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Advisory Committee on Assisted Reproductive Technology

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Proposed Changes to the Guidelines for Extending the Storage Period of Gametes and Embryos

Consultation document

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Advisory Committee on Assisted Reproductive Technology

Contents

Introduction

1. In New Zealand, fertility services providers can store gametes and embryos for up to 10 years from first storage, as a single period of 10 years, or 10 years comprised of two or more periods of less than 10 years. This period is legislated in the Human Assisted Reproductive Technology Act 2004 (the HART Act). The Ethics Committee on Assisted Reproductive Technology (ECART) may grant extensions to that storage by using guidelines issued by the Advisory Committee on Assisted Reproductive Technology (ACART).

2. In Part I, ACART is seeking feedback on a proposal to amend the Guidelines for Extending the Storage Period of Gametes and Embryos (the guidelines) to address an apparent anomaly that affects the extension of the storage of embryos created using donated gametes (sperm and/or eggs). These amendments also aim to make it easier to understand the guidelines on who needs to provide consent in which situations.

3. In addition to the above proposal, ACART is seeking the public's views on other parts of the guidelines, which will provide further information on how the public interprets them or identify whether any changes are needed. Part II outlines the questions on these additional issues.

Part I: Proposal to amend guideline

1. Background

4. ACART's position on who has authority over a gamete or embryo is that people have authority over their own gametes or embryos up until they are used in a procedure. For embryos created with one or more donated gametes, the joining of the gametes is the procedure, and the embryo is considered a new entity. Therefore, the authority over an embryo created using donated gametes lies with the intending parents.[1] This sole authority exists to manage the risks to the intending parents that could arise if the gamete donors were to change their minds about their donations after the embryos had been formed. In the case of donated embryos, the embryo donor has authority up until the embryos are used in a procedure – that is, in implantation – and they keep authority over those embryos. A similar arrangement exists for gametes. Table 1 summarises the existing guidelines and Table 2 sets out the proposed policies in this area.

Table 1: Current guidelines

Application for extending the storage of:		**Who has authority? (who must be asked to consent to extending storage)**
1	Gametes	The person who produced the gametes.
2	Donated gametes	The person who produced the gametes and the recipient(s).
3	Embryos	The people for whom the embryos were created (ie, the intending parents).
4	Embryos created with a donated gamete	The gamete providers (including donors) and the intending parents (as long as the use is consistent with any conditions of the original gamete donation).
5	Donated embryos	The original people for whom the embryos were created (embryo donors) and the recipient(s).
6	On-donated embryos (where a recipient of a donated embryo then on-donates it to another person)	*This is a very rare situation now, possibly due to changes in the guidelines for donations. Please refer to those guidelines.* The original people for whom the embryos were created (the original donors) and/or the family that has children who would be full-genetic siblings to the embryos, and the recipient(s). Consent to extension of storage should be consistent with consent to use.

[1] The authority over embryos created using donated gametes lies with the intending parents provided that: 1. the gamete donor gave full informed consent for their donation to form the embryo; and 2. the intending parents are complying with any conditions that the donor might have placed on that consent to donate, for example, a condition that they do not make an on-donation to another intending parent.

Table 2: Intended ACART policies

Application for extending the storage of:	Who has authority? (who must be asked to consent to extending storage
1 Gametes	The person who produced the gametes.
2 Donated gametes	The person who produced the gametes and the recipient(s).
3 Embryos	The people for whom the embryos were created (ie, the intending parents).
4 Embryos created with a donated gamete	The intending parents (as long as the use is consistent with any conditions of the original gamete donation).
5 Donated embryos	The original people for whom the embryos were created (embryo donors) and the recipient(s).
6 On-donated embryos (where a recipient of a donated embryo then on-donates it to another person)	*This is a very rare situation now, possibly due to changes in the guidelines for donations. Please refer to those guidelines.* The original people for whom the embryos were created (the original donors) and/or the family that has children who would be full-genetic siblings to the embryos, and the recipient(s). Consent to extension of storage should be consistent with consent to use.

5. Consent to extend storage is an opportunity to confirm ongoing consent to the use of a donation, if gametes and embryos have not been used yet.

2. Why ACART is reviewing the guidelines

6. The current guidelines require gamete donors to re-consent when intending parents seek an extension to the storage of the embryos they created from the donated gametes (case 4 in Table 1). This requirement contradicts the understanding of both ACART and the fertility services providers that, when intending parents create embryos from donated gametes, the resulting embryos are under the sole authority of the intending parents.

7. The sector has told ACART that asking gamete donors to consent to storage extension after their gametes have been used to form an embryo is contrary to their understanding of who has authority over embryos. Due to the time period that has often passed by this point, it can also be difficult to contact the gamete donor to gain their consent in practice.

8. The current provision in the guidelines that ACART proposes to change reads:

> 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) whether all gamete providers (including donors) have given informed consent, **including where an embryo has been created from the gametes** ... [emphasis added]

9. ACART's proposed changes to the guidelines would confirm that the authority over stored embryos, created from donated gametes (or one donated gamete plus a gamete of the intending parents), will be solely with the intending parents. ACART expects this change will create a smoother process for individuals, clinics and ECART when intending parents seek a storage extension and will bring the guidelines into line with other ACART policies.

3. Matters that ACART has considered

Te Tiriti o Waitangi | The Treaty of Waitangi

10. ACART has a responsibility to contribute to the Crown's commitment to meeting its obligations under Te Tiriti o Waitangi | The Treaty of Waitangi. ACART endeavours to follow, or work in the spirit of, the goals set out by the Ministry of Health's (the Ministry's) obligations under Te Tiriti o Waitangi.

11. For more details about ACART's efforts to meet Te Tiriti o Waitangi obligations, see *Summaries of the regulation of assisted reproduction in New Zealand and the legal, ethical and cultural issues often involved in assisted reproduction*.[2] This online document sets out ACART's functions and the regulatory and ethical setting in which it operates.

Te Ao Māori

12. Te Ao Māori places great significance on whakapapa. Whakapapa is generally referred to as genealogy – the connections between generations – but also includes historical, contemporary, spiritual and mythological aspects of heritage. According to tikanga of some iwi and hapū, whakapapa, including genetic connection through assisted reproductive technology, gives offspring rights to resources under the kaitiaki (guardianship) of iwi and Māori, and so storage extension supports and broadens those rights.

13. The guidelines support tino rangatiratanga (self-determination) of gamete donors by enabling them to set conditions on their donations such as cultural, religious or family status requirements. Gamete donors can maintain authority and consent rights over their gametes up until the point they are used (to form embryos). After that point, any original conditions must continue to be honoured, but the proposal is to no longer ask the donors to consent to storage extension (see paragraph 9 above).

[2] ACART. 2020. *Summaries of the regulation of assisted reproduction in New Zealand and the legal, ethical and cultural issues often involved in assisted reproduction*. Wellington: Advisory Committee on Assisted Reproductive Technology. URL: https://acart.health.govt.nz/publications-and-resources/publications/summaries-of-the-regulation-of-assisted-reproduction-in-new-zealand-and-the-legal-ethical-and-cultural-issues-often-involved-in-assisted-reproduction/ (accessed 15 June 2022).

14. The guidelines acknowledge the patient has the tino rangatiratanga to include their whānau in the decision-making process, for example, enabling patients to involve their wider whānau in counselling as a group. The guidelines also allow for ECART to check counselling has been culturally appropriate for the patient.

15. To protect considerations related to whakapapa, or knowledge of heritage, donors must be named in the HART Register. That means offspring will have opportunities to know who their donor was.

16. One of the proposals in this document reflects the idea that someone can consent to the use of their reproductive material up to a 'point of no return'. For gamete donors, that point is when the gametes are transferred to the uterus of a woman or when they are used to create embryos. After that, the tino rangatiratanga of the resulting embryo lies with the person gestating it, or intending parents (even if the embryo remains in storage for a while longer). For embryos, people consent to any donation up to the point of transfer to the uterus, after which the tino rangatiratanga lies with the person gestating the embryo. These ideas mean that the intending parents are the ones who are asked for consent to extend the storage of reproductive material.

17. Māori recipients who wish to honour their cultural practices may do so, for example, by maintaining contact with the donor and consulting them on decisions to do with the embryo and offspring. However, such practices should not be encoded in law so that it becomes a requirement for everyone to do so. Once the donor's gamete has been used to create the embryo, it has become a new entity, or potential being, over which the intending parents now have kaitiaki or protection responsibilities.

18. The practice of not requiring the donor to consent to storage extension has one exception. That is where embryos have been 'on-donated', particularly if there are offspring with the same genetics as the embryos in storage. This exception protects whanaungatanga, whakapapa and the idea that the families with full-genetic siblings may want children to be able to get to know one another, or may want to have a say in whether those embryos can continue to be stored after the 10-year limit. In the case of donated embryos, the tino rangatiratanga remains with the original intending parents until the embryo is used. That means it remains with them until it is transferred to a womb | whare tamariki of the recipient.

Cultural considerations

19. New Zealand is a culturally and ethnically diverse country, and ACART has taken into account when addressing the proposed revisions. Principle 4(g) of the HART Act requires the different ethical, spiritual and cultural perspectives to be considered and treated with respect in the context of assisted reproduction.

20. In relation to storage extension, ACART considered the expectation of intending parents that they would have authority over embryos they have made for themselves. This would include expecting to be able to apply to extend storage without other parties intervening in the decision. This is consistent with the ethical principal of autonomy, and also with the rights of patients under the Code of Health and Disability Services Consumers' Rights 1996.

21. Overall, ACART considered gamete donors have adequate safeguards. They do not need any further authority over storage extensions provided that the proposed embryo use complies with the conditions the gamete donors set in their original consent.

Disability perspective

22. When developing guidelines or advice, ACART must consider the perspectives of people with disabilities, including tāngata whaikaha (Māori disabled people). In summary, people with disabilities are entitled to the same considerations as all people in fertility treatment. The Human Rights Act 1993 prohibits discrimination against individuals on the basis of disability, and failing to provide information in accessible formats to people with disabilities can be seen as discrimination. Article 23(1)(b) of the United Nations Convention on the Rights of Persons with Disabilities also protects recognition of the right to decide freely and responsibly on the number and spacing of children and to have access to age-appropriate information, reproductive and family planning education.[3] Article 23(1)(b) also states that people with disabilities must be provided with the means necessary to enable them to exercise these rights.

23. In relation to extending storage, the guidelines recognise that people with disabilities may receive information in accessible forms. In addition, they may give their consent in ways suitable to the individual. For example, they may give their consent orally if they are not able to give it in writing.

Ethical considerations

24. When considering this matter, ACART referred to its ethical framework, which incorporates the principles of the HART Act and generally accepted ethical principles. The ethical framework considers the welfare of those affected by the procedure and the autonomy of those involved, as well as altruism, social trust and responsibility, the special status of the embryo, and justice and equality.[4]

25. ACART can also consider any ethical matters raised from other world views and welcomes feedback on these matters.

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[3] https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-23-respect-for-home-and-the-family.html

[4] https://acart.health.govt.nz/publications-and-resources/publications/ethical-framework-for-acart/

4. The proposed revised guidelines

When an application to extend the storage of gametes or embryos should require consent from a donor

26. ACART is proposing three main amendments to section 5 of the guidelines to differentiate between the consent requirements for stored gametes and those for stored embryos. ACART is interested in your thoughts on when an application to extend the storage of a gamete or embryo should require consent from any gamete or embryo donors.

27. ACART notes that **storage** can be seen as significantly different from **use**. One argument is that the primary interest of the parties is in the use of the gametes or embryos, and that storage is a less significant matter. In this view, storage would generally be a standard part of the donation agreement, with no special significance.

28. However, another argument is that certain factors give donors a legitimate interest in the extension of storage. Of particular note is that the gametes or embryos are, or were, theirs. Other factors can include: (a) the genetic links between the donated embryos and children the donors already have; (b) whether the donors had embryos created for themselves; and (c) whether the donors had already consented to extensions.

29. Previous advice about consent suggested that it should be 'continual consent' up to a given point in time (a point of no return). For embryo donation, for example, the point of no return is when the embryo is transferred to a uterus; after that point, the donor cannot require the patient to stop using it. For gamete donors, the point of no return is when a gamete is fused with another gamete to form an embryo. When the embryo is created, becoming another whole entity, it is considered that the gamete donor's consent to donation has been fulfilled at that point. After this 'point of no return', the donor should not be able to place new conditions on the use of the embryo.

30. Gametes and embryos may also be stored for use in research that is not part of clinical treatment. While use of viable embryos in research is not currently permitted, because the current guidelines do not enable it, those guidelines are under review, so that in future donation of all types of stored reproductive material for research use may be permitted. ACART proposes that, for simplicity, donations for research will include transfer of authority over the reproductive material to the researcher(s) named in the ECART ethics approval, except when it is being used in clinical treatment.

31. ACART is consulting on four key proposals for the revised guidelines.

- Proposal 1. Consent from any **gamete** donor(s) should not be required when applying to extend the storage of an **embryo**.
- Proposal 2. Consent from any **gamete** donor(s) should be required when applying to extend the storage of **gametes**.
- Proposal 3. Consent from any **embryo** donor(s) should be required when applying to extend the storage of an **embryo**.
- Proposal 4. Consent from the **researcher(s)** named in the ECART ethics approval should be required when applying to extend the storage of reproductive material donated to **research**.

*Proposal 1: Consent from any **gamete** donor(s) should not be required when applying to extend the storage of an **embryo***

32. ACART proposes a change to the guidelines to include a provision stating that an application to extend the storage of embryos created using one or more donated gametes should require consent only from the intending parents, and that consent is not required from gamete donors. This is assuming the gamete donors gave informed consent up to the point of embryo creation, with the knowledge storage could be extended, and had placed any conditions they wanted when they originally donated the gametes.

Rationale

33. By amending the guidelines, ACART will affirm the position that only the intending parents, who had the embryos created for their use, should be required to consent to extension of embryo storage. They should keep authority over embryos created for their use.

34. The current guidelines for extending storage require gamete donors to consent when intending parents seek an extension to the storage of the embryos they created from the donated gametes. This requirement contradicts previous advice on consent that allows gamete donors to withdraw their consent only up to the point when an embryo is made. After that point, the conditions on their consent must continue to be honoured, but they can no longer withdraw consent to the gamete donation.

35. As both ACART and the fertility services providers understand it, when intending parents have embryos created from one or more donated gametes, the embryos are under the sole authority of the intending parents. This is at odds with the current requirement in the storage extension guidelines.

36. While gamete donors can obviously have an interest in the use of their donations, it is important that, once embryos have been created from the donated gamete(s), donors cannot prevent the recipient from extending storage of the embryos (unless they set a storage limit before making the donation). The reason for this is that each embryo is another entity that the intending parents have a specific interest in and intend to use.

37. If the gamete donors had a further say in the use of the embryos by being able to withdraw consent to storage, this would affect the opportunities of the intending parents and potentially cause distress to them and any existing children they have. The interests of the gamete donor are protected because they can place ‘conditions’ on their donation. It is important to note that any conditions the gamete donor(s) have set in advance still apply even after their gametes have been used to form an embryo. For example, they could consent to their gametes being used to form an embryo on the condition that the embryo is used within 10 years.

38. It is critical that gamete donors are aware of this policy – that the recipient can seek extension of storage of an embryo without their consent – when they donate their gametes in the first place. It is also important that the donor's consent is valid and current when embryos are created from gametes. ACART expects gamete donors to be fully informed of all the potential uses of the embryo, how long embryos formed from their gametes may be stored, that storage extension may be granted and that embryos may even be donated to another recipient.

*Proposal 2: Consent from any **gamete** donor(s) should be required when applying to extend the storage of **gametes***

39. ACART proposes that the guidelines retain the provision that an application to extend the storage of gametes should require the consent of any gamete donors.

Rationale

40. A person has authority over his or her gametes up until such time as they those gametes are used in a fertility procedure, and that authority continues after the person has donated those gametes. Consequently, the revised guidelines will retain the provision that the gamete donors must consent to any extension to the storage of the gametes.

41. This proposal upholds the rights and interests of donors, including the tino rangatiratanga of a Māori donor.

42. The guidelines allow some room for relaxing this requirement where it is not possible to contact the gamete provider to obtain that consent. Provision 5(b) of the guidelines states:

> 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:
>
> ...
>
> 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 ...

*Proposal 3: Consent from any **embryo** donor(s) should be required when applying to extend the storage of an **embryo***

43. ACART proposes that the guidelines include a provision that clearly states that an application to extend the storage of donated embryos should require consent from the embryo donor.

Rationale

44. The wording of the current guidelines is ambiguous about if and when embryo donors should consent to extending the storage of the embryos they donated.

45. The policy in these guidelines is that gamete donors have authority over their donated gametes. It would be consistent with this policy to state further that embryo donors must consent to the extension of storage of those embryos. Such a statement would also be consistent with the part of ACART's guidelines concerned with donations (of gametes and embryos) and surrogacy. Those guidelines state that embryo donors have authority over embryos they have donated, until the embryo is transferred to the uterus of the intending birth mother. This is also consistent with ACART's previous advice on consent: that a donor can give fully informed consent to the use of their embryos, and withhold that consent, up to a 'point of no return' – where that point is implantation into the uterus.

46. It could be useful to revise the guidelines to be more flexible so that ECART can authorise extension of storage in cases when embryo donors cannot be contacted, or when there are existing children who would be full-genetic siblings to the children born from the embryo. Provision 5(f) of the proposed revised guidelines allows for these circumstances:

> 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:
>
> ...
>
> 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 ...

*Proposal 4: Consent from **researcher(s)** named in the ECART ethics approval should be required for extending the storage of reproductive material donated to **research***

47. ACART proposes that consent from the researcher(s) named in the ECART ethics approval should be required for extending storage of reproductive material donated to research.

Rationale

48. Gametes and embryos may be stored for use in research that is not part of clinical treatment. While use of embryos in research is not currently permitted because the guidelines do not cover it, the guidelines are under review to address this issue, so that in future donation of all types of stored reproductive material for research use might be permitted. ACART proposes that, for simplicity, donations for research will include transfer of authority over the reproductive material to the researcher(s) named in the ECART ethics approval, except when it is being used in clinical treatment. The donor can withdraw their consent up until the time when their material is used for research. It is the donor's responsibility to contact the researcher in order to withdraw their consent.

49. If the guidelines for research are amended to allow research on viable embryos, authority over those embryos would transfer to the researcher(s) named in the ECART ethics approval in cases where those embryos were donated for non-clinical research. The researchers would be responsible for the biobank[5] if they are running it and they would need ethics approval to run it. If the biobank was run by some other party that party would be responsible for running it and would do so only with ethical approval.

50. Donating embryos to non-clinical research is one way that intending parents can 'dispose' of those embryos without immediately thawing them for no useful purpose and instead passing them on to a potentially useful purpose. They may or may not want to be informed of future research processes or activities that use the embryos. However, donors might like to be kept informed about the status of the embryos, including any changes in the storage. They can make conditions on their consent to donation to research, such as being contacted if the storage period expires or, indeed, when the researchers use or otherwise dispose of the embryos.

[5] A biobank is a storage facility for biological materials, often cryopreserved, that may be intended for specific or non-specific use, for example, research or sperm banks.

51. Under Right 7(9) of the Code of Health and Disability Services Consumers' Rights 1996 (the Code), donors have the right to make a decision about the return or disposal of any tissue removed or obtained in the course of a health care procedure. Further, Right 7(10) of the Code provides that tissue removed or obtained in the course of a health care procedure cannot be stored, preserved or used unless (a) informed consent of the donor has been obtained or (b) it is for the purposes of research that an ethics committee has approved.[6] Individual health care institutions have their own policies on the return or disposal of tissue.

52. On the question of disposal of tissue, the Ministry's *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* state that information for donors should cover where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. Tikanga should be available to guide the storage, disposal and/or return of gametes specifically for Māori.

53. In the context of biobanking, the Ao Māori view is that tissue, DNA and the associated data are taonga (precious items), which are tapu (sacred) and so subject to restriction and greater respect.[7] These conditions apply to the return/disposal process as well. The main restriction is that the taonga are under the responsibility of a kaitiaki who monitors access to and use of the specific taonga. Māori participation and values as they relate to taonga should inform policy and practice of the biobank activities, such as operational, governance and community engagement.[8]

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6 Health and Disability Commissioner. 1996. Code of Health and Disability Services Consumers' Rights. URL: www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/ (accessed 17 June 2022).

7 Beaton A, Hudson M, Milne M, et al. 2017. Engaging Māori in biobanking and genomic research: a model for biobanks to guide culturally informed governance, operational, and community engagement activities. *Genetics in Medicine* 19(3): 345–351.

8 Ibid.

Minor change to preamble of guidelines

54. ACART will remove a paragraph in the preamble to the storage extension guidelines, that refers to an outdated provision. This paragraph was only relevant in the period between 2004 and 2014.

55. The remaining preamble outlines the legal requirements set out in the HART Act.

The proposed revised guidelines

Guidelines on extending the storage of gametes and embryos

Preamble

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.

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 [This is the section with substantive change. The original text for informed consent follows this revised section.]

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:

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

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 an embryo donor has died, whether there is a written record or other 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 after 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

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.

~~*Informed consent*~~ *[The original provisions for informed consent: these will be removed.]*

~~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) whether all gamete providers (including donors) have given informed consent, including where an embryo has been created from the gametes~~

~~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 or of embryos created from the gametes, whether there is a written record or other evidence that he or she gave informed consent to extending the storage period of the gametes or embryos created from his or her gametes~~

~~d) whether a fresh consent is needed in cases where a lengthy period has elapsed since the consent was given.~~

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.

Part II: Consultation on other parts of the guidelines

56. While Part I of this consultation focused on proposed changes to the guidelines, the questions in Part II focus on related matters that ACART is also seeking the public's views on. Although this feedback may not necessarily result in any further changes to the guidelines at this time, we welcome comments and suggestions on any part of the guidelines or HART Act that relates to the storage of gametes and embryos.

57. The questions in Part II explore the wider principles behind the storage of gametes and embryos, such as how long they can be stored, who should be responsible for granting extensions and whether there are circumstances in which an extension should not be granted. A key theme across these questions is the risks that may be associated with storing gametes and embryos, including the following.

- Risks to offspring and families: It is possible that storage could have intergenerational effects on children. For example, offspring may not know their genetic parents or lose a sense of belonging to a particular generation. This could also impact whakapapa and the whānau structure, have implications for tikanga and transgress collective rights.
- Risks of age discrimination: The risk of discrimination arises if a maximum reproductive age range is imposed even if this is to protect the health and wellbeing of offspring.
- Risks to clinics: Clinics might be held accountable for ethical decisions that perhaps sit better with a specialist ethics body.

5. Question: Should storage and/or storage extensions have a time limit?

58. Under section 10A of the HART Act, ECART may grant an extension to the storage of gametes and embryos. Although section 10 of the HART Act places an initial 10-year limit on the length of storage, it does not set any upper limit as to how long or how often storage may be extended.

59. ECART's current practice is to grant storage extensions for up to 10 years. Although this practice is consistent with the initial 10-year limit, the HART Act does not actually specify any minimum or maximum period that ECART can extend storage by. This could enable ECART to grant storage extensions for longer than 10 years in certain circumstances, such as where the applicant is young (eg, 20 years old). However, it does not currently do so in practice as no clear guidance on the matter is available.

60. ACART would like to know what the public thinks about time limits to storage and storage extensions. This may include whether the 10-year limit should be increased or decreased, or remain the same, or whether storage extensions should have a maximum total length.

6. Question: Should fertility clinics, rather than ECART, be responsible for approving storage extension applications?

61. Under the HART Act, ECART is the body that decides all applications to extend the storage of gametes and embryos. An alternative option, however, could be for patients to apply directly to their fertility clinic for an extension of storage. The main benefit of this change is that patients would no longer need to wait for ECART approval for storage extensions. Fertility clinics would have a list of criteria under the HART Act to consider when reviewing applications. This change would require an amendment to the HART Act.

62. We are interested in hearing the public's views on whether ECART should remain the decision maker for storage extension applications, or whether fertility clinics should have this responsibility instead.

Implications

63. As clinics would be accountable for storage decisions, ACART would need to carefully consult on what criteria to create for clinics to refer to in making storage decisions. Clinics would be accountable and monitored through accreditation as providers of fertility services in line with *Ngā Paerewa: Health and disability services standard*.

64. If fertility clinics oversee management of storage periods, this may help to prevent delays and decrease the time patients wait to receive a decision on their applications. Patients would not need to wait until the next available ECART meeting for a decision and ECART would have fewer applications to consider.

7. Question: In what circumstances should ECART decline an application for storage extension?

65. ECART typically considers several factors when deciding whether to grant a storage extension. These include the applicant's rationale for requesting the extension, the total length of time that the gametes or embryos have been stored to date, and the applicant's plans (if any) to use or donate their stored gametes or embryos.

66. ECART has also reported to ACART that it regularly considers repeat applications, where people continue to roll over their storage with no clear intention of using their gametes or embryos. These applications generally fall into three categories:

    a) applicants who do not wish to dispose of their embryos due to religious or cultural beliefs

    b) older applicants who wish to store gametes or embryos in case they might decide, at a later date, to have a child or more children, even beyond the age of normal reproductive capability

    c) individuals who do not want to dispose of gametes or embryos or to donate or use them, but would like to continue paying for storage so that at some time in the future they may be used for research.

67. Section 10D(2)(c) of the HART Act provides grounds for ECART to cancel an approval if ECART has become aware that the approved storage of the gamete or embryo presents a serious risk to human health and safety.

68. Below are two possible harms to consider in relation to storage extensions.

Age

69. Currently, there is no age limit as to who may apply for a storage extension. This is to avoid potential discrimination under the Human Rights Act 1993, and to enable clinics to make treatment decisions based on clinical factors.

70. A person's age in relation to their normal reproductive lifespan is a principle that could apply when determining the length of a storage extension. For example, a teenager or young person could be given a longer period of storage, whereas someone past the reproductive age range could be given a shorter time within which to decide whether to use or dispose of the material. However, any such decision would require strong justification as this change could constitute discrimination on the basis of age. ACART would like to consult on whether society has a view about a maximum reproductive age range. A factor involved in this consideration could include actual risks to the health and wellbeing of offspring.

Intergenerational effects

71. The current guidelines for extending storage state:

> When considering an application to extend the storage period of gametes and embryos beyond the original 10-year storage limit, ECART must take into account:
>
> a) any previous periods of extended storage, the total time elapsed since the embryos or gametes were originally stored
>
> b) any **intergenerational effects** on children when extending the storage for the purposes of fertility storage or fertility preservation. [emphasis added]

72. There are ethical considerations regarding the intergenerational effects on children when extending storage. Through extended storage arrangements, people may be, for example, siblings but born 30, 40 or 50 years apart. This may interfere with the child's nurture, based on the family hierarchy, and impact family relationships.[9] Children of older parents may miss out on the opportunities to develop adult relationships with their parents and may not experience the influence of grandparents during their childhoods, while their own children are likely to miss out on grandparent–grandchild relationships in future.[10] Further, some people may consider their sense of 'belonging to a generation' is linked to being born to people who are of conventional child-bearing age. However, this view might not be widespread in society because assisted reproductive technology has had a longstanding role in enabling families to form over a greater range of ages.

73. Conversely, some intergenerational effects on children may be positive. Intergenerational donations involve the transfer of some of the recipient's genes to the child. Accordingly, gametes from family members may be preferred because they can be thought to preserve the family's genetic heritage and kinship. A sense of 'genetic closeness' between the child and family can be achieved.[11]

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[9] Haskovic M, Poot WJ, van Golde R, et al. 2018. Intrafamilial oocyte donation in classic galactosemia: ethical and societal aspects. *Journal of Inherited Metabolic Disease* 41(5): 791–7. DOI: 10.1007/s10545-018-0179-y (accessed 20 June 2022).

[10] Zweifel JE. 2015. Donor conception from the viewpoint of the child: positives, negatives, and promoting the welfare of the child. *Fertility and Sterility* 104(3): 513–9. DOI: 10.1016/j.fertnstert.2015.06.014 (accessed 20 June 2022).

[11] Ethics Committee of the American Society for Reproductive Medicine. 2004. Family members as gamete donors and surrogates. *Fertility and Sterility* 82(1): 217–23. DOI: 10.1016/j.fertnstert.2004.05.010 (accessed 20 June 2022).

74. Gamete donation between generations may impact whakapapa and the whānau structure, have implications for tikanga and transgress collective rights.[12] For example, if a father donated sperm to a son, the child would biologically be the child of the grandparent, putting them on the same generational level as their father, uncles and aunts.[13] This may confuse relationships and affect tikanga, for example, about the responsibilities and obligations to tuakana–teina (sibling order) relationships.[14] It could complicate the line of descent and inheritance of knowledge and status.

[12] Glover M, Rousseau B. 2007. 'Your child is your whakapapa': Māori considerations of assisted reproduction and human relatedness. *Sites: A Journal of Social Anthropology and Cultural Studies* 4(2): 117–36. DOI: 10.11157/sites-vol4iss2id76 (accessed 20 June 2022).

[13] Ibid.

[14] Ibid.

8. Question: Should ECART be able to extend storage of materials intended for future unspecified research?

75. Some people may seek storage extension of materials that are intended for research that has not yet been specified. Research is permitted under the HART Act and the storage extension guidelines allow for this too. However, New Zealand does not yet have an appropriate climate for conducting research on gametes or embryos.

76. It is possible that ECART should not be concerned about proposed uses of stored material, given that people can change their minds, or not reveal a planned use. The facts related to storage may be the only ones necessary for ECART to consider.

77. An important factor to consider in relation to storage for future unspecified research is the possibility that gametes or embryos could be shipped overseas without consent. Both researchers and ECART, as the relevant ethics approval committee, would need to carefully evaluate the use of materials for this type of research, because this carries unquantifiable but potentially high risks for the participant/ donor.[15] If study samples are sent overseas for analysis and/or storage, they move beyond the jurisdiction of New Zealand law.[16] This can be a point of significant sensitivity in Te Ao Māori. The body is considered tapu (sacred) and so requires specific consideration and respect. Overseas facilities or ethics committees may not be familiar with Māori protocols for handling and disposing of tissue.[17] Further, many Māori favour the recognition of both individual and collective consents because for some ethical issues it is useful for an individual to consider and consent to them, while other ethical issues require community engagement.[18] Some Māori will consider that human tissue contains genetic material that whānau, hapū and iwi collectively 'own' and may wish to discuss this with their whānau, hapū or iwi.

78. Also of note is that ACART is reviewing its Guidelines on Human Reproductive Research. The current guidelines on this matter were published in 2005 and have not been revised since then. They give only general instructions, and allow the use of only gametes and non-viable embryos, making the guidelines effectively unworkable. The guidelines also do not cater for social research. ACART's scope of the review of the guidelines includes research on human embryos whether they are viable or not.

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15 Medical and Health Sciences. nd. Human tissue and genetics. URL: www.auckland.ac.nz/en/fmhs/about-the-faculty/tkhm/Responsiveness-to-Maori/human-tissue-and-genetics.html (accessed 21 June 2022).

16 Ibid.

17 Ministry of Health. 2007. *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes: Submissions summary*. Wellington: Ministry of Health.

18 Hudson M. 2009. Think globally, act locally: 'collective consent' and the ethics of knowledge production. *International Social Science Journal* 60(195): 125–33.

How to have your say

Your feedback can help ACART ensure the guidelines for extending the storage of gametes and embryos are fit for purpose. ACART welcomes your views on the proposed guidelines and related issues.

Please take this opportunity to have your say. A feedback form is at the back of this document. You may give feedback on your own behalf or as a member of an organisation. You can contribute your views by:

1. completing the Citizen Space link through ACART's or the Ministry of Health's web page, or
2. emailing a completed feedback form or your comments to acart@moh.govt.nz, or
3. posting a completed feedback form or your comments to:

   ACART Secretariat
   PO Box 5013
   Wellington.

Publication of feedback

We may publish all submissions or a summary of submissions on ACART's website.

Official Information Act requests – name and contact details

In line with guidance from the Ombudsman, the Ministry of Health's standard procedure is to not release the name and contact details of any submitter who has given feedback in their private capacity (ie, not in a professional capacity or on behalf of an organisation) and who has requested that their personal information not be published by ticking the relevant boxes on the feedback form.

Where a person has given feedback on behalf of an organisation, the Ministry of Health will release the name and contact details of the submitter and the organisation unless there are other reasons for withholding the information in accordance with the Official Information Act 1982. If you consider that we should withhold your or your organisation's name and/or contact details under the Official Information Act 1982, please make this clear on your feedback form, noting your reasons.

For further guidance on releasing information under the Official Information Act 1982, go to the Ombudsman's website at: www.ombudsman.parliament.nz/resources-and-publications.

The closing date for feedback is 30 September 2022.

Feedback form

Please provide your contact details below.

Name	
If this feedback is on behalf of an organisation, please name the organisation	
Please provide a brief description of the organisation (if applicable)	
Address/email	
Interest in this topic (eg, consumer, health professional, researcher, member of public)	

Feedback as an individual. Are you:

☐ Male ☐ Female ☐ Other gender identity

Would you like to make an oral submission? (Can be in person or using electronic communications.)

☐ Yes ☐ No

Which of the following age groups do you belong to?

☐ 13 to 24 years ☐ 25 to 44 years ☐ 45 to 64 years ☐ 65+ years

What is your ethnicity? (Please tick all that you identify with.)

☐ NZ European ☐ Māori ☐ Pacific peoples
☐ Asian ☐ Other

Privacy

We may publish all submissions or a summary of submissions on the Ministry of Health's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information. You can also choose to have your personal details withheld if your submission is requested under the Official Information Act 1982.

If you do not want your submission published on the Ministry's website, please tick this box:

☐ Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

☐ Remove my personal details from responses to Official Information Act requests.

If your submission contains commercially sensitive information that you do not wish to be released, please tick this box:

☐ This submission contains commercially sensitive information.

Part I

Question 1

Do you agree with ACART's proposal that consent from any **gamete** donor(s) should not be required when applying to extend the storage of an **embryo**?

Yes ☐ No ☐

Comments

Question 2

Do you agree with ACART's proposal that consent from any **gamete** donor(s) should be required when applying to extend the storage of **gametes**?

Yes ☐ No ☐

Comments

Question 3

Do you agree with ACART's proposal that consent from any **embryo** donor(s) should be required when applying to extend the storage of an **embryo**?

Yes ☐ No ☐

Comments

Question 4

Do you agree with ACART's proposal that consent from the **researcher(s)** named in the ECART ethics approval should be required for extending the storage of reproductive material donated to **research**?

Yes ☐ No ☐

Comments

Part II

Question 5

Should storage and storage extensions have a time limit?

Yes ☐ No ☐

Comments

Question 6

Should fertility clinics, rather than ECART, be responsible for approving storage extension applications?

Yes ☐ No ☐

Comments

Question 7

In what circumstances should ECART decline an application for storage extension?

Comments

Question 8

Should ECART be able to extend storage of materials intended for future unspecified research?

Yes ☐ No ☐

Comments

Question 9

Do you have any other comments on the extension of storage of gametes and embryos?

Yes ☐ No ☐

Comments

Glossary

This glossary expands on terms used throughout this document to help with a general understanding of them. It does not present technical definitions.

Advisory Committee on Assisted Reproductive Technology (ACART)	The advisory committee established under the New Zealand Human Assisted Reproductive Technology Act 2004 (HART Act). The Minister of Health appoints members. See www.acart.health.govt.nz for more information.
Assisted reproductive procedure	The HART Act defines an assisted reproductive procedure as a procedure performed for the purpose of assisting human reproduction that involves: • the creation of an in-vitro human embryo, or • the storage, manipulation or use of an in-vitro human gamete or an in-vitro human embryo, or • the use of cells derived from an in-vitro embryo, or • the implantation into a human being of human gametes or human embryos; but does not include an established procedure.
Biobank	A storage facility for biological materials, often cryopreserved, that may be intended for specific or non-specific use, for example, research or sperm banks.
Donation	The giving of gametes or embryos for reproductive purposes.
Donor	A person who gives their gametes or embryos for another person to use in assisted reproduction. See section 5 of the HART Act.
Embryo	The product of the division of the zygote to the end of the embryonic stage, eight weeks after fertilisation.
Ethics Committee on Assisted Reproductive Technology (ECART)	The ethics committee established under the HART Act. On a case-by-case basis, ECART reviews and decides on applications to undertake assisted reproductive procedures, to undertake human reproductive research and to extend the statutory storage period of gametes and embryos. The Minister of Health appoints members. See www.ecart.health.govt.nz for more information.
Extended storage	Storage of a gamete or embryo beyond the period originally applied for and approved by ECART.
Gamete	An egg or sperm, whether mature or not, or any other cell (whether naturally occurring or artificially formed or modified) that contains only one copy of all or most chromosomes and is capable of being used for reproductive purposes.
Gamete provider	A person who provides gametes for use by their partner or themselves.

Human Assisted Reproductive Technology (HART) legislation	The Human Assisted Reproductive Technology Act 2004 and Human Assisted Reproductive Technology Order 2005. ACART and ECART were established under the HART Act.
Intergenerational effects	Ethical, social and psychological issues associated with forming family relationships with complex generational dimensions (such as full-genetic siblings born decades apart).
Tapu	'Sacred' or 'spiritual restriction', containing a strong imposition of rules and prohibitions.
Whakapapa	A line of descent from the ancestors of a whānau through their descendants; a cultural expression of genealogy in te Ao Māori.