Supplementary Advice for the Guidelines for the Posthumous Use of Gametes, Reproductive Tissue and Embryos

A. Purpose of this advice

1. This document should be read alongside the *Guidelines for the Posthumous Use of Gametes, Reproductive Tissue and Embryos* (the Guidelines). The purpose of this advice is to ensure that:
   - it is clear why the Advisory Committee on Assisted Reproductive Technology (ACART) has revised the Guidelines in the way that it has
   - all parties understand how the consent process in the guidelines works
   - the Ethics Committee on Assisted Reproductive Technology (ECART) understands how to apply the guidelines as ACART intended.

B. Why ACART has revised the guidelines

2. ACART must review its guidelines regularly, as required under section 35(1)(a) of the Human Assisted Reproductive Technology Act (the HART Act).

3. The previous guidelines did not account for recent scientific and technological developments. The previous *Guidelines for the Storage, Use, and Disposal of Sperm from a Deceased Man* had been published, by the National Ethics Committee on Assisted Human Reproduction (NECAHR), in 2000, before the HART Act was introduced and subsequently adopted by ACART.

4. These new guidelines are broader in scope, and provide for the use of eggs, testicular or ovarian tissue and embryos stored before a person's death.

5. The guidelines enable people to apply to ECART to use gametes or reproductive tissue, from a deceased person, that was taken either when the person was alive or after that person's death. The guidelines also enable people to apply to ECART to use embryos that were stored before the now deceased died.

6. ACART's new guidelines also provide specifically for the management of certain risks. These risks include:
   a) the resulting child/ren will never have the opportunity to meet one or both of the genetic parents
   b) that there could be disagreement within a family/whānau about the proposed fertility treatment
   c) uncertainty about the legal status of any resulting child or implications for inheritance rights, the child's birth certificate and other family relationships.

C. ECART approval is currently required for some posthumous uses of eggs, sperm or embryos

7. The posthumous use of some gametes, reproductive tissue and embryos are **not** currently listed as "established procedures" (EPs) in the HART Order. Those that are not EPs are "assisted reproductive procedures" and must go to ECART for consideration, in accordance with the Guidelines.

8. Clinics consider the posthumous use of embryos to be an EP for women if consent was given prior to the death of the male partner. The posthumous use of sperm is also an EP if the deceased had consented to the specific, posthumous use before his death.

9. The requirements for the use of gametes, tissue or embryos could differ depending on whether they were collected or created before or after the person's death.

Some cases of posthumous use could become established procedures in the future…

10. ACART also believes that some situations of posthumous use may not necessarily require ECART approval. The most likely scenario is where the deceased had already stored their gametes, reproductive tissue or embryos, and had provided clear consent that a specific person could use these in the event of their death.

11. For example, when sperm or eggs are collected and stored by a fertility clinic while a person is alive, it is standard practice in New Zealand for fertility clinics, at the time of storage, to record what that person wants to happen to their sperm/eggs if they die. Some people may agree that their partner, or another named person, may use their stored sperm/eggs to have a child, in the event of their death. This consent is usually collected in writing as part of the clinical consent form.

… but a change to the HART Order would first be required

12. For cases to be established procedures, they will need to be specified as such in the HART Order. Until the HART Order is changed, some cases of posthumous use will continue to be assisted reproductive procedures, and so will need to be considered by ECART.

When retrieval is after death, use must be subject to ECART

13. ACART believes that all instances of posthumous use where the gametes or reproductive tissue have been **retrieved** from a person **after** they have died should require ECART approval. Posthumous retrieval is discussed in more detail in section F, below.

D. Consent

ECART can approve an application for posthumous use only when there is evidence that the deceased provided specific consent to posthumous use by a specific person

14. The Guidelines let ECART approve applications for the posthumous use of gametes, reproductive tissue or embryos when there is clear evidence of consent to this use from the deceased. This consent must specifically refer to posthumous use (rather than use in general), and it must identify the specific person(s) who can use the gametes, reproductive tissue or embryos after their death.

Consent to posthumous use must be informed consent

15. To be consistent with the HART Act, the deceased must have made an informed choice and given informed consent to the posthumous use of their gametes, reproductive tissue or stored embryos

16. The consent needs to be clear that the person understood that they were consenting to their gametes, tissue or embryos being used to enable a pregnancy (or for research, where allowed) **after** their death. If a couple had begun fertility treatment (such as through IVF) but one partner died, the fact that they intended to have a baby together is **not** evidence of consent to have a baby after the death of one parent. Clinics can clarify this intent through consent forms and by discussing what would happen if one were to die.

17. In some cases, after someone had consented to their gametes being used to make a baby after their death, their circumstances could have changed so much that there is doubt about whether the earlier consent is really what the person's final wishes would have been. For example, the person might have separated from their partner of that time and/or entered a relationship with someone else. ECART must be satisfied that the now deceased person is likely to have intended the consent to apply to the present circumstances and the proposed fertility procedure.

What is acceptable evidence of informed consent?

18. Evidence of consent can take many forms. Inferred consent based on discussions and behaviour are not usually adequate, as it will be difficult to demonstrate that the deceased had specifically considered having a child after their death. Where the deceased person hadn't recorded their consent, it is unlikely that there will be adequate evidence and ECART might not approve the application.

19. Evidence of consent is best where it is written down, such as in a consent form at a fertility clinic, in a will, or in a letter or diary entry. Alternatively, it could be spoken or oral consent that was witnessed by an independent person (ie someone without a vested interest; eg not the intending parent or their immediate family).

20. An example of witnessed oral consent could be in a hospital where the person who is dying advises a medical professional attending them that they want their gametes, or reproductive tissue, extracted after death so that their partner (or other identified

person) can have their children. This conversation should be recorded in medical notes by the attending medical professional so there is adequate evidence for ECART.

21. Oral consent can also be provided in a sound or video recording. ECART will need to be sure the sound or written record is bona fide so the intending parent might need to produce further evidence of that.

22. These examples are intended to give an idea of how robust the evidence of consent should be and are not an exhaustive list. ECART may consider any form of consent in making its decisions.

E. Specific use by a specific person

23. The Guidelines note that the HART Order uses the phrase 'specific use' for cases of reproduction involving a deceased person. For these Guidelines, ACART proposes that 'specific use' means that the deceased person gave informed consent for a specific person(s) to use their gametes, reproductive tissue or embryos after their death, for the specific person(s) reproductive purposes.

What is a specific use?

24. The posthumous use of gametes, reproductive tissue and embryos is limited to the reproductive purposes of the specific person(s), but may include such reproduction with the assistance of a surrogate.

25. The definition of 'specific use' is particularly important to consider for situations where a surrogate might be needed, because the birth mother would be the legal parent until adoption by the specific person(s)(the intending parents).[1]

26. Any gametes, reproductive tissue or embryos left to a specific person(s) may only be used for research if this was specifically consented to by the deceased.

27. Gametes, reproductive tissue and embryos may not be on-donated (or re-donated) by the specific person(s).

Who is a specific person?

28. For gametes, reproductive tissue or stored embryos to be used after a person's death, the Guidelines require that ECART is satisfied that the consent either:
    a) specifically names the person(s) who can use the gametes, reproductive tissue or embryos posthumously, or

    b) refers to this person(s) through the nature of their relationship to the deceased (for example, their sister(s), partner at the time, etc), or

    c) refers to a type of person by the nature of the procedure eg a surrogate for the (named) intending parents.

29. The gametes, reproductive tissue or embryos must be used by the specific person(s) (or with a surrogate) to create a child that the specific people will parent.

30. If the baby is to be gestated by a surrogate, then the specific person(s), who will be the intending parent(s), **must** have been named or referred to by the now deceased in their consent.

31. This provision lets a surviving partner or other specified individual use the gametes, reproductive tissue or embryos to have a child to parent. The case might involve a new partner or surrogate, and this would be acceptable if the deceased had consented to such involvement.

32. Whatever the circumstances, the deceased must have been clear about the specifics of the posthumous use of their gametes, reproductive tissue or embryos.

[1] Under the proposed changes to surrogacy law, this might be amended.

33. The guidelines do not require the specific person to be named. That is because naming a particular person in all cases is impractical and cannot take into account all the situations in which gametes, reproductive tissue or embryos might be used. For example, they may be used by a surrogate, a new partner, or the siblings or siblings-in-law of the deceased. The guidelines are worded in such a way to ensure that one's apparent consent is not invalidated by the requirements for specificity of consent.

34. By requiring the consent to use to be specific, ACART does not intend to fully close an exception for **clinic** sperm donors.[2] However, ACART's view is that a deceased donor's stored gametes can only be used by a family or person who has already had a child using the donor's gametes, to create a genetic sibling. The deceased donor must have also consented to the use of their stored gametes posthumously.

[2] "Clinic" donors are those donors whose gametes could be used by a number of different recipients who weren't known to the donor at the time of donation. The other type of donor is a "known" donor, who donates to a specific recipient or recipients that they already know at the time of their donation.

F. Posthumous retrieval

The guidelines do not authorise ECART to approve the retrieval of eggs, sperm or reproductive tissue after death

35. Provided the consent and all other requirements are met, the Guidelines let ECART authorise the **use** of gametes, or reproductive tissue which has been **retrieved** (collected) posthumously. However, the guidelines do not let ECART authorise the posthumous retrieval of sperm/eggs or testicular or ovarian tissue.

36. The HART Act does not discuss ECART's role in approving posthumous retrieval, and ACART does not believe that it can issue guidelines which would let ECART do so. ACART also believes that it would be impractical for ECART to approve applications for posthumous retrieval, due to the urgency that such applications would need to be heard.

37. If ACART is correct about the law, any posthumous retrieval of sperm, eggs or ovarian or testicular tissue would need to be approved by the High Court. ACART believes that anyone retrieving tissue or gametes without a Court Order may be in breach of the HART Act if it is an assisted reproductive procedure, or section 150 of the Crimes Act (1961).

38. Authorisation of retrieval by the High Court would enable the gametes or reproductive tissue to be retrieved before the gametes or tissue dies — ie while they were still viable for subsequent use. For example, sperm needs to be retrieved from a dead body before 72 hours, otherwise all of the sperm may be dead. Once the gametes or reproductive tissue is stored, ECART could then consider whether to allow the subsequent use of the gametes or reproductive tissue. This is consistent with Justice Heath's view (stated in the case Lee v Long) that the High Court can authorise the retrieval and storage of sperm/eggs or testicular or ovarian tissue, with ECART later considering the use of such material under guidelines issued by ACART.

39. It is unlikely that the High Court would allow retrieval when there is no chance of future use: for example, due to lack of proof that the now deceased person had consented, and the use therefore not meeting the requirements of the Guidelines. Likewise, authorisation of retrieval by the High Court will not necessarily mean use will later be permitted, as that is a decision to be made by ECART, in accordance with the Guidelines.

G. Research

40. Someone can consent to the posthumous use of their gametes, reproductive tissue or embryos for research (embryos can only be used in research if they are not viable, and so in practice can only be used in non-clinical research). For ECART to approve any such use, it must also be consistent with the current research guidelines.

H. Children

41. Someone whose gametes or reproductive tissue were collected when they were a minor (under age 16) cannot consent to someone else using their gametes in the event of their death (due to Section 12 of the Act). If the Act were to be amended, there may be a possibility that the child could consent after age 16 to someone else using their gametes, including posthumously.

I. Glossary

42. This Glossary is intended to support this document, and should not be relied on as a legal interpretation of the terms listed.

Advisory Committee on Assisted Reproductive Technology (ACART)	The Advisory Committee established under New Zealand's Human Assisted Reproductive Technology Act 2004. Members are appointed by the Minister of Health. ACART's website is acart.health.govt.nz.
Assisted reproductive procedure	The Human Assisted Reproductive Technology Act 2004 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* human embryo, or • the implantation into a human being of human gametes or human embryos.
Clinical research	Research including people who are undergoing clinical treatment. Includes clinical trials, and may include quality improvement or laboratory validation processes.
Consent	Agreeing or asking something to be done, knowing all the relevant factors so they are able to make a clear decision on the matter (also called 'informed consent').
Deceased	Dead.
Disposal	Throwing away (done in a secure way to avoid biological hazard).
Donated embryo	Means an *in vitro* human embryo that is donated for reproductive purposes.
Donor	A person whose gametes or embryos are given to another person for use in assisted reproduction or research. See s 5 of the HART Act. Note that the legal definition under the HART Act means that a person who gives a gamete to his or her partner is not considered a donor.
Donor offspring	Children born from assisted reproduction in which a donor has been involved.
Embryo	Includes a zygote and a cell or a group of cells that has the capacity to develop into an individual; but does not include stem cells derived from an embryo.
Established procedure	'Permitted' procedures. Established procedures are declared in the Human Assisted Reproductive Order 2005 (HART Order), and do not require ECART review and approval. The Minister of Health is responsible for the HART Order.
Ethics Committee on Assisted Reproductive Technology (ECART)	The Ethics Committee established under New Zealand's Human Assisted Reproductive Technology Act 2004. ECART reviews and decides case by case applications to undertake assisted reproductive procedures, human reproductive research and to extend the statutory storage period of gametes and embryos. Members are appointed by the Minister of Health. ECART's website is ecart.health.govt.nz.
Fertility services provider	A fertility clinic.
Fertility Services Standard	A standard issued under the Health and Disability Services (Safety) Act 2001 that sets out the safety and quality measures that all New Zealand fertility services providers must meet. This standard came into force in 2009 and was superseded by the "Ngā paerewa Health and disability services standard" in 2021.

Gamete	An egg or sperm, whether mature or not, or any other cell (whether naturally occurring or artificially formed or modified) that (i) contains only one copy of all or most chromosomes and (ii) is capable of being used for reproductive purposes.
Gestate	Carry a fetus in the womb.
Hapū	Sub-tribe or group of related families / whānau.
Human Assisted Reproductive Technology Act 2004 (HART Act 2004)	New Zealand's human assisted reproductive technology legislation, under which ACART and ECART were established. The Minister of Justice is responsible for the HART Act.
Human Assisted Reproductive Technology research (HART research)	Any research that uses human gametes or embryos. The term 'use' includes in clinical research, where the research is studying any aspect of clinical fertility treatment. For clarity, this does not include synthetic 'gametes' or 'embryo-like organoids', unless they are intended for transfer to the uterus and capable of developing into a fetus.
Informed consent	A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.
***In-vitro* fertilisation (IVF)**	The uniting of egg and sperm outside the body (in the laboratory).
Posthumous	After death.
Reproductive tissue	Reproductive tissue is any tissue (ovarian or testicular) that holds sperm and eggs (can be used in reproduction).
Third party assistance	Assisted reproductive procedures that require a party other than intended parents to contribute to family formation and where a fertility services provider is involved.
Training	In the context of this paper, training is the process by which relevant staff or researchers learn about the techniques and equipment, and theories relevant to those techniques and equipment, used in a fertility clinic or a laboratory.
Whakapapa	Genealogy, ancestral history, descent.
Whānau	Family group. In the modern context, the term is sometimes used to include friends who may not have any genetic ties to other members.