Advisory Committee on
Assisted Reproductive Technology

Guidelines for extending the storage of gametes and embryos

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Preamble

A. Guidance on terms used

In these guidelines, unless the context indicates otherwise, words should be interpreted in accordance with definitions given in the Human Assisted Reproductive Technology Act 2004 and the Human Assisted Reproductive Technology Order 2005.

B. Background

Parliament amended the Human Assisted Reproductive Technology Act (the HART Act) in 2010 to clarify provisions relating to the storage and extending storage of gametes and embryos beyond the original 10-year limit. The amended legislation covers the following points.

a) The original 10-year limit for storing gametes and embryos is counted from 22 November 2004, when the HART Act commenced, or later, depending on the date of first storage.

b) The original 10-year storage limit or an approved extended storage period for embryos includes any storage time for the gametes used to create the embryos.

c) In calculating the original 10-year storage limit or an approved extended storage period, storage time outside New Zealand is to be counted.

d) There will be a grace period of six months from the expiry of the original 10-year storage limit, or from the expiry of an approved extended storage period, solely to enable those responsible for the storage of the gametes or embryos to manage the disposal of the gametes or embryos. Gametes and embryos must not be used during this period.

e) The role of the Advisory Committee on Assisted Reproductive Technology (ACART) includes issuing guidelines or giving advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on matters that ECART must take into account in considering whether to give, change or cancel an approval to extend the storage period of human in vitro gametes and embryos beyond the original 10-year storage limit, or beyond an approved extended storage period.

f) Applications to ECART must be made, and any approval given, before the end of the original 10-year storage limit or before the end of an approved extended storage period.

g) Applications to ECART to extend the storage period of gametes and embryos beyond the original 10-year storage limit, or beyond an approved extended storage period, must be in writing.

h) ECART may approve more than one extension to the original 10-year storage limit.

i) ECART may give an approval subject to any conditions it thinks fit to impose.

C. Interpretation

In these guidelines:

a) unless the context indicates otherwise, words should be interpreted in accordance with definitions given in the HART Act 2004 and the HART Order 2005

b) the word ‘gamete’ must be read to include sperm, eggs, cryopreserved testicular tissue and cryopreserved ovarian tissue

c) the word ‘consumer’ must be read to include any person receiving treatment, or providing gametes in relation to treatment, at a fertility service. This includes prospective parents, those involved in surrogacy arrangements, and gamete and embryo donors

d) any extension to the original 10-year storage limit or an approved extended storage period begins at the end of the original 10-year storage limit or the approved extended storage period.

e) a donated embryo is an embryo that was created for use by one person/couple and then, surplus to their needs, has been donated to new intending parents.

Note

Some subsequent uses of stored gametes and embryos will require further ECART approval where the use is an assisted reproductive procedure or human reproductive research and ACART has issued guidelines.

Principles of the Human Assisted Reproductive Technology Act 2004

1. When considering an application to extend the storage period of gametes or embryos beyond the original 10-year storage limit or beyond an approved extended storage period, ECART must be guided by the principles of the Human Assisted Reproductive Technology Act 2004.

All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function.

a) The health and wellbeing of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure.

b) The human health, safety and dignity of present and future generations should be preserved and promoted.

c) While all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and wellbeing of women must be protected in the use of these procedures.

d) No assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent.

e) Donor offspring should be made aware of their genetic origins and be able to access information about those origins.

f) The needs, values and beliefs of Māori should be considered and treated with respect.

g) The different ethical, spiritual and cultural perspectives in society should be considered and treated with respect.

Making an application

2. An application to extend the storage period of gametes or embryos beyond the original 10-year storage limit or beyond an approved extended storage period:

a) may be made by any person, for example consumers (including donors), clinics, or others with an interest in an extension, where extending storage is for the purposes of fertility treatment or fertility preservation

b) may be made by a researcher where extending storage is for the purposes of human reproductive research.

Consider storage history

3. When considering an application to extend the storage period of gametes or embryos beyond the original 10-year storage limit or beyond an approved extended storage period, ECART must determine the following matters about the storage history of the gametes or embryos:

    a) the length of time that gametes have already been stored, both in New Zealand and overseas

    b) the length of time that embryos have already been stored, both in New Zealand and overseas, including any time during which gametes used to create embryos have already been stored

    c) the expiry date of a current approved storage period.

The extension must be consistent with the purposes of the HART Act

4. When considering an application to extend the storage period of gametes or embryos beyond the original 10-year limit or beyond an approved extended storage period, ECART must take into account whether extending the storage period is consistent with the purposes of the HART Act which is (section 3(a)) 'to secure the benefits of assisted reproductive procedures, established procedures, and human reproductive research for individuals and society in general by taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research'. Examples are:

    - where gametes or embryos were originally stored because of family medical history (eg, a family medical history of early menopause)
    - where gametes or embryos were originally stored before medical treatment that may impair an individual's fertility
    - where gametes or embryos have been stored to provide a future opportunity to have a child
    - human reproductive research.

Informed consent

5. When considering an application to extend the storage period of gametes or embryos beyond the initial 10-year storage limit or beyond an approved extended storage period, ECART must take the following matters into account:

A. Gametes

a) where the application is to extend the storage of gametes, whether all gamete providers (including donors) have given informed consent

b) where an application does not include a gamete provider's informed consent to extending storage:

   i) whether there is evidence that all reasonable efforts have been made to contact the gamete provider, and

   ii) whether the consequences would be unduly harsh for interested parties if ECART declined the application on the grounds that informed consent by all gamete providers was not available

c) where a gamete provider has died after the storage of his or her gametes, whether there is a written record or other evidence that he or she gave informed consent to extending the storage period of these gametes, and the use of those gametes after their death.

B. Embryos

d) where the application is to extend the storage of one or more embryos, whether the intending parent(s) consented

e) where the application is to extend the storage of one or more donated embryos, whether the embryo donors and the now intending parents have all consented

f) where an application does not include an embryo donor's informed consent to extending storage:

   i) whether there is evidence that all reasonable efforts have been made to contact the embryo donor(s), and

   ii) whether the consequences would be unduly harsh for interested parties if ECART declined the application on the grounds that continued informed consent from the embryo donors was not available

g) where a person has died who has embryos stored made from their own gametes, evidence that he or she gave informed consent to extending the storage period of

embryos created from his or her gametes and the use of those gametes/embryos after their death

h) where the application is for embryos made with any donated gametes, whether the gamete donor(s) had attached any advanced conditions that would affect an application to extend storage

C. Gametes and Embryos

i) whether a renewed consent is needed in cases where a lengthy period has elapsed since the consent was given

j) in cases of material stored for non-clinical research (ie, not part of clinical treatment), the researcher named in the ECART ethics approval is to provide the consent.

Periods of extended storage

6. When considering an application to extend the storage period of gametes or embryos beyond the original 10-year storage limit or beyond an approved extended storage period, ECART must take into account:

   a) any previous periods of extended storage and the total time elapsed since the gametes or embryos were stored

   b) any intergenerational effects on children where extending storage is for the purposes of fertility treatment or fertility preservation. Examples are the:

      - potential for siblings to be born one or more generations apart
      - possibility that genetic parents may no longer be alive following the birth of a child born from the stored gametes or embryos
      - potential loss of access to family history
      - potential loss of access to whakapapa and associated whakapapa rights