Review Panel’s role in applications to extend storage of gametes and embryos?

# *Gametes*

The Panel may approve a longer or further gamete storage period under section 31A of the ART Act, if:

* it considers that there are reasonable grounds to do so; AND
* the person who produced the gametes has given written approval for a specified longer storage period; AND
* the application to the Panel is made before the expiry of the current storage period.

The Panel may also approve a longer or further gamete storage period in the following two situations if the Panel considers that there are exceptional circumstances for doing so:

* if the person who produced the gametes is unable to give written approval, or their written approval cannot be obtained;
* when the application is made after the expiry of the statutory storage period.

The Panel’s discretion to extend the storage of gametes in exceptional circumstances applies both where the gametes are for use in the person’s own treatment procedure and where the gametes have been donated and are being stored for use by another person or persons.

# *Embryos*

The Panel may approve a longer or further embryo storage period under section 33A of the ART Act if:

* it considers that there are reasonable grounds to do so; AND
* if the persons who produced the gametes from which the embryo has been formed have given written approval for a specified longer storage period; AND
* the application to the Panel is made before the expiry of the current storage period.

The Panel may also approve a longer or further embryos storage period in the following two situations if the Panel considers that there are exceptional circumstances for doing so:

* if one of the persons who produced the gametes from which the embryo has been formed is unable to give written approval, or their written approval is unable to be obtained;
* when the application is made after the expiry of the statutory storage period.

The Panel’s discretion to extend the storage of embryos in exceptional circumstances also applies to donor embryos which are stored for use by a person or persons who did not produce the gametes that formed the embryos.

# Making an application to the Panel

Applicants should complete in full the application form found on the Panel’s website or provided by the ART clinic or storage facility.

Applicants are encouraged to provide as much detail as possible on the application form about why they are making an application for an extension of the storage period (e.g. what is the intended use of the gamete(s) or embryo(s); the timeframe in which they intend to use the gamete(s) or embryo(s)).

Applications for extension of storage of both gametes and embryos must specify the length of time sought. Applications that do not specify this will be incomplete and will not be considered by the Panel until this information is provided.

Applicants should, wherever possible, make their application before the expiry of the current storage period of their gametes or embryos.

Applicants should provide a copy of their application to both the Panel and their ART provider **or the storage facility** to ensure that their gametes or embryos remain in storage while the Panel considers their application.

Applicants who choose to apply to the Panel via their ART provider should ensure they provide their application form to their ART provider with sufficient time to allow the provider to forward it on to the Panel before the expiry date. It is the responsibility of applicants to ensure that their ART provider has forwarded their application to the Panel before the expiry of the current storage period.

It is the Panel’s preference that application forms be submitted via email to: [prpstorage@health.vic.gov.au](mailto:prpstorage@health.vic.gov.au).

# What does the Panel consider when making a decision about extensions of storage for gametes and embryos?

The Panel must have regard to the legislative context, including the purpose of the Act (to regulate assisted reproductive treatment in Victoria) and the guiding principles set out in section 5 of the Act.[[5]](#footnote-6) The Panel will also consider the following matters.

# *“Reasonable grounds”*

When considering whether there are reasonable grounds to approve an extension of storage, the Panel will look at whether there is an intention that the gametes or embryos will be used in a future ART procedure. As such, while every application is considered on a case-by-case basis, if an application is made for a reason other than for assisted reproductive treatment (for example, for use in personal non-fertility related medical treatment) then the Panel may not consider that there are reasonable grounds to approve an extension of storage.

The Panel will also consider how long the gametes or embryos have been in storage and any previous extensions that have been granted, as the Act sets out time-limits for the storage of gametes and embryos and a process where approval is required for a further storage period. This indicates that the Act does not contemplate ongoing or open-ended storage of gametes or embryos.

# *Period of extension sought*

Gametes - Extensions for gamete storage are usually provided for a period of up to a 10 years. Applications for a longer period may also be considered where the gametes have been taken from a child or a person at risk of becoming prematurely infertile because of a medical procedure or condition.

Embryos - Extensions for embryo storage are usually granted for a period of up to 5 years. The Panel’s preference is to grant a shorter period for embryos in comparison to gametes. This is to ensure that embryos do not remain in storage without the consent of both the gamete providers, that there remains an intention to use the embryos in a treatment procedure, and that decisions about the use and ongoing storage of embryos are regularly reviewed by both persons who are equally responsible for decision-making about embryos. It also reflects the different initial storage periods for gametes and embryos set out in the ART Act.

# *Applications made after the expiry of the storage period – “exceptional circumstances”*

Where an application for extension of storage is made after the statutory storage period has expired, the Panel must consider whether there are exceptional circumstances for the failure to seek approval before the expiry of the storage period, before it can consider whether reasonable grounds exist to approve a further storage period.

There is no guidance in the Act as to what constitutes an ‘exceptional circumstance’. This question has been the subject of limited consideration by the Victorian Civil and Administrative Tribunal (VCAT) in *HA v Patient Review Panel (Human Rights)*.[[6]](#footnote-7) In that case, the VCAT referred to *R v Kelly (Edward)*[[7]](#footnote-8) for guidance:

*We must construe ‘exceptional’ as an ordinary, familiar English adjective, and not as a term of art. It describes a circumstance which is such as to form an exception, which is out of the ordinary course, or unusual, or special, or uncommon. To be exceptional a circumstance need not be unique, or unprecedented, or very rare; but it cannot be one that is regularly, or routinely, or normally encountered.*

The Panel considers whether the circumstances resulting in an application being made after the expiry period on a case-by-case basis. Applicants should provide as much information as possible regarding why they submit that the circumstances resulting in them lodging an application after the expiry of the storage period are ‘exceptional’. The Panel may request further information if applications provide insufficient information. If further requested information is not provided, the Panel may be unable to approve the application.

Where applications are made to the Panel after the expiration of the current storage period, the person(s) making the application should advise their ART provider/storage facility as soon as possible of their intent to make the application (so that their stored gametes or embryos are retained in storage whilst the application is pending).

# *Applications made without written approval from a person who provided the gametes – “exceptional circumstances”*

Where an application for extension of storage is made in circumstances where:

* for gametes: a person who provided the gametes is unable to give written approval, or their written approval cannot be obtained, the Panel must consider that there are exceptional circumstances for approving a longer storage period, before it can consider whether reasonable grounds exist to do so;
* for embryos: a person who provided the gametes is unable to give written approval, or their written approval is unable to be obtained, the Panel must consider that there are exceptional circumstances for approving a longer storage period, before it can consider whether reasonable grounds exist to do so.

Again, there is no guidance in the Act as to what constitutes an ‘exceptional circumstance’ (see discussion on previous page). The Panel considers whether there are exceptional circumstances to approve a longer storage period without the written consent of a gamete provider on a case-by-case basis.

Applicants should provide as much information as possible regarding why the gamete provider’s approval is unable to be obtained or cannot be obtained, and why they submit there are ‘exceptional circumstances’ for the Panel to approve the longer storage period. Applications which fail to do so may not be approved by the Panel.

## *Where a gamete provider has not been able to be contacted, and a storage facility or an ART clinic is making the application*

ART clinic and storage facility applications should indicate clearly what steps it has taken to contact the gamete provider, including the dates of any such steps.

## *Where a gamete provider is deceased, and the application is being made by their partner*

If the deceased person has provided written consent for their partner to use their gametes, and/or embryos created from their gametes, please provide copies of these documents with the extension of storage application form, as this will be helpful for the Panel in considering the application.

# *Storage of gametes or embryos pending a decision of the Patient Review Panel*

If an application is received by the Panel after the storage period has expired or if the storage period expires while the matter is being considered by the Panel, the ART Act allows gametes and embryos to be lawfully stored once the Panel has received and accepted an application for extension of storage, and until the Panel has made a decision. Although the Act requires the Panel to hear applications as expeditiously as possible, the Act does not stipulate any time limits within which the Panel must consider applications.

If the Panel approves a further storage period, the gametes or embryos may remain in storage until up to 3 months after the end of the further storage period approved by the Panel.

If the Panel does not approve a further storage period, the Act allows gametes or embryos to remain in storage for 28 days, to allow an applicant to seek a review of the Panel’s decision at the VCAT. If no review is sought then they may remain in storage up to 3 months from the end of that 28 days.

If the decision of the Panel not to approve a further storage period is reviewed by the VCAT, then the gametes or embryos may also lawfully remain in storage until the VCAT makes its decision. If the VCAT also refuses a further period of storage then the Act allows gametes or embryos to remain in storage for up to 3 months from the date of the VCAT’s decision.

# Procedures of the Panel

The procedure of the Panel is at the discretion of the Chairperson subject to the requirements of the ART Act. The process to determine how applications will be considered by the Panel (i.e. whether a decision will be made “on the papers” or following a hearing before either a full division of the Panel or a single member determined by the Chairperson) is made on a case-by-case basis as outlined below.

At any stage of the application process (including prior to making a determination about whether the applicant is requested to attend a hearing), the Panel may request that applicants provide additional information in support of their application. For example, the Panel may ask applicants whether they have discussed their intended future use of their stored gametes or embryos with their ART provider and, if so, whether the ART provider would be likely to use those gametes or embryos for that intended purpose.

# *Applications considered ‘on the papers’*

The Panel may decide an application “on the papers” where there is:

* written approval from all gamete providers for a specified further period of storage; AND
* the gametes or embryos are intended to be used in an ART procedure.

This means that the applicants are not required to attend a hearing, although applicants are entitled to attend should they wish to. These applications will be determined as soon as practicable upon receipt of the application. The Panel will then send a certificate confirming the decision to approve the extension to the applicant and relevant ART provider/storage facility.

# *Applications where the applicants are requested to attend a hearing*

In some situations, applicants may be asked to attend a hearing.

This may occur:

* if the application was not received prior to the expiry of the storage period;
* where consent has not been obtained from one gamete provider;
* where there is no intention to use the gametes or embryos in an ART procedure; or
* where the Chairperson otherwise considers that it is appropriate to convene a hearing of the application.

Where a hearing is convened, the application may be considered by a full five-member division of the Panel or a single member determined by the Chairperson. A division of the Panel is constituted by the Chairperson, a Deputy Chairperson and three Panel members, one of whom has expertise in child protection. Up to three Panel staff members may also be in attendance to take notes and/or provide legal advice to the Panel members. The decision as to whether an application is heard by a single member or a division of the Panel rests with the Chairperson.

Applications will be listed for hearing as soon as practicable once a complete application is submitted to the Panel. Applications are not considered to be complete until missing or requested additional information has been received. If applications are incomplete but applicants insist on being listed for hearing, then the matter will be referred by Panel staff to the Panel Chairperson for review prior to listing for hearing.

Once a hearing date has been allocated, applicants will receive a Notice of Hearing stating:

1. the nature of the hearing; and
2. the time and place of the hearing; and
3. that the applicant is entitled to be present at the hearing, to make submissions and to be accompanied by another person; and
4. that the hearing is not open to the public; and
5. that there is no right to legal representation at the hearing without leave from the Panel; and
6. the possible findings or orders that the Panel may make.

When face-to-face Panel hearings are convened, they are held at the Department of Health Head Office located at **50 Lonsdale Street, Melbourne, Victoria, 3000** unless otherwise advised. Upon arriving at 50 Lonsdale Street, applicants will need to pick up a security pass from the ground floor reception and make their way up to the level where the hearing is being held.

Every level has a foyer area with chairs and applicants should use their passes to enter the foyer and take a seat until they are invited into the hearing room by either one of the Panel members or a Panel staff member.

Hearing of storage applications generally last for half an hour (or longer if required) and towards the end of the hearing applicants will be asked to leave the room for a short period of time to allow the members to discuss the application. If there are two applicants, the Panel may also request to speak to one of applicants separately.

Where an application is made by a storage facility or ART provider on behalf of a patient, the Panel may wish to discuss the application with an appropriate representative from the storage facility or ART clinic via a teleconference or video conference at the hearing.

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| **IMPORTANT NOTE:**  **In light of the COVID-19 pandemic, the Panel will conduct all hearings by videoconference using Microsoft Teams from April 2020 until further notice.**  **Comprehensive instructions to assist applicants to participate in hearings conducted by videoconference will be provided together with the Notice of Hearing.**  **Applicants who are unable to participate in a hearing by videoconference are advised to communicate with Panel staff as soon as possible upon receipt of the Notice of Hearing to formally request an alternative method of participating in the hearing (such as attending via teleconference, subject to the approval of the Panel Chairperson).** |

# The Panel’s decision

Where possible, the Panel will advise applicants attending a hearing whether the application has been approved or not via email or telephone communication by Panel staff on either the day of the hearing or the following day. At times, it will require more time to consider the application or may require more information before it makes its decision.

If the Panel does not consider that it can make a decision within 1-2 days of the hearing then it will advise applicants within that time frame and advise them of what will happen next.

***Certificate***

Once the Panel has made a decision, applicants will be provided with a certificate stating the decision within 14 days of the date that the decision was made. An electronic copy of this certificate will also be provided to the relevant ART clinic or storage facility for their records.

Under section 91(3) of the ART Act, the Panel may impose any conditions it considers necessary and reasonable in the circumstances of the decision and, if the Panel chooses to place a condition on its decision, it will be stated on the certificate.

***Reasons for decision***

The Panel is also required by the ART Act to provide applicants with written reasons for its decision.

Where an application has been heard on the papers, the reasons will be stated on the certificate.

Where an application has been heard at a hearing, then written reasons will be provided to the applicants in due course after they receive their certificate.

***Review of a Panel decision not to approve an extension of storage***

A decision of the Panel not to approve the period during which gametes or an embryo may be stored may be subject to review by the VCAT.[[8]](#footnote-9)

An application for review must be made within 28 days after the day on which the Panel’s decision is made.[[9]](#footnote-10)

For further information about applying to VCAT for a review of a Panel decision, please visit <https://www.vcat.vic.gov.au/privacy-and-health-records/review-of-a-decision-by-the-patient-review-panel>.

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1. *Assisted Reproductive Treatment Regulations 2019.* [↑](#footnote-ref-2)
2. Second Reading Speech, *Assisted Reproductive Treatment Amendment Bill Act 2012,* Hansard, Legislative Assembly, 12 December 2012, at page 5487. [↑](#footnote-ref-3)
3. This process is managed by ART providers and does not require Panel approval. [↑](#footnote-ref-4)
4. Extensions sought on this basis are managed by ART providers and do not require Panel approval. [↑](#footnote-ref-5)
5. *JS and LS v Patient Review Panel* [2011] VCAT 856 at paragraph 14. [↑](#footnote-ref-6)
6. [2013] VCAT 1628, 24. [↑](#footnote-ref-7)
7. [2000] QB 198. [↑](#footnote-ref-8)
8. *Assisted Reproductive Treatment Act 2008* (Vic), s 96(e). [↑](#footnote-ref-9)
9. *Assisted Reproductive Treatment Act 2008* (Vic), s 98. [↑](#footnote-ref-10)