



**Advisory Committee on
Assisted Reproductive Technology**

**Advice on the Amended Guidelines for
Extending the Storage Period of
Gametes and Embryos**

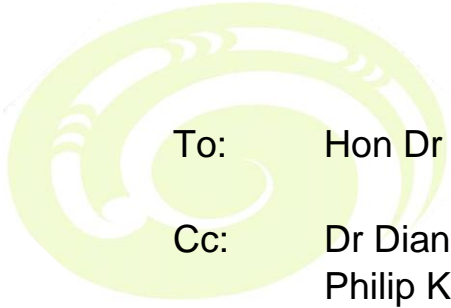
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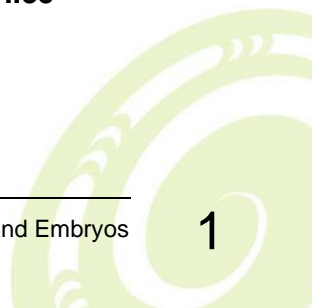
To: Hon Dr Ayesha Verrall

Cc: Dr Diana Sarfati
Philip Knipe

Title: Advice on the Amended Guidelines for Extending the Storage
Period of Gametes and Embryos

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A Executive summary

1. The purpose of this report is to advise you that the Advisory Committee on Assisted Reproductive Technology (ACART) intends to publish amended Guidelines for Extending the Storage Period of Gametes and Embryos (the amended Guidelines). ACART aims to publish the guidelines by late 2023. This advice is the way in which ACART is consulting you under section 35(1)(b)(ii) of the HART Act.
2. The main amendment to the guidelines is that there will no longer be a requirement to seek consent from donors of gametes that were used to create embryos, when people are applying for embryo storage extensions. Consent will be provided by the intending parents who plan to use the embryo. ACART considers that gamete donors already have adequate safeguards. If the proposed use of the embryo complies with the conditions the gamete donors set out in their original consent, then no further authority is necessary in respect of the storage extensions. Further details are provided in this briefing.
3. ACART has followed the legislative requirements to develop these guidelines. This project is part of ACART's work programme, as agreed to by the then Associate Minister of Health, Hon Jenny Salesa.
4. Between July and September 2022, ACART consulted the public on a proposal to amend the current guidelines. The primary purpose of the proposed amendments was to update guidelines on issues around consent, although ACART invited submitters to comment on broader issues around storage. ACART received 22 submissions from individuals and organisations.
5. This report also advises you that ACART is investigating additional matters relating to the storage of gametes and embryos, that were raised in the consultation. This includes whether further changes are required around age limits and storage limits for gametes and embryos. ACART will subsequently advise you about if and how those matters might be addressed through regulation.
6. ACART has given a copy of the advice to the Ministry of Health, in case you decide to seek parallel advice. ACART's Chair is available to discuss the advice with you, if you wish. ACART plans to publish this advice on its website in 2023, once the amended Guidelines have also been published.
7. A list of submitters is included as **Appendix 1** and a summary of submissions from the consultation is included as **Appendix 2**. The revised guidelines document is included as **Appendix 3**.



B Recommendations

8. **Note** that ACART aims to publish the amended Guidelines for Extending the Storage Period of Gametes and Embryos late in 2023.
9. **Note** that ACART also intends to investigate further matters raised in the consultation including the age of donors when a child is conceived and storage extension limits. ACART expects these issues will require further ethical and legal analysis. ACART will continue this work throughout 2023 and 2024.

Calum Barrett

Chair, Advisory Committee on Assisted Reproductive Technology

Hon Dr Ayesha Verrall

Minister of Health

Date:

Calum Barrett		Elsie Coleman	
Chair, Advisory Committee on Assisted Reproductive Technology		Assistant Advisor, Ethics, Quality Assurance and Safety, Te Pou Whakaritrite Ratonga, Ministry of Health	
Phone		Phone	



C Purpose of this report

10. This purpose of this report is to inform you that ACART intends to publish the amended guidelines and investigate further issues raised in the consultation.
11. Under Section 39 of the Human Assisted Reproductive Technology Act 2004 (HART ACT), ACART is required to consult with the public before giving significant advice, including publishing new or update guidelines. Section 35(1)(b)(ii) of the Human Assisted Reproductive Technology Act 2004 (HART ACT) requires ACART to advise you following public consultation.
12. ACART has undertaken analysis as required under Section 6 of the HART Act. In developing its advice, ACART has considered:
 - the principles of the HART Act
 - other common ethical principles, including wellbeing, autonomy, justice and equality
 - wider public policy considerations, including the Code of Health and Disability Services Consumers' Rights (the Code)
 - feedback from public consultation in 2022.

Structure of this report

13. This report discusses:
 - D. The current guidelines for the storage of gametes and embryos
 - E. Why ACART is reviewing the guidelines
 - F. Amended guidelines and rationale
 - G. ACART's consultation process
 - H. Matters that ACART has considered
 - I. Ethical analysis
 - J. ACART's recommendations
 - K. Next steps
- Appendices:
1. List of submitters
 2. Summary of submissions
 3. Revised Guidelines

D The current guidelines for the storage of gametes and embryos

How assisted reproduction is regulated in New Zealand

13. New Zealand's requirements for assisted reproduction are set out in
- the HART Act and the HART Order
 - the Code of Health and Disability Services Consumers' Rights (the Code)
 - guidelines issued by ACART to ECART
 - The Ngā Paerewa Health and Disability Services Standard.

The HART Act

14. The HART Act is the principal law regulating human assisted reproductive technology and human reproductive research in New Zealand. The HART Act requires ACART to advise the Minister of Health on a number of matters related to assisted reproduction. This advice must not be inconsistent with the Code.

The HART Order

15. The HART Order lists established procedures and the exceptions to those established procedures.

The Code of Health and Disability Services Consumers' Rights

16. Any medical procedure a person undergoes is also subject to the Code.

Guidelines issued by ACART to ECART

17. The guidelines are for assisted reproductive procedures that need to be considered and approved on a case-by-case basis by ECART.

The Ngā Paerewa Health and Disability Services Standard

18. Providers of fertility services in New Zealand must operate in accordance with the Ngā Paerewa Health and Disability Services Standard 2021 (the Standard), which sets out requirements for the safety and quality of fertility services in New Zealand. The Standard is a form of regulation issued under the Health and Disability Services (Safety) Act 2001.

Informed consent

19. Applications to extend the storage of gametes and embryos would need to comply with New Zealand's general requirements for informed consent.
20. A well-established body of law and practice concerning informed consent for medical procedures upholds the principle that autonomous individuals have the right to make decisions about procedures carried out on them.

21. Informed consent is addressed in s.4 of the HART Act (Principles), which provides:
- (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.
22. Rights 5, 6 and 7 of the Code give every consumer the right to effective communication, to be fully informed, to make an informed choice and to give informed consent. Right 7 also gives every consumer the right to make decisions about what happens to their body parts or bodily substances removed or obtained in the course of a health care procedure.
23. When carrying out any medical activity, providers must ensure that consumers receive information about all important aspects of their procedures. Appropriate consent forms for the activity are required, and providers must have clear policies and procedures to obtain informed consent from consumers.

Current guidelines for the storage of gametes and embryos

24. 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 (eg a period stored as a gamete then a period stored as an embryo). This period is legislated in the HART Act. ECART may grant extensions to that storage by using guidelines issued by ACART. Extensions are sought via application, which are considered by ECART's members at their bi-monthly meeting. Table 1 summarises the current guidelines.

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).

Application for extending the storage of:	Who has authority? (who must be asked to consent to extending storage)
6. On-donated embryos (where a recipient of a donated embryo then on-donates it to another person)	<p><i>This is a very rare situation now, possibly due to changes in the guidelines for donations. Please refer to those guidelines.</i></p> <p>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).</p> <p>Consent to extension of storage should be consistent with consent to use.</p>

Why ACART is reviewing the guidelines

25. 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.
26. In the Donation and Surrogacy Guidelines, gamete donors can vary or withdraw consent only up until an embryo is created.
27. 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.
28. The current provision in the guidelines, that ACART proposes to change, reads:

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]

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.

Table 2: Proposed ACART guidelines (changes from Table 1 underlined)

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	<u>The intending parents (as long as the use is consistent with any conditions of the original gamete donation).</u>
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)	<p><i>This is a very rare situation now, possibly due to changes in the guidelines for donations. Please refer to those guidelines.</i></p> <p>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).</p> <p>Consent to extension of storage should be consistent with consent to use.</p>



E Amended guidelines and rationale

29. ACART is proposing three main amendments to the informed consent section of the guidelines to clarify the consent requirements where storage involves donated gametes or embryos. These amendments will update the guidelines so that they are consistent with ACART's other published guidelines.
30. These amendments clarify that:
 - a. *consent from any **gamete** donor(s) is not required when applying to extend the storage of an **embryo***
 - b. *consent from any **gamete** donor(s) is required when applying to extend the storage of **gametes***
 - c. *consent from any **embryo** donor(s) is required when applying to extend the storage of an **embryo***
31. ACART also proposes an additional amendment to clarify consent requirements where reproductive material is being stored for the purposes of research:
 - a. *consent from **researcher(s)** named in the ECART ethics approval should be required for extending the storage of reproductive material donated to **research***
32. 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.
33. 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.
34. 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 cannot place new conditions on the use of the embryo. In both cases, 'conditions' on the donation, for example only to be used by the named recipients, or to be used within a certain timeframe, will still apply, as any use must comply with original consents.

35. 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 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.

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

36. ACART proposed 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

37. 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.
38. 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 the Donation and Surrogacy Guidelines that allow 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.
39. 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.
40. 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 the donor has 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.
41. 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 original 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.

42. 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.

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

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

Rationale

44. 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.
45. This proposal upholds the rights and interests of donors, including the tino rangatiratanga of a Māori donor.
46. 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:

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.

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

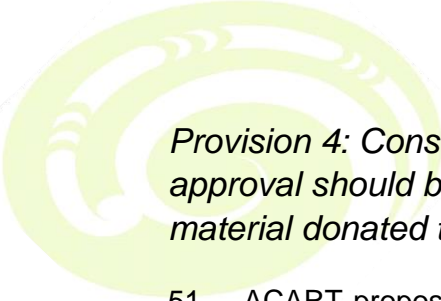
47. ACART proposed that the guidelines include a provision that clearly states that an application to extend the storage of donated embryos should require consent from the embryo donor.

Rationale

48. 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.
49. 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.
50. 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 revised guidelines now allows for these circumstances:

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.



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

51. ACART proposed 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

52. 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. Donors 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.
53. 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 biobank¹ 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.
54. 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.
55. 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

¹ 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.

an ethics committee has approved.² Individual health care institutions have their own policies on the return or disposal of tissue.

56. 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.
57. 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.³ These conditions apply to the return/disposal process as well. The main restriction is that the taonga are under the responsibility of a kaitiaki (protector) 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.
58. The Committee noted that ACART's work to produce new guidelines for human reproductive research could have a bearing on the guidelines for extending storage and the exact wording of the provisions for storing human reproductive materials. That work will be done over the next two to three years.

² Health and Disability Commissioner. 1996. Code of Health and Disability Services Consumers' Rights. URL:(accessed 17 June 2022).

³ 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.

F ACART'S consultation process

59. Under section 36 of the HART Act, ACART can only issue guidelines after it has:
 - a) on the basis of a discussion paper, or outline of the proposed guidelines, given interested parties and members of the public a reasonable opportunity to make submissions, and
 - b) taken submissions into account.
60. Under section 41 of the HART Act, before issuing guidelines or giving advice to the Minister of Health, ACART must consult with:
 - a) any members of the public the Committee considers appropriate
 - b) appropriate government departments and agencies
 - c) any other person or group the Committee considers appropriate.
61. Before issuing guidelines, ACART must also consult the Minister of Health. ACART is using this advice to meet that requirement for consultation.
62. ACART's consultation document was published on 8 July 2022 on the ACART website, along with a press release, on the Ministry's website, prepared by the Ministry's communications team.
63. ACART emailed the consultation document to its comprehensive stakeholder list. ACART's stakeholder list includes all of New Zealand's fertility service providers, the Ethics Committee on Assisted Reproductive Technology (ECART) and other government departments, including the Ministry of Justice (which administers the HART Act). It also includes consumer, religious and ethnic groups, and medical associations. In total, ACART emailed the consultation document to approximately 300 people/groups. It encouraged stakeholders to forward the consultation on to their networks.
64. Submitters could have their say through a digital platform for consultation (Citizen Space) by following a link on the Ministry of Health's website that ACART provided. They could also email a completed feedback form or comments to acart@moh.govt.nz.
65. To meet its obligation to hold public meetings, ACART invited people to request meetings if they wished to make oral submissions — the meetings were open to any interested parties. Where submitters did wish to make oral submissions, ACART invited them to online or in person meetings.
66. Submissions closed on 30 September 2022 and ACART accepted one submission in October 2022 to give the party more time to prepare its submission.

67. Submissions were received from 22 individuals and organisations. Submitters included Donor Conceived Aotearoa, the Auckland Women's Health Council, Fertility New Zealand, ECART, Professional Association for Transgender Health Aotearoa, InterChurch Bioethics Council, Muskaan Care Trust New Zealand, Repromed, New Zealand College of Midwives, Fertility Associates, National Fertility Preservation Working Group, as well as consumers and interested members of the public.
68. ACART received two oral submissions: one from Donor Conceived Aotearoa and one from a consumer.
69. ACART plans to publish the submissions on its website.
70. ACART notes that this consultation and analysis do not purport to represent views in society, but only of submitters.
71. Overall, submitters supported ACART's proposed guidelines. ACART's recommendations and advice to you take their comments into account. A list of submitters is included as Appendix 2. A summary of submissions is included as Appendix 3.



G Matters that ACART has considered

Te Tiriti o Waitangi | The Treaty of Waitangi

72. 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.
73. For more details about ACART's efforts to meet Te Tiriti o Waitangi obligations, see the *Summaries of the regulation of assisted reproduction in New Zealand and the legal, ethical and cultural issues often involved in assisted reproduction*.⁴ This online document sets out ACART's functions and the regulatory and ethical setting in which it operates.

Te Ao Māori

74. 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.
75. 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 extensions (or subsequent uses that comply with their consent).
76. The guidelines acknowledge the person 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.

⁴ Summaries of the regulation of assisted reproduction in New Zealand and the legal, ethical and cultural issues often involved in assisted reproduction | Advisory Committee on Assisted Reproductive Technology (health.govt.nz)

77. 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.
78. 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.
79. 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.
80. 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 the authority remains with them until it is transferred to a womb | whare tamariki of the recipient.

Cultural considerations

81. New Zealand is a culturally and ethnically diverse country, and ACART has taken this 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.
82. 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 (gamete donors) 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.
83. Consent will be provided by the intending parents who plan to use the embryo. ACART considers that gamete donors already have adequate safeguards. If the proposed use of the embryo complies with the conditions the gamete donors set out

in their original consent, then no further authority is necessary in respect of the storage extensions.

Disability perspective

84. 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 protects 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.⁵ Article 23(1)(b) also states that people with disabilities must be provided with the means necessary to enable them to exercise these rights.
85. 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.

⁵ <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-23-respect-for-home-and-the-family.html>



H Ethical analysis

86. ACART must identify and consider ethical issues that arise from assisted reproductive treatment. ACART is guided by its ethical framework,⁶ which incorporates principles of the HART Act and generally accepted ethical principles, to make these ethical deliberations.

Principles of the HART Act

87. ACART's ethical analysis is guided by the principles of the HART Act.⁷ Overall, ACART has not identified any ethical issues that are inconsistent with the health and wellbeing of children; human health, safety and dignity; donation and donor offspring; or the health and wellbeing of women. ACART considers that the amended guidelines are consistent with the ethical principles of the HART Act.

Autonomy

88. ACART noted that, if the donors are not contactable, the guidelines enable ECART to extend the storage if the clinic demonstrates that it made a reasonable attempt to contact the donors and that declining the extension would be unduly harsh on the recipients. ACART settled on its current policy being suitable for this matter as the alternative would be an unjustified barrier to reproductive autonomy of recipients (ie if any donors were uncontactable).

⁶ Ethical framework for ACART (2012) <https://acart.health.govt.nz/publications-and-resources/publications/ethical-framework-for-acart/>

⁷ Section 4 HART Act 2004.

I ACART'S recommendations

89. Following analysis of the submissions, ACART believes that there was overall support for the proposed amendments to the Guidelines for Extending the Storage Period of Gametes and Embryos. Following this consultation with you, ACART intends to publish the amended guidelines later in 2023.
90. Alongside ACART's proposals, submitters were invited to comment on any other matters related to the storage of gametes and embryos. Responses in this area have identified a number of issues with the wider regulatory regime which ACART believes needs further investigation. This includes matters relating to the age of donors (particularly with regards a donor conceived child's ability to connect with their biological parents), and whether a "one size fits all" approach to storage continues to be appropriate. Some solutions to these issues would require amendment to the HART Act.
91. ACART intends to investigate these matters further. However, these issues involve complex ethical and legal problems that will require significant investigation including liaison with human rights experts, legal experts, as well as clinic and consumer perspectives. ACART will continue this work throughout 2023 and 2024.



J Next steps

92. ACART have given a copy of the advice to the Ministry of Health in case you decide to seek parallel advice.
93. ACART's Chair is available to discuss the advice with you, if you wish.
94. ACART plans to publish this advice and the amended guidelines on ACART's website in 2023.
95. ACART is investigating further issues around the storage of gametes and embryos that might require a change to the HART Act.

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: <ul style="list-style-type: none">• 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	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	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



Appendix 1: List of submitters

Submissions received

Through Citizenspace (online)

Sorted alphabetically by (1) name of organisation then (2) individuals by surname.

1. Auckland Women's Health Council. (Contact not stated.)
2. Fertility New Zealand. (Contact is Hannah Owenson).
3. InterChurch Bioethics Council. (Contact is Joy McIntosh.)
4. Muskaan Care Trust New Zealand. (Contact is Monica Sharma.)
5. Brennen Clyde. Consumer
6. Myfanwy Fanning-Randall. Donor Conceived Person
7. Jessica Hammond. Not stated
8. Sarah Hunter. Member of the National Fertility Preservation Working Group.
9. Emily Just. Member of Public
10. Laura Mackay. Consumer and gamete donor
11. Jeanette MacKenzie. Health professional
12. Robyn Minns. Researcher
13. Victoria Troake. Member of the public
14. Grace Troake. Member of the public
15. Zoe (no surname given). Member of the public
16. Unnamed member of public

By e-mail / written document

1. Donor Conceived Aotearoa. (Contact is Emma Chan)
2. Ethics Committee on Assisted Reproductive Technology. (Contact is the ECART Secretariat)
3. Fertility Associates. (Contact is Suzanne Sherwin)
4. New Zealand College of Midwives. (Contact is Carol Bartle)
5. Professional Association for Transgender Health Aotearoa. (Contact is Moira Clunie)
6. Repromed. (Contact is Debbie Blake)



Appendix 2: Summary of submissions

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?

There were 21 responses to this question.

Option	Total	Percent
Yes	18 (of 21)	86%
No	3 (of 21)	14%
Not answered	1 (of 22)	5%

Submitters who supported this proposal gave various reasons, including:

- the authority over the embryos transfers to the recipients once the gametes have been used to create embryos
- not having to locate gamete donors for additional approval would make it easier procedurally for clinics, particularly when the gametes have been donated earlier
- having authority for extensions would give the recipients a better experience as it would allow them more time to complete their treatment at their own pace
- consent should not be required if the intended use for the embryos is consistent with the conditions of the original gamete donation.

Three of the submitters said that they agreed with the proposal on the condition that gamete donor(s) are well informed of: 1. The ‘point of no return’ where they are no longer able to withdraw their consent when a gamete is fused with another to form an embryo; and 2. That the recipients will not need their consent to extend the storage of the embryos beyond 10 years.

One submitter recommended a ‘grand-fathering’ in the new policy; that is, the embryos with gametes donated prior to the policy change should continue to require consent from the gamete donor(s) for an extension.

Of the submitters who opposed the proposal:

- one did so on the basis that the current gamete donor(s) have been informed that their donated material would have to be used within the 10 years
- the other two did so due to the potential repercussions to the donor conceived person.

One of these submitters opposed the proposal in a couple of circumstances. First, where the purpose of extended storage would be for the creation of a pregnancy in a family who have not yet had any children using the donated gametes. Second, where the purpose would be for on-donation to another family. However, they would support it if the purpose

was to achieve a pregnancy for a full genetic sibling in the family or for compassionate reasons because the family did not want to make a decision about discarding the embryos.

The submitter also suggested that the age of the donor(s) should be considered for extensions to ensure that children born from assisted reproductive technologies have a reasonable chance of finding their donor parent(s) alive later. They suggested ACART should set an upper age limit for gamete donor(s) to protect the wellbeing of the donor conceived person.

Summary

Submitters generally agreed with this proposal. The opposing submissions raised some potentially important points for consideration. Specifically, if the purpose for extending storage should influence whether donor consent is required, as well as consideration of the age of the gamete donor(s).

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?

There were 20 responses to this question.

Option	Total	Percent
Yes	15 (of 20)	75%
No	5 (of 20)	25%
Not answered	2 (of 22)	9%

Of the submitters who opposed this proposal:

- three submitters did not think additional consent would be needed so long as the gamete donor(s) had been informed of this possibility at the time of donation. One suggested that whether extensions would be permitted could be decided on at the time of donation based on the likely ability of the donor(s) to be available for resulting donor conceived children in the future
- one submitter noted the current shortage of donor sperm and that compliance on extending storage could result in the reduction of supply
- one noted that donors can withdraw their consent at any time before their gametes are used.

Reasons provided by those who supported the proposal included:

- as the donation material has not changed form, the donor(s) should be consulted to ensure all parties are still on the same page
- extending storage potentially increases the time range of donors being genetic parents and the relationship responsibility this brings needs to be considered.

One submitter said that though they supported the proposal, they did not agree that there should be 'room for relaxing this requirement where it is not possible to contact the gamete

provider to obtain their consent'. They noted that important information would be missed if a gamete donor was uncontactable, including accurate identifying information to register the donor conceived person on the HART register, up-to-date medical history, information about the donor's age, and whether they have passed away. These factors could impact the wellbeing of the donor conceived child.

Summary

Submitters were generally in favour of this proposal. One submitter noted concerns about the negative implications to the donor conceived child if there was 'room for relaxing the requirement where it is not possible to contact the gamete donor'.

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?

There were 20 responses to this question.

Option	Total	Percent
Yes	16 (of 20)	80%
No	4 (of 20)	20%
Not answered	2 (of 22)	9%

Submitters who supported the proposal gave various reasons, including:

- as the donation material has not changed form, the consent of the embryo donor(s) should still be required (x1)
- the embryo donor(s) should be consulted to ensure all parties are still on the same page (x3).

One submitter gave the same response as in Q2: they agreed with the proposal but not with the suggestion to 'revise the guidelines to be more flexible so that ECART can authorise extension of storage in cases when embryo donors cannot be contacted. This is for the same reason that uncontactable embryo donors cannot provides details such as an up-to-date medical history, and that this information is important to protect the health and wellbeing of the donor conceived child.

Reasons provided by those who opposed the proposal included:

- that the embryo donation has already gone through detailed ECART approval (x1)
- consent should not be needed to extend embryo storage beyond 10 years, so long as the embryo donor(s) are informed of this possibility at the time of donation (x2) and unless the donor(s) specifically request that contact is made for the purposes of seeking their consent (x1).

One submitter suggested that the extension should apply to the embryos rather than the applicants so that if the recipients return the embryos to the donor, the donors can continue storage if they choose.



Summary

Submitters were generally in favour of this proposal and many of those who opposed it were comfortable with additional consent not being required so long as any embryo donor(s) were clearly informed of this possibility at the time of donation.

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?

There were 20 responses to this question.

Option	Total	Percent
Yes	15 (of 20)	75%
No	5 (of 20)	25%
Not answered	2 (of 22)	9%

Most of those who disagreed with this proposal did not provide a reason. The one reason provided was that the donor(s) of the material should still be involved in decisions rather than a researcher/third party.

Of those who supported the proposal:

- two agreed with the proposal subject to the donors being informed at the time of donation
- one noted that this is a more efficient process and that future guidelines should allow for donor consent to be withdrawn
- one said that the research material comes under the kaitiaki of the researcher when it is donated for research.

One submitter agreed with this proposal but noted that it was not clear from the consultation document how changes to research guidelines would affect consent. For example, if donors had consented to donation when certain research was prohibited and subsequently this research became allowed.

One submitter suggested that this question should be considered in the context of ACART's current work on the Human Reproductive Research Guidelines.

Summary

More submitters favoured this proposal than did not; however, there was some ambiguity in the reasons given due to different interpretations of the question. Comments indicated that some submitters did not read or fully understand the additional information provided.

Question 5

Should storage and storage extensions have a time limit?

There were 20 responses to this question.

Option	Total	Percent
Yes	8 (of 20)	40%
No	12 (of 20)	60%
Not answered	2 (of 22)	9%

Submitters who thought there should be a time limit gave various reasons, including:

- unlimited extension may have intergenerational effects on children, particularly in the case of donated gametes and may reduce the ability to meaningfully engage with the donor if desired (x3)
- a timeframe enables the discard of material where the owner has stopped paying and ensures that clinics do not accumulate unwanted material (x1)
- decisions to store reproductive material are made for specific reasons and in a certain context. Having time limits allows for any changes in one's circumstances to be taken into consideration and for people to remain cognisant of their decision (x2)
- the formal ECART process allows for the interests of the future child and their family to be taken into consideration (x1).

Eight submitters (four who agreed with a time limit and four who did not) noted that there should be a longer initial time period for individuals storing reproductive material at a young age for the purpose of fertility preservation. For example, children storing material prior to cancer treatment or transgender people accessing fertility preservation services at a young age.

Submitters who thought there should not be a time limit gave various reasons, including:

- storage of reproductive material is an emotional and sensitive issue. Time allows for well-informed decisions and to remove the pressure of making decisions during uncontrollable circumstances such as a global pandemic (x2)
- the ten-year limit is very restrictive for patients who store their samples overseas where there is no time limit and subsequently want to import them into New Zealand. This poses the risk that samples may be expired before they get to New Zealand (x2)
- placing a limit on someone's bodily autonomy is ridiculous (x1).

One submitter noted that although there should not be a time limit on storage of reproductive materials, any longer storage and use must be weighed with medical outcomes and risks for the resulting child.

Summary

There were mixed responses to this question, with more opposing a storage time limit. However, one area where there was more agreement was in extending the initial time period for tissue stored from very young people.

Question 6

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

There were 19 responses to this question.

Option	Total	Percent
Yes	12 (of 19)	63%
No	7 (of 19)	37%
Not answered	3 (of 22)	14%

Of the submitters who opposed this option, three commented on the potential conflict of interests that clinics would have (as they would be both holders of the material (with a profit motive) and decision makers about holding it). One noted the benefits of having distance between the service provider and the decision maker in matters with significant emotional components.

One submitter said that clinics could consider the straightforward requests and that ECART should consider the more complex cases.

Submitters who supported this option gave various reasons, including:

- they could only do so within agreed criteria (three submitters made this point)
- clinics have good knowledge of the people involved and therefore are well placed to decide on extensions (this respondent appears to suggest that ECART doesn't understand the situation of the people who have the material stored).

One submitter who supported the decision also said that the decision should be up to the donors: the submitter's reason contradicts her statement of support for the option.

Summary

More submitters supported than opposed the option. However, the reasons given for opposing the option were compelling as they addressed important matters including the risks of conflicts of interest and the need for decisions about ethical matters to be made independently from the service providers.

Question 7

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

There were 14 responses to this question.

Submitters gave a range of responses, both supporting and opposing the idea.

Submitters who believe that ECART should not decline applications to extend storage said:

- it is not ECART’s place to do so
- it is not ECART’s place to do so because the material does not belong to ECART
- donors, or immediate families of deceased donors, not ECART, should have the authority.

Submitters who support ECART being able to decline applications to extend storage said applications could be declined if/when:

- a gamete donor removes consent (x4)
- clinical safety criteria indicate that declining the application is appropriate (x4)
- any donors have requested a limit on the duration of the storage of their material
- there is a disagreement between parties
- the donor has died without giving consent for use posthumously
- not all relevant parties can be contacted.

One submitter said ECART could decline applications when “the person is deceased” but did not state which person.

Summary

More submitters supported than opposed the idea.

Although ACART did not ask whether ECART should have the authority to approve or decline the storage of people’s material, some submitters opposed ECART having that authority. These submitters focused on the individuals’ rights to decide what is in their best interests.

Submitters who support ECART being able to decline applications to extend storage noted in several instances there will be clear reasons for declining applications.

Question 8

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

There were 19 responses to this question.

Option	Total	Percent
Yes	16	84%
No	3	16%
Not answered	3 (of 22)	14%

Of the three submitters who opposed this idea:

- one said there would be little need or value in doing so
- one said it should not be possible but qualified their opposition saying such extensions could be permitted only if the donor or family consent
- the third did not explain.

Of the submitters who supported this idea:

- two agreed that material should be able to be stored for unspecified future use but did not agree that ECART should make decisions about the duration of storage
- three said that consumers might wish to do so, and that the research itself would still need to be approved in a separate process
- one noted the limited supply of material and that it would therefore make sense to have it available.

Question 9

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

1. There were 13 responses to this question (of 22 total submitters).
2. Priority needs to be on the potential people created. Donor-conceived people deserve the right to know their genetic family. (x2)
3. People who store tissue at a young age must have the opportunity to extend the storage of their material as they are initially too young to use the tissue, or even to know their fertility status. (x3)
4. There should never be a time limit: it is important to allow time, so that decisions will not be rushed into. Posthumous reproduction is a very sensitive situation that has a grieving person(s) involved and to force any decisions or even destroy any material due to time, is cruel. It is also not the place of a third party eg ECART to make this decision. Any decision regarding the timing of storage of material from a person who has passed away, should be the family's choice.
5. The reason for the 10 year limit is that when the HART Act was introduced, thawing material for use was less developed and held less chance for successful treatment. This is no longer the case and the limit needs to be reviewed.
6. The 10-year initial storage period is too short. Even with a relatively straightforward journey, it may take recipients more than 10 years to complete their family. I expect it would reduce ECART's workload and save recipients unnecessary stress to extend the initial storage period by 5 to 10 years.
7. People must have plans for using gametes and embryos, including an end point of use or discarding — therefore, there must be a storage end date (which may be updated).

8. Extension of storage should not be prohibited due to a patient or clinic error or oversight (e.g. a patient applying a few days late). There should be an extension period available for exceptional circumstances e.g. procedural error.
9. Clear guidance should be provided on whether these changes (in this consultation) are retrospective.
10. We would like confirmation that the extension for storage is on the material, and not restricted to the recipient of the extension. At present our process is to discard donated material that could be passed to other patients when the recipient has stopped reserving extended material because the extension is in the recipient's name.
11. We request that clinics be able to request an extension for unallocated donor sperm so it can be allocated to new recipients when we are ready and thereby maximise use of the limited resources of donor sperm. This will help reduce waiting times because currently we discard donor sperm that has expired, even though the maximum allowed family allocation has not been reached.
12. Donors' contact details and medical history should be regularly updated. DCPs need these details, for knowing genetic parents and knowing about heritable medical matters. Removing the need for donor consent for extending storage should not be based on the lack of adequate record keeping by fertility clinics.
13. Using donated gametes, or embryos created from those gametes (for reproduction), when the donors can no longer be contacted is unethical. Consent cannot be assumed if a donor cannot be contacted. An exemption to this rule would be to create a 100% genetic sibling to an existing child.
14. Donors and intending parents need to consider the needs of the DCP. Posthumous reproduction is unethical and does not protect the health and wellbeing of DCP. An exemption to this rule would be to create a 100% genetic sibling to an existing child.
15. The cut-off for extending storage needs to be changed so that people can apply for an extension after the storage period ends.



Appendix 3: Guidelines for extending the storage of gametes and embryos
