



Associate Minister of Health

Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures

3 October 2024

These Cabinet and briefing documents have been proactively released by the Ministry of Health on behalf of Hon Casey Costello, Associate Minister of Health.

The Cabinet paper seeks Cabinet's agreement to amend the Human Assisted Reproductive Technology Order 2005 (the HART Order) to make certain procedures 'established procedures', meaning they can be performed routinely, without case-by-case ethical approval.

Title of Cabinet paper:

- Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures

Title of Cabinet minutes:

- Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures (SOU-24-MIN-0086)
- Report of the Cabinet Social Outcomes Committee: Period Ended 2 August 2024 (CAB-24-MIN-0280)

Title of briefing:

- Recommendations to amend the Human Assisted Reproductive Technology Order 2005 (H2024039493)

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Redaction codes:

- Out of scope of this proactive release.
- S 9(2)(a) to protect the privacy of natural persons.



Cabinet

Minute of Decision

This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.

Report of the Cabinet Social Outcomes Committee: Period Ended 2 August 2024

On 5 August 2024, Cabinet made the following decisions on the work of the Cabinet Social Outcomes Committee for the period ended 2 August 2024:

Out of scope

SOU-24-MIN-0086

Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures
Portfolio: Associate Health (Hon Casey Costello)

CONFIRMED

Rachel Hayward
Secretary of the Cabinet



Cabinet Social Outcomes Committee

Minute of Decision

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Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures

Portfolio Associate Health (Hon Casey Costello)

On 31 July 2024, the Cabinet Social Outcomes Committee:

Background

- 1 **noted** that as part of its statutory role, the Advisory Committee on Assisted Reproductive Technology (ACART) has advised the Associate Minister of Health (Hon Casey Costello) (the Associate Minister) as to which procedures should be declared established procedures, under the Human Assisted Reproductive Technology Act 2004 (the HART Act), if certain conditions are met;
- 2 **noted** that declaring a procedure an established procedure means it can be performed routinely during fertility treatment without case-by-case ethics approval, under certain conditions, if specified;
- 3 **noted** that actioning each of the policy proposals in the submission under SOU-24-SUB-0086 will require an amendment to the Human Assisted Reproductive Technology Order 2005 (the HART Order), by Order in Council;

Testicular tissue cryopreservation

- 4 **noted** that testicular tissue cryopreservation is a simple and routinely used procedure for male infertility to preserve biopsy testicular tissue for later extraction of sperm;
- 5 **agreed** that the HART Order be amended to declare testicular tissue cryopreservation to be an established procedure;

Embryo donation

- 6 **noted** that embryo donation is an arrangement where a person or couple gives an embryo to another person or couple, and all arrangements currently undergo ethical review;
- 7 **agreed** that the HART Order be amended to provide that, where a person is using an embryo created in a previous relationship, and their previous partner has consented to the use of the embryo in this context, the procedures associated with embryo donation are established procedures;

- 8 **noted** that all other cases of embryo donation will require Ethics Committee on Assisted Reproductive Technology (ECART) approval to be performed;

Posthumous reproduction

- 9 **noted** that posthumous reproduction is very rare, however individual cases have highlighted gaps in the law;
- 10 **agreed** that the HART Order be amended to provide that posthumous use of sperm, eggs, and reproductive tissue, retrieved before death, and stored embryos, is an established procedure if the deceased gave specific consent to the posthumous use;
- 11 **noted** that other forms of posthumous reproduction will not be able to take place without ECART approval (or High Court authorisation);
- 12 **authorised** the Associate Minister to issue drafting instructions to the Parliamentary Counsel Office to give effect to the decisions in paragraphs 5, 7, and 10.

Jenny Vickers
Committee Secretary

Present:

Hon David Seymour
Hon Dr Shane Reti
Hon Erica Stanford
Hon Paul Goldsmith
Hon Louise Upston (Chair)
Hon Mark Mitchell
Hon Tama Potaka
Hon Matt Doocey
Hon Nicole McKee
Hon Casey Costello
Hon Penny Simmonds
Hon Melissa Lee
Hon Chris Penk
Hon Karen Chhour
Hon Nicola Grigg

Officials present from:

Office of the Prime Minister
Officials Committee for SOU
Office of the Deputy Chair of SOU

In Confidence

Office of the Associate Minister of Health
Chair, Cabinet Social Outcomes Committee

Ensuring Appropriate Ethical Review of Assisted Reproductive Procedures

Proposal

- 1 This paper seeks agreement to amend the Human Assisted Reproductive Technology Order 2005 (the HART Order) to make certain procedures 'established procedures', meaning they can be performed routinely, without case-by-case ethical approval.

Relation to government priorities

- 2 The proposed policy changes and clarifications are in line with the Government's aims for regulatory quality and efficiency.

Executive Summary

- 3 Whether ethical approval is needed to perform a fertility procedure depends on whether it is an established procedure, as listed in the HART Order. Established procedures are procedures that are done routinely during fertility treatment and do not require case-by-case ethical approval (for example in vitro fertilisation [IVF]). Updates to the list of established procedures are routinely required as technology changes and ethical issues are clarified.
- 4 As part of their statutory role, the Advisory Committee on Assisted Reproductive Technology (ACART) has advised me as to which procedures should be declared established procedures, and under what conditions. Advice has been issued on the topics of testicular tissue cryopreservation, embryo donation, and posthumous reproduction. I have considered their advice and propose the following amendments to the HART Order.
- 5 Testicular tissue cryopreservation is a simple and routinely used procedure for male infertility to preserve biopsy testicular tissue for later extraction of sperm. It is not explicitly provided for in the HART Order. Therefore, I propose to include testicular tissue cryopreservation in the list of established procedures.
- 6 Embryo donation is an arrangement where a person or couple gives an embryo to another person or couple. All such arrangements currently undergo ethical review. ACART has recommended that ethical approval for embryo donation is unnecessary in cases where a person is using an embryo created in a previous relationship, and their previous partner has consented to the use of the embryo in this context. I agree with this advice and propose amending the HART Order to that effect.

- 7 Posthumous reproduction is very rare, however individual cases have highlighted gaps in the law. ACART has recently revised their guidelines to cover the posthumous use of eggs, sperm, reproductive tissue (testicular and ovarian), and stored embryos. However, they advise that ethical approval should not be required in cases where there is clear evidence that the deceased consented (at retrieval or after) to a specific person using their reproductive material after their death. I accept their advice and propose amending the HART Order to that effect.

Background

- 8 Whether ethical approval is needed to perform a fertility procedure depends on whether it is an established procedure, under the Human Assisted Reproductive Technology Act 2004 (the HART Act). Established procedures are procedures that are done routinely during fertility treatment and are not considered to require case-by-case ethical approval (for example in vitro fertilisation [IVF]). Established procedures are listed in the Human Assisted Reproductive Technology Order 2005 (the HART Order).
- 9 If not identified as an established procedure in the HART Order (or otherwise prohibited), procedures are termed ‘assisted reproductive procedures’ and require case-by-case ethical approval in order to allow them to be performed.
- 10 The HART Order can be amended to declare certain procedures to be established procedures. These changes are made on the basis of advice tendered by the Advisory Committee on Assisted Reproductive Technology (ACART) and are made by Order in Council. Updates to the list of established procedures are routinely required as technology develops and ethical issues are clarified.

ACART and ECART

- 11 ACART is a Ministerial ethics committee established under the HART Act. ACART provides independent advice to the Minister of Health or their delegate, including advice as to which procedures should be declared established procedures, and under what conditions. It also issues guidelines and advice to the Ethics Committee on Assisted Reproductive Technology (ECART). ACART’s advice is based on an assessment of the known health risks and benefits of the procedure or treatment, an ethical analysis, and public consultation.
- 12 ECART assesses applications to perform assisted reproductive procedures. ECART may not approve any procedures for which there are no ACART guidelines or advice. ECART does not charge an application fee, however fertility clinics charge applicants to compile their application.
- 13 ACART has provided me with advice on testicular tissue cryopreservation, embryo donation, and posthumous reproduction, with recommendations on procedures to be made established procedures. I have considered ACART’s advice and now seek Cabinet’s approval to specific amendments to the HART Order. If agreed, the next step will be to issue instructions to the Parliamentary Counsel Office to draft an Order in Council.

Analysis

Summary of proposed amendments

- 14 Based on ACART's advice, I propose that the following are made established procedures, meaning they can be performed without case-by-case ethical approval:
 - 14.1 Testicular tissue cryopreservation.
 - 14.2 The procedures associated with embryo donation, where a person is using an embryo created in a previous relationship and their previous partner has consented to the use of the embryo in this context.
 - 14.3 Posthumous use of sperm, eggs, and reproductive tissue (testicular and ovarian) retrieved before death, and stored embryos, where the deceased gave specific consent to its use in the event of their death.
- 15 Other cases of embryo donation and posthumous reproduction, including where there is unclear or invalid consent, should require case-by-case ethical approval. ACART has recommended further clarifying changes to this effect, which will be considered in drafting.

Testicular tissue cryopreservation

- 16 Testicular tissue cryopreservation is a simple and routinely used procedure for male infertility to preserve biopsy testicular tissue for later extraction of sperm. In fertility treatment, a testicular tissue biopsy can be used to retrieve sperm for people who cannot give a sperm sample through ejaculation. Testicular tissue cryopreservation is also used to preserve the fertility of prepubertal boys undergoing cancer treatment.
- 17 There is some ambiguity as to the legal status of testicular tissue cryopreservation. The HART Order describes sperm cryopreservation as an established procedure but does not explicitly include testicular tissue. To align this with other cryopreservation procedures, including cryopreservation of ovarian tissue, I propose that testicular tissue cryopreservation be listed as an established procedure.
- 18 ACART consulted the public on this proposed amendment. Submitters were generally in favour, with some concern about the *use* of cryopreserved testicular tissue for transplantation becoming an established procedure. As a result, ACART amended its recommendation to state that the *cryopreservation* of testicular tissue, rather than its use, should become an established procedure. Other uses such as transplantation back into the patient after cancer treatment are considered experimental and are not to be included.

Embryo donation

- 19 Embryo donation is when a person or couple gives an embryo formed by IVF to another person or couple. A person or couple can choose to donate their stored embryos to another person or couple, where this is considered the best or only opportunity for the recipient party to have a child.

- 20 ECART currently reviews all applications for embryo donation for reproductive purposes using guidelines issued by ACART under the HART Act. On average, ECART reviews approximately 10 to 15 applications for embryo donation per year, and 2 to 3 applications per year for surrogacy that involve a donated embryo.
- 21 There are ethical risks associated with embryo donation due to the complex genetic and social relationships. Ethical issues include the wellbeing of any resulting children in the context of these complex relationships; and whether offspring can access information about their genetic origins and whakapapa (genealogy, ancestry).
- 22 ACART has advised that ethical approval for embryo donation is unnecessary in cases where the donated embryos will be used by a person for whom they were created, but with a new partner, if the former partner has consented to that specific use. Although the expected case volume is less than one per year on average, this change will increase clarity and enable time and cost savings for ECART and intended parents in this specific scenario.
- 23 Risk may arise if there is a change in circumstance that brings the validity of consent from the previous partner into question, for example a change in relationship status. This risk can be addressed by fertility clinics evaluating whether the consent is informed and valid, and seeking non-binding ethical advice from ECART if they are uncertain.
- 24 ACART consulted the public on this proposal among other proposed changes to their guidelines. Overall, thirteen submitters supported the proposal and three opposed it. Those supporting the proposal stated that because embryo donation is ethically complex, it should be carefully managed. One submitter thought that all embryo donation cases should require ECART approval while another thought that virtually all embryo donation cases could be handled by clinics without needing ECART involvement. ACART concluded that none of the submissions outweighed their rationale.
- 25 I propose that the HART Order be amended to provide that, where a person is using an embryo created in a previous relationship, and their previous partner has consented to the use of the embryo in this context, the procedures associated with embryo donation are established procedures. The amendment will also clarify that ECART approval is needed for all other embryo donations.

Posthumous reproduction

- 26 Posthumous reproduction involves using a person's reproductive tissue (testicular and ovarian), sperm, eggs, or stored embryos after their death. Posthumous reproduction is any reproductive process involving a person who died before the process took place. It raises ethical issues including the wellbeing of any resulting children who will never have the chance to meet their deceased genetic parent; and the significance of consent and whether a person can agree to become a genetic parent after their death.
- 27 Posthumous reproduction is very rare, however individual cases have highlighted gaps in the law. In the case *Re Lee*¹, the New Zealand High Court was asked to authorise the retrieval of sperm from a man who unexpectedly died. This case

¹ *Re Lee (Deceased)* [2017] NZHC 3263.

highlighted shortcomings of the current posthumous reproduction regulations and caused ACART to review and revise their guidelines. ACART guidelines now cover the posthumous use of eggs, sperm, reproductive tissue, and stored embryos.

- 28 While guidelines enable ECART to review posthumous use of reproductive material, ACART has recommended that ethical approval should not be required where there is clear evidence that the deceased gave consent (at retrieval or after) to a specific person using their reproductive material after their death.
- 29 The posthumous use of sperm retrieved before death, where the deceased gave specific consent to its use in the event of their death, is already an established procedure, and fertility clinics have interpreted this to include use of embryos by a female partner if their male partner dies. The proposed amendment would also make the posthumous use of eggs and reproductive tissue retrieved before death, and stored embryos, an established procedure, provided there is clear and specific consent. Although the expected case volume is less than one per year on average, this change will increase clarity and enable time and cost savings in this specific scenario.
- 30 As with embryo donation, risk may arise if there is a change in circumstance that brings the validity of consent from the deceased into question. This risk can be managed by fertility clinics evaluating the consent and seeking non-binding ethical advice from ECART.
- 31 ACART consulted the public on this change alongside proposed changes to their guidelines. Overall, there was a strong consensus that where a deceased person's wishes had been recorded in a legally recognised document, this takes priority, and such cases should not necessarily require ethical review by ECART.
- 32 ACART also heard from submitters who stated that choices, decisions, and rights for Māori (and those of other cultures) do not necessarily operate in an individualistic paradigm but in one that involves recognition of whānau, hapū and iwi relationships and potential impacts on those relationships, including on whakapapa. Along this line of reasoning, a number of submitters talked about the importance of the support of whānau in using gametes posthumously and in carrying out an individual's wishes following their death.
- 33 Other forms of posthumous reproduction will not be able to take place without ethical approval. As individuals must consent to the specific use of their reproductive material at the time of its retrieval or afterwards, any *use* of material retrieved after death will not be an established procedure. Moreover, the *retrieval* of reproductive material from a deceased individual will not be able to occur without ECART approval (or High Court authorisation).
- 34 I propose amending the HART Order to clarify the rules around posthumous use and retrieval of reproductive material as outlined above.

Cost-of-living Implications

- 35 There are no significant cost-of-living implications from this proposal.

Financial Implications

36 There are no additional financial implications associated with this proposal.

Legislative Implications

37 The proposal would require amendments to the Human Assisted Reproductive Technology Order 2005 by an Order in Council. The Parliamentary Counsel Office has been consulted.

Impact Analysis

Regulatory Impact Statement

38 The Ministry for Regulation has determined that the proposed amendments to the HART Order are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that, overall, they have no or only minor impacts on businesses, individuals, and not-for-profit entities.

Climate Implications of Policy Assessment

39 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal.

Population Implications

40 There are no population implications arising from this paper.

Human Rights

41 The proposals in this paper are not inconsistent with the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Use of external Resources

42 No contractors or consultants have been involved in developing this paper.

Consultation

43 In developing this paper, Health New Zealand and the Treasury have been consulted. The Ministry of Justice and the Department of the Prime Minister and Cabinet have been informed.

44 ACART carried out public consultation on their proposed advice, as required under section 41 of the HART Act. Consulted parties included ECART, fertility clinics, religious and ethnic groups, and medical associations.

Communications

45 Communications will be sent to impacted stakeholders if the proposed amendments are approved.

Proactive Release

- 46 This Cabinet paper will be released within 30 business days of decisions being confirmed by Cabinet, with redactions as appropriate under the Official Information Act 1982.

Recommendations

The Associate Minister of Health recommends that the Committee:

- 1 **note** that as part of their statutory role, the Advisory Committee on Assisted Reproductive Technology (ACART) has advised the Associate Minister of Health as to which procedures should be declared established procedures, under the Human Assisted Reproductive Technology Act 2004 (the HART Act), if certain conditions are met
- 2 **note** that declaring a procedure an established procedure means it can be performed routinely during fertility treatment without case-by-case ethics approval, under certain conditions if specified
- 3 **note** that actioning each of these policy proposals will require an amendment to the Human Assisted Reproductive Technology Order 2005 (the HART Order), by Order in Council

Testicular tissue cryopreservation

- 4 **note** that testicular tissue cryopreservation is a simple and routinely used procedure for male infertility to preserve biopsy testicular tissue for later extraction of sperm
- 5 **agree** that that the HART Order be amended to declare testicular tissue cryopreservation to be an established procedure

Embryo donation

- 6 **note** that embryo donation is an arrangement where a person or couple gives an embryo to another person or couple, and all arrangements currently undergo ethical review
- 7 **agree** that the HART Order be amended to provide that, where a person is using an embryo created in a previous relationship, and their previous partner has consented to the use of the embryo in this context, the procedures associated with embryo donation are established procedures
- 8 **note** that that all other cases of embryo donation will require ECART approval to be performed

Posthumous reproduction

- 9 **note** that posthumous reproduction is very rare, however individual cases have highlighted gaps in the law

- 10 **agree** that the HART Order be amended to provide that posthumous use of sperm, eggs, and reproductive tissue, retrieved before death, and stored embryos, is an established procedure if the deceased gave specific consent to the posthumous use
- 11 **note** that other forms of posthumous reproduction will not be able to take place without ECART approval (or High Court authorisation)
- 12 **authorise** the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations 5, 7, and 10.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health

PROACTIVELY RELEASED

Briefing

Recommendations to amend the Human Assisted Reproductive Technology Order 2005

Date due to MO:	N/A	Action required by:	13 May 2024
Security level:	IN CONFIDENCE	Health Report number:	H2024039493
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: <input type="checkbox"/> Māori Health Authority: <input type="checkbox"/>		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, Strategy Policy & Legislation	s 9(2)(a)
Suzanne Townsend	Manager, Regulatory Policy, Strategy Policy & Legislation	s 9(2)(a)

Minister's office to complete:

- | | | |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

Recommendations to amend the Human Assisted Reproductive Technology Order

Security level: IN CONFIDENCE **Date:** 6 May 2024

To: Hon Casey Costello, Associate Minister of Health

Purpose of report

1. This briefing seeks your decisions on six recommendations from the Advisory Committee on Assisted Reproductive Technology (ACART) which have been agreed to by previous Ministers of Health. We are seeking your agreement to amend the Human Assisted Reproductive Technology Order 2005 (the HART Order), to action ACART's recommendations. If you agree, we will provide a draft Cabinet paper proposing the changes.

Summary

2. Assisted reproduction is the process of artificially assisting conception and pregnancy. Examples of assisted reproduction activities include cryopreservation of gametes (eggs and sperm) and embryos, artificial insemination, and in vitro fertilisation (IVF).
3. Assisted reproduction is regulated under the Human Assisted Reproductive Technology Act 2004 (the HART Act) and the Human Assisted Reproductive Technology Order 2005 (the HART Order).
4. The default position under the HART Act is that procedures cannot be performed unless the Ethics Committee on Assisted Reproductive Technology (ECART) has given approval for the particular clinician to perform that procedure. The HART Order lists procedures that are declared to be "established procedures" which do not require ECART approval.
5. ACART issues guidelines for ECART to use when deciding whether to approve applications to perform assisted reproductive procedures. ACART also advises you about which procedures should be established procedures, and under what conditions.
6. Since 2019, ACART has submitted advice containing recommendations to previous Ministers of Health on embryo donation, posthumous reproduction, and the cryopreservation of testicular tissue.
7. From this advice, there are six individual recommendations which previous Ministers of Health have agreed to which have not yet been implemented due to competing priorities. Actioning each of these recommendations would require an amendment to the HART Order, by Order in Council.
8. If you agree with the recommendations in this briefing, we will develop a Cabinet paper seeking agreement to amend the HART Order.

Recommendations

We recommend you:

- a) **Note** that the Advisory Committee on Assisted Reproductive Technology (ACART) has made six recommendations on established procedures which previous Ministers of Health have agreed to which have not yet been implemented..
- b) **Accept** ACART's 2019 recommendation 2 to amend the HART Order to explicitly state that embryo donations are not established procedures, except as per ACART's 2019 recommendation 3. **Yes/No**
- c) **Accept** ACART's 2019 recommendation 3 to amend the HART Order to declare embryo donation as an established procedure if a person is using an embryo created in a previous relationship and their previous partner has consented. **Yes/No**
- d) **Accept** ACART's 2022 recommendation 3A that the HART Order should be amended to clarify that posthumous use of gametes and embryos is an established procedure if the deceased gave specific consent to the posthumous use of the gametes or embryos. **Yes/No**
- e) **Accept** ACART's 2022 recommendation 3B that the HART Order should be amended to clarify that other established procedures only apply to living people. **Yes/No**
- f) **Accept** ACART's 2022 recommendation 4 that the HART Order should be amended to clarify that use of posthumously retrieved gametes and tissue is never an established procedure. **Yes/No**
- g) **Accept** ACART's 2022 recommendation 1 to amend the HART Order to make testicular cryopreservation an established procedure. **Yes/No**
- h) **Agree** that the Ministry of Health should develop a Cabinet paper seeking approval to implement recommendations b) to g) above – where you accept them – to amend the HART Order. **Yes/No**



Maree Roberts
Deputy Director-General
Strategy Policy & Legislation

Date: 3 May 2024

Hon Casey Costello
Associate Minister of Health

Date:

Recommendations to amend the HART Order

Background: Regulation of assisted reproduction

9. Assisted reproduction is the process of artificially assisting conception and pregnancy. Examples of assisted reproduction activities include cryopreservation of gametes (eggs and sperm) and embryos, artificial insemination, and in vitro fertilisation (IVF).
10. Human assisted reproduction in New Zealand is regulated under the Human Assisted Reproductive Technology Act 2004 (the HART Act). One of the purposes of the HART Act is to secure the benefits of assisted reproduction while protecting and promoting the health, safety, dignity, and rights of people involved, especially women and children. The HART Act is administered by the Ministry of Justice, but the responsible Minister (defined in s5) is the Minister of Health.
11. The HART Act sets out the roles of the Advisory Committee on Assisted Reproductive Technology (ACART) and the Ethics Committee on Assisted Reproductive Technology (ECART).
 - a. A key function of ACART is to issue guidelines and advice to ECART, including on ECART decision-making in relation to assisted reproductive procedures, and to keep such guidelines and advice under review. These guidelines are secondary legislation.
 - b. ECART reviews, decides, and monitors applications for assisted reproductive procedures, in accordance with the guidelines issued by ACART.
 - c. ACART is also required to provide you with advice on aspects of, or issues arising, assisted reproductive procedures, including providing advice on any kind of procedure or treatment which should be declared an established procedure.

Categorisation of assisted reproduction activities

12. Under the HART Act, all assisted reproduction activities are either:
 - a. **Prohibited actions**, which are illegal to carry out; or
 - b. **Established procedures**, which can be carried out without approval from ECART; or
 - c. **Assisted reproductive procedures**, which require approval of ECART on a case-by-case basis. An assisted reproductive procedure is any procedure for assisted reproduction which is not defined as a prohibited action or an established procedure.
13. Under the HART Act (s6), the Governor-General may declare a procedure to be an established procedure by Order in Council. Orders in Council are made on the recommendation of the Minister of Health, given after advice tendered by ACART.

The HART Order

14. The Human Assisted Reproductive Technology Order 2005 (the HART Order) lists all established procedures. Most fertility procedures are established procedures: they

include in vitro fertilisation (IVF); collection of sperm and eggs for donation; cryopreservation of sperm, eggs, ovarian tissue, and embryos.

15. The HART Order also sets out some specific situations in which a procedure that is listed as an established procedure is instead an assisted reproductive procedure requiring ECART approval. For example, the use of sperm collected from someone who has since died, and who did not give consent to the specific use of their sperm.
16. The HART Order is administered by the Ministry of Health.

Outstanding ACART recommendations which require an amendment to the HART Order

17. Since 2019, ACART has submitted the following advice containing recommendations to previous Ministers of Health:
 - a. *ACART is about to publish guidelines for gamete and embryo donation and surrogacy.* Submitted to the previous Associate Minister of Health Hon Jenny Salesa in 2019.
 - b. *Advice that testicular tissue cryopreservation should be included within the existing established procedure of sperm cryopreservation.* Submitted to the previous Minister of Health Hon Andrew Little in 2022.
 - c. *ACART is about to publish a new set of guidelines called Guidelines for the Posthumous Use of Gametes, Reproductive Tissue and Stored Embryos.* Submitted to the previous Minister of Health Hon Andrew Little in 2022.
18. From this advice, there are six individual recommendations which previous Ministers have agreed to which have not yet been implemented due to competing priorities. Actioning each of these recommendations would require an amendment to the HART Order by Order in Council. This briefing provides you with advice on these individual recommendations.
19. In August 2023 the previous Minister of Health, Hon Dr Ayesha Verrall, accepted the ACART recommendations in this paper and agreed to the Ministry of Health developing a Cabinet paper to amend the HART Order. The briefing paper has been proactively released.¹

Embryo donation

20. There are two outstanding recommendations relating to embryo donation from the 2019 ACART advice:

2019 Rec 2	Amend the HART Order to explicitly state that embryo donations are not established procedures, except in the following scenario.
2019 Rec 3	Amend the HART Order to make embryo donation an established procedure if a person is using an embryo created in a previous relationship, and their previous partner has consented.

¹ Available at: <https://www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents/documents-related-recommendations-regulation-assisted-reproduction>

21. Embryo donation is when a person or couple gives an embryo formed by IVF to another person or couple. The regulatory status of embryo donation is not explicitly stated in the HART Act or the HART Order.
22. ACART advise that embryo donation is ethically complex, as a child born from a donated embryo will be the genetic child of the donor parents, and the sibling (or half sibling) of any other children of the donor parents. There is significant risk of emotional harm if parties do not agree in advance on matters such as ongoing contact.
23. ECART consideration of embryo donations would address the risks arising from this ethical complexity, by ensuring that the interests of all parties (including the donor-born child and any siblings) are considered, and any problems resolved before the embryo is implanted. The recommended change would also improve clarity for fertility service providers and their clients.
24. Where a couple has an embryo formed and the relationship subsequently ends, one former partner may wish to use the embryo with a new partner. Depending on the origin of the gametes, this may be an embryo donation, even though one of the intending parents remains the same.
25. ACART consider that, where the other former partner gives informed consent, this situation is less ethically complex than embryo donation generally. Hence, they recommend that use of an embryo by a person in a new relationship should be an established procedure, provided the previous partner consents.
26. Risk from this form of embryo donation would usually arise from former partners not meaningfully consenting to the donation. This risk is adequately addressed through existing and well-established legal provisions for informed consent. The recommended change will benefit intended parents and ECART by not requiring time and resources to be spent confirming a situation which already has informed consent.

Posthumous reproduction

27. There are three outstanding recommendations relating to posthumous reproduction from the 2022 ACART advice:

2022 Rec 3A	Amend the HART Order to clarify that posthumous use of gametes and embryos is an established procedure if the deceased gave specific consent to the posthumous use of the gametes or embryos.
2022 Rec 3B	Amend the HART Order to clarify that other established procedures only apply to living people (including retrieval of gametes).
2022 Rec 4	Amend the HART Order to clarify that use of posthumously retrieved gametes and tissue is never an established procedure.

28. Posthumous reproduction is any reproductive process involving a person who died before the process took place. The most common example is the use of a deceased man's sperm to produce a child, typically carried by his surviving female partner. Posthumous reproduction is only possible through assisted reproduction and is therefore regulated under the HART Act and Order.

Use of gametes and embryos from a person who has since died

29. Currently under the HART Order, posthumous use of sperm is not an established procedure if it involves the use of sperm that was collected from a person, who has since died, who did not give consent to the specific use of the sperm before that person's death. This means that these activities require case by case approval from ECART. Where the deceased has given clear consent to posthumous use of his sperm by the surviving female partner, this is treated as an established procedure.
30. The HART Order specifies that the posthumous use of eggs is not an established procedure, however there is no exception for the deceased having given specific consent to the posthumous use of the eggs.
31. The HART Order does not specify the regulatory status of procedures involving an embryo formed from the gametes of one or more person who has since died. We understand that fertility clinics treat posthumous embryo use as an established procedure if the woman is still alive and wishes to use the embryo, and the deceased man consented to her using the embryo after his death.
32. ACART's recommendation 3A is to amend the HART Order to make posthumous use of all gametes and embryos an established procedure, provided that:
 - a. the gametes or embryos were stored prior to the person's death, and
 - b. the deceased gave specific consent to the posthumous use of the gametes or embryos.
33. This change would make the HART Order explicitly state that posthumous use of sperm is an established procedure if the person specifically consented to its posthumous use. It would also enable eggs and embryos to be used posthumously when appropriate. This change would benefit fertility providers and service users.
34. ACART considers that there is "no clear benefit" to the ECART approval process where the deceased gave specific consent to posthumous use. We agree with this assessment and note that fertility clinics are already treating posthumous use of sperm as an established procedure in these circumstances, and that this is not creating any adverse effects.
35. In some cases, changed circumstances will make it unclear whether consent still applies, creating risk of inappropriate posthumous use of gametes and embryos. This risk could be addressed by rejecting this recommendation and requiring ECART approval whenever significant change has occurred. However, any definition of significant change is likely to be arbitrary. For example, a newly diagnosed health condition which increases risk may be relevant, but there is no hard line for when this would call consent into question. Requiring ECART consideration in the event of any significant change would consume applicant and ECART time and resources for limited benefit.
36. Fertility clinics can and do seek non-binding ECART advice on ethical questions when not required to do so, for example in relation to clinic-assisted traditional surrogacies. We expect that clinics will address any risk by seeking ECART advice if they are uncertain as to whether consent remains valid. ECART will give this advice based on ACART's new guidelines on posthumous reproduction.
37. We recommend that you accept posthumous reproduction recommendation 3A, as the benefits of clarity and enabling consented posthumous use outweigh a minor increase in risk where circumstances have changed since consent was given.

Posthumous retrieval of gametes and tissue

38. Currently the HART Order states that the collection of gametes is an established procedure but does not specify whether this only applies in cases where the person is still living.
39. ACART recommendation 3B is to define all established procedures in the HART Order, other than those covered in recommendation 3A, as relating only to living people. This means that other procedures involving deceased people would require ECART approval on a case-by-case basis, including when there is clear consent.
40. The only procedure that the clarification would encompass is posthumous retrieval of eggs or sperm for purposes of donation. Posthumous retrieval is the extraction of gametes or reproductive tissue from a person who has died within the previous 48 hours, generally in order that the gametes can be used to conceive a child. Posthumous retrieval is usually sought by the surviving partner of the deceased. There have also been cases where a parent of the deceased has sought retrieval for future conception of a grandchild using their child's gametes.
41. Making posthumous retrieval of gametes and tissue an assisted reproductive procedure would mean that ECART approval is required on a case-by-case basis. In practice, consideration by ECART is usually not possible. Gametes and tissue must be retrieved within about 48 hours of death in order to be viable, and ECART does not meet frequently enough to consider urgent matters.
42. Whether a specific instance of posthumous retrieval would be lawful has historically been determined by the High Court. The one reported case on this matter, *Lee v Long*, focused on whether the deceased had given clear consent to posthumous use of his sperm.
43. If the HART Order is amended, the logistic issues explained above mean that the High Court would continue to consider applications for posthumous retrieval.
44. The practical effect of the recommended amendment would be to confirm that posthumous retrieval requires case-by-case consideration. Case-by-case consideration, whether by ECART or the High Court, is likely to make posthumous retrieval inaccessible to some people for cost and logistic reasons. Despite this, we consider that case-by-case consideration is appropriate given the highly complex ethical challenges and risks from this procedure. We therefore recommend that you accept this recommendation.

Use of gametes from a person who was dead at the time of retrieval

45. Regarding procedures involving gametes collected from a person who was dead at the time of collection, the HART Order states that any procedure involving the use of eggs collected from a person who is dead when the eggs are collected is not an established procedure. However, it does not specify the regulatory status of procedures involving sperm collected from a person who was dead at the time of collection.
46. ACART has recommended that the HART Order be amended to clarify that use of posthumously retrieved gametes or tissue is never an established procedure. This means that any use of gametes or tissue retrieved after a person's death would require case by case ECART approval.
47. As noted above, gametes and tissue must be retrieved within about 48 hours of death, so decisions about retrieval must be made by the High Court on short notice, potentially with incomplete information.

48. It is therefore appropriate that ECART approval be required for any use of posthumously retrieved gametes or tissue. ECART will give expert consideration of any issues that may have come to light between retrieval and the application for use. This will address any ethical risk arising from posthumous use. We therefore recommend that you accept this recommendation.

Cryopreservation of testicular tissue

49. There is one outstanding recommendation from the 2022 ACART advice on testicular tissue cryopreservation:

2022 Rec 1	Amend the HART Order to make testicular cryopreservation an established procedure.
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50. Biopsies of testicular tissue can be used to retrieve sperm for reproductive purposes where a person has an obstruction of the vas deferens. Biopsy samples may be cryopreserved and later thawed to collect sperm for fertility treatments.
51. The HART Order lists cryopreservation of sperm as an established procedure but does not mention cryopreservation of testicular tissue. However, many fertility clinicians consider that cryopreservation of testicular tissue is a form of sperm cryopreservation and are treating it as an established procedure.
52. ACART have recommended that testicular tissue cryopreservation should be included within the existing established procedure of sperm cryopreservation.
53. We understand that testicular tissue cryopreservation is already being carried out as an established procedure, without detrimental impacts. Formalising this situation through a HART Order amendment would therefore not create any new risks or ethical concerns but would improve certainty for fertility providers and their patients. We therefore recommend that you accept this recommendation.

Equity

54. The proposals in this paper will make the regulatory system more equitable because the law will be clarified and some procedures simplified, thus reducing costs to affected persons. The proposals will not have a significant impact on equity of access to services, since the numbers affected are small.
55. As per the HART Act Principles, ACART must ensure the needs, values, and beliefs of Māori are considered and treated with respect. The committee includes members with expertise in Māori customary values and practice and the ability to articulate issues from a Māori perspective. ACART conducts formal consultation on its draft guidelines including consideration of Treaty obligations and impacts on disadvantaged groups.

Next steps

56. Amendments to the HART Order involve seeking Cabinet agreement to the policy and then to the specific amendments. If you agree to amend the Order, we will draft the initial Cabinet paper and Regulatory Impact Statement.

ENDS.

Minister's Notes

PROACTIVELY RELEASED