Briefing

ACART and ECART overview

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To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Matt Doocey, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

ACART and ECART overview

Security level:	IN CONFIDENCE	**Date:**	27 May 2024
To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. Following your meeting with the Ministry of Health - Manatū Hauora (the Ministry) on Friday 17 May 2024, this briefing introduces the Advisory Committee on Assisted Reproductive Technology (ACART) and the Ethics Committee on Assisted Reproductive Technology (ECART) and recommends actions you take to support the committees.
2. This paper first briefly explains your role as the Minister responsible for ACART and ECART.
3. Appendices 1-3 present the regulatory settings for assisted reproduction in New Zealand, ACART and ECART's membership, and relationships with the Ministry and the sector.

ACART and ECART

4. ACART and ECART are independent Ministerial committees, established under the Human Assisted Reproductive Technology Act 2004 (the HART Act). ACART and ECART's members are appointed by the Cabinet Honours and Appointments Committee, on the recommendation of the Minister of Health (the Minister). They report to you under your delegation from the Minister of Health and require your input from time to time.
5. ACART is part of the regulatory framework for assisted reproductive services and human reproductive research in New Zealand. ACART issues guidelines that have criteria for ethical approval of certain procedures (for example, embryo donation) and for human reproductive research. ACART also provides you advice and agrees its work programme with you.
6. Section 28 of the HART Act sets out ECART's function (explained in paragraph 33, below) as the committee that considers applications for assisted reproductive procedures and human reproductive research, using guidelines issued by ACART. Section 28 also gives ECART the function of liaising with ACART on general and specific matters relating to assisted reproductive procedures and human reproductive research.

Your role as Minister responsible for ACART

7. As the Associate Minister responsible for ACART, your role is to:
   - agree its work programme, including all significant projects
   - request advice or information on other relevant matters if you choose
   - be consulted on any new or amended guidelines that ACART issues
   - accept their annual report and table it in the House of Representatives.

ACART is about to publish new guidelines for posthumous reproduction

8. ACART is about to publish new guidelines for posthumous reproduction by the end of May 2024. The guidelines will enable people to use stored reproductive material from people who are deceased, in limited circumstances.

Meeting the Chairs of ACART and ECART

9. We recommend you meet the Chairs of ACART (Calum Barrett) and ECART (Jeanne Snelling) in July 2024. Meeting them will help you discuss the matters the committees face and demonstrate your commitment to supporting their work and subsequently the people using or providing fertility services, and those undertaking human reproductive research.

10. The Chairs are likely to raise (a) ACART's work programme and (b) the changes recommended by ACART to previous Ministers, to the HART Act and Order.

Recommendations

We recommend you:

a)	**Note** that ACART will publish guidelines for posthumous reproduction by the end of May 2024.	**Noted**
b)	**Note** that ACART is currently revising its work programme for your agreement.	**Noted**
c)	**Note** over the coming months we will provide you our advice on: • the ACART and ECART annual reports for 2022/23 • ACART's draft work programme.	**Noted**
d)	**Agree** to meet with the Chairs of ACART and ECART in July to discuss their work programmes.	**Yes/No**

Simon Medcalf
Deputy Director-General
Regulation and Monitoring | Te Pou Whakamaru

Date: 27 May 2024

Hon Casey Costello
Associate Minister of Health
Date:

ACART and ECART overview

The HART Act

1. The HART Act is the principal act that regulates human assisted reproductive technology (ART) and human reproductive research in New Zealand. The HART Act's guiding principles include securing the benefits of assisted reproductive technologies while protecting and promoting the health and well-being of children conceived from assisted reproduction and all other parties involved. The principles (and the broader regulatory setting) are explained in full in Appendix 1 and cover a range of matters.
2. The HART Act prohibits certain actions, including commercial supply of gametes and embryos; commercial surrogacy arrangements; sex selection of embryos for social reasons; storing gametes and embryos for longer than 10 years without ethical approval; and the use of hybrid and cloned embryos in ART procedures.

ACART's roles and responsibilities

3. ACART's functions are set out in the HART Act (s.35). These functions include:
    - issuing guidelines and providing advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on assisted reproductive procedures requiring case by case ethical approval (eg, embryo donation, surrogacy), human reproductive research, and extending the storage period of gametes and embryos
    - keeping such guidelines and advice under review
    - providing independent advice to the Minister on matters concerned with human reproductive research and human assisted reproduction.
4. The scope of such advice includes:
    - specific matters set out in sections 37 and 38 of the HART Act (eg, informed consent, import and export of gametes and embryos, gametes derived from deceased persons)
    - whether a procedure should require ethical review on a case-by-case basis ("assisted reproductive procedure")
    - whether a procedure should be declared an "established procedure" and thus not require ethical review
    - whether the HART Act or other legislation should be amended to prohibit or provide for a procedure or human reproductive research
    - whether a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research
    - whether regulations should be made to regulate the performance of any kind of assisted reproductive procedure or human reproductive research.
    - monitoring the application and outcomes of assisted reproduction and monitoring developments in human reproductive research.
5. ACART must consult the public before issuing guidelines to ECART and before giving significant advice to ECART and/or the Minister.

6. ACART does not have any functions associated with public funding of fertility treatment or auditing fertility services.

How ACART works with the Minister

ACART agrees its work programme with the Minister

7. ACART's Terms of Reference require it to agree its work programme with the Minister. ACART seeks the Minister's agreement to all significant projects, including where public consultation is likely to be required. ACART briefs the Minister and may request that the Minister meet the Chair to discuss the work programme.

8. ACART's current work programme (in addition to its regular functions of monitoring and reporting) includes two projects to produce guidelines and advice. One project (likely to be advice only) is a review of the suitability of the regulation of the storage of reproductive material. The other project is on possible guidelines and advice for human reproductive research. This latter project includes possible research using human embryos.

9. ACART plans to submit a letter to you, within the next few months, seeking your agreement to its work programme. The Chair will be happy to meet you if you wish to discuss the programme. The Ministry will also advise you on ACART's proposed programme.

ACART advises the Minister of its public consultations

10. ACART provides the Minister with a copy of any public consultation document, for the Minister's information, before publishing and beginning public consultation.

11. ACART will carry out a targeted consultation, in mid-2024, on options for the initial storage period of reproductive material. Later in 2024, or early in 2025, ACART will publish a consultation document on revised guidelines for human reproductive research.

ACART advises the Minister of its guidelines

12. ACART is required to consult the Minister before issuing guidelines. The Minister does not have the role of approving guidelines.

13. ACART must advise the Minister when guidelines are issued. By the end of May 2024 ACART aims to have published amended guidelines for posthumous reproduction. A copy will be provided to your office.

ACART advises the Minister on various matters

14. The HART Act states the matters on which ACART is required to advise the Minister, within timeframes agreed with the Minister (s.37 and s.38).

15. ACART also briefs the Minister on:

    - any other matters where the Minister requests advice or information
    - any matters that ACART considers may be of interest to the Minister or where the Minister's agreement is needed.

ACART provides the Minister regular reports

16. Under the HART Act, ACART must give the Minister a report, after each 12-month period ending 30 June, on its progress in carrying out its functions, and on the number and kinds of decisions made by ECART in that period.

17. ACART also provides the Minister a copy of the annual monitoring reports *Assisted Reproductive Technology in New Zealand,* commissioned from the University of New South Wales, and drawing on data reported by New Zealand fertility services providers.

The HART Order and the Minister's role in amending it

18. The HART Order sets out "established procedures." Established procedures do not require ethical approval, so are not subject to ACART guidelines. Most fertility procedures are established procedures: they include *in vitro* fertilisation; collection of sperm and eggs for donation; cryopreservation of sperm, eggs and embryos.

19. The HART Order sets out some exceptions to the established procedures - these exceptions are subject to ACART guidelines and ECART approval (e.g., sperm or egg donation between certain family members).

20. If ACART recommends an amendment to the HART Order and you agree your role is to take the recommended change to Cabinet to seek the amendment to the Order in Council. The Ministry would provide you with the necessary briefing and Cabinet papers.

Note recent advice from the Ministry about changes to the Order

21. In recent years, ACART has recommended several changes to the HART Order relating to embryo donation, posthumous reproduction, and the cryopreservation of testicular tissue. In May 2024, the Ministry provided you with advice on these recommendations (H2024039493 refers).

22. ACART is about to publish revised guidelines for posthumous reproduction. The new guidelines will enable people to use stored eggs, sperm and embryos from people who are deceased, in limited circumstances. Specifically, people will be able to use the reproductive material of now deceased people if the deceased had previously consented to the specified person using their reproductive material after their death. ACART consulted the public in 2018 and again in 2020 then consulted the previous government in 2022.

23. ACART's current guidelines for posthumous reproduction allow assisted reproduction posthumously only for stored sperm. There are gaps in the guidelines, particularly that they do not enable the posthumous use of stored eggs and embryos. ACART's revised guidelines and advice address those gaps and clarify what is allowed and what is prohibited.

24. The Ministry has assessed the revised guidelines, and the advice that ACART submitted to the previous government and supports ACART's recommendations.

25. The publication of the guidelines has been delayed due to other priorities. We are now working to publish these as soon as possible. ACART's advice and guidelines will be provided to you before publication.

A further change to the guidelines will follow

26. We also note that, if Cabinet changes the HART Order (as discussed above in paragraphs 18 to 20), ACART will then issue further amended guidelines. The further update will state that

all cases must be considered by ECART if they use reproductive material that was collected after the person died. (This activity is likely to be rare.) The further amendments will also note that when there is specific informed consent, this will be an established procedure and such cases will not need approval from ECART.

27. The amended guidelines may generate media interest. ACART and the Ministry have prepared responses for any enquiries or media interest that might arise. We can provide your office with back-pocket notes and responses to likely questions at your request. Any risks associated with these guidelines can be managed. Risks include media attention, concerns about the activity from some members of the public, and concerns about the wellbeing of the parties involved including the offspring.

Membership of the committees

28. Committee members will be appointed to ACART and ECART on the recommendation of Associate Minister Doocey, and with Cabinet endorsement. Appendices 2 and 3 present details of the members of both committees.

29. In 2024, several members of both ACART and ECART will need to be appointed or have their terms renewed. The Ministry is now working to recruit and renew members and will provide Associate Minister Doocey more detailed advice and will copy the advice to you. The appointment of members should be a priority so that ACART and ECART can carry out their functions.

ACART recommendations to change the HART Act

30. In the near future, ACART will recommend four changes to the HART Act. The Ministry will provide separate advice on ACART's recommendations along with options for progressing any changes to the HART Act. Timing for providing the advice is yet to be confirmed. Any proposal to amend the act would involve discussions with the Minister and Ministry of Justice who are responsible for the HART Act.

Ministry appraisal of the Act

31. The Ministry has not reviewed the whole HART Act but knows that several provisions could be improved. These changes, combined with ACART's recommendations, would make a strong case for a review of the HART Act. The changes would have real world benefits for people wishing to use fertility services and would fix some anomalous and restrictive provisions.

32. Further, the work by the Law Commission on surrogacy law reform identified some aspects of the HART Act that could be improved and the current surrogacy bill is addressing the matter of adults donating gametes they had stored as minors. Depending on the progress of the surrogacy bill, that particular change to the HART Act might be progressed either as part of that bill or in a separate process.

ECART's roles and responsibilities

33. ECART has the following functions:

    - to consider and determine applications for assisted reproductive procedures or human reproductive research

- to keep under review any approvals previously given, including those applications approved prior to the existence of ECART, and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals
- to liaise with ACART on matters relating to assisted reproductive procedures and human reproductive research and, to forward to ACART reports received under section 19(5) of the HART Act together with any comments or requests for advice that ECART considers appropriate
- to consult with any persons who, in the opinion of the committee, are able to assist it perform its functions
- any other functions that the Minister of Health assigns to the committee by written notice.

Equity

34. ACART has a role in upholding Te Tiriti o Waitangi. The HART Act ensures Māori perspectives are included with a Māori representative on the Committee, although we had a vacancy for almost two years for this position until October 2020. The current member is supporting the committee to improve its Māori consultation processes going forward. The Principles of the HART Act specifically includes, in section 4(f) that, the needs, values, and beliefs of Māori should be considered and treated with respect.

35. ACART has one member appointed in the role of expertise in Māori tikanga and the ability to articulate issues from a Māori perspective. The member is currently serving as the Deputy Chair, having been appointed in March 2022. In total, ACART has three Māori members, two of whom are appointed in other membership categories.

36. In recent years, ACART has worked to establish more relationships with a range of Māori stakeholders. This work continues and ACART is gradually engaging more with Māori. ACART now includes more narrative in its consultation material that is designed to increase Māori participation in its work.

37. ACART's monitoring reports now include ethnicity data.

38. ECART has four members with Māori heritage, one with Samoan and one with Asian.

Next steps

39. ACART will publish its revised guidelines for posthumous reproduction and will continue working with the fertility services to ensure the guidelines are successfully implemented.

40. ACART will send you a draft work programme and the Ministry will brief you about that programme before you meet the chairs of ACART and ECART (subject to your agreement to meet them).

41. During 2024, the Ministry will provide Associate Minister Doocey with information about candidates to join the ACART and ECART committees. The exact timing is yet to be confirmed.

42. We will send you the annual reports of both ACART and ECART for your approval and tabling in Parliament. The exact timing is yet to be confirmed.

END.

Minister's Notes

Appendix 1: The regulatory setting

The HART Act

1. The HART Act is the principal Act that regulates human assisted reproductive technology (ART) and human reproductive research in New Zealand. Important features of the HART Act include the following.

2. **Guiding Principles**: to secure the benefits of assisted reproductive technologies by protecting and promoting the health and well-being of children conceived from assisted reproduction; the health, safety and dignity of future generations; the health and well-being of women; informed consent; access by donor offspring to information about genetic origins; consideration and respect for the needs, values and beliefs of Māori; and consideration and respect for different ethical, spiritual and cultural perspectives.

3. **Prohibitions** against certain actions including commercial supply of gametes and embryos; commercial surrogacy arrangements; sex selection of embryos for social reasons; storing gametes and embryos for longer than 10 years without ethical approval; and the use of hybrid and cloned embryos in ART procedures.

4. Established procedures, which are fertility activities that clinics can carry out without needing approval from the ethics committee.

5. Registers to record information about gamete and embryo donors, and about people born from donated embryos or donated cells, so donor offspring have the ability to find out about their genetic origins (Part 3).

6. Processes and institutional arrangements that allow for a flexible system that can have some changes without Parliament's involvement. The HART Act delegates to ACART responsibility for establishing the requirements for using some procedures. ACART is required to consult the public and the Minister before issuing new guidelines or making significant changes to guidelines.

7. Enabling regulations to be made about both specific issues (eg, informed consent, importing and exporting gametes and embryos) and any other matters necessary for giving full effect to the HART Act (s.76).

8. The HART Act is the responsibility of the Minister of Justice. The Ministry of Justice, the Ministry of Health and the Department of Internal Affairs all contribute to the administration of the legislation. The Customs Service also has some functions under the HART Act.

Assisted reproductive activities that require ethical approval

9. ACART develops and issues guidelines for activities requiring approval by the Ethics Committee on Assisted Reproductive Technology (ECART) which is a specialist ethics committee. ECART's functions, membership and relationship with ACART are set out in the HART Act.

10. ACART is a policy and regulatory committee and ECART is the operational committee. They make decisions independently of one another.

11. ACART guidelines fall under three categories:

- assisted reproductive procedures
- extending the storage period of gametes and embryos
- human reproductive research.

12. ACART has issued, or has responsibility for, guidelines that address the following matters.

Assisted reproductive procedures

- Surrogacy involving assisted reproductive procedures.
- Embryo donation for reproductive purposes.
- Creation and use, for reproductive purposes, of an embryo created from donated eggs in conjunction with donated sperm.
- Donation of eggs or sperm between certain family members.
- Preimplantation genetic diagnosis with human leucocyte antigen tissue typing (selecting an embryo that is compatible with an existing seriously ill sibling, with a view to using donated cord blood or bone marrow from resulting child).
- Storage, use and disposal of sperm from a deceased man (issued before the HART Act and still in force).

Extending storage of gametes and embryos

- Extending the storage period of gametes and embryos beyond 10 years.

Human reproductive research

- Research on gametes and non-viable embryos (issued before the HART Act and still in force).

13. ACART's guidelines and ECART's decisions only cover assisted reproductive procedures in New Zealand where they are carried out by a New Zealand fertility services provider.

The Human Assisted Reproductive Technology Order 2005 (Hart Order)

14. The HART Order sets out procedures that are declared to be "established procedures." Established procedures do not require ethical approval and therefore are not subject to ACART guidelines.

15. Most fertility procedures are established procedures: they include in vitro fertilisation; collection of sperm and eggs for donation; cryopreservation of sperm, eggs and embryos.

16. The HART Order also sets out some exceptions where the use of specific procedures is subject to ACART guidelines and ECART approval (eg, sperm or egg donation between certain family members).

Nga pāerewa Health and disability services standard

17. *Nga pāerewa Health and disability services standard* (NZS8134:2021) sets out the requirements for the safety and quality of health and disability services, including fertility services, in New Zealand. Providers are audited and certified against the standard, which is administered by the Ministry of Health. ACART does not have any responsibility for the standard, though is consulted by the Ministry of Health when it is reviewing the standard.

Code of Health and Disability Services Consumers' Rights

18. Patients of fertility services providers are protected by the Code of Health and Disability Services Consumers' Rights (the Code).

19. We note that egg and sperm donors are not considered patients under the Code for the purposes of fertility treatment. Consequently, donors might, from time to time, wish to seek assistance under the Code but be precluded from doing so.

Appendix 2: ACART's membership

1. Members are often appointed for three years at a time, often serving six years in total. Changes in membership are usually staggered to ensure continuity of knowledge on the committee.
2. ACART must have at least 8 members and not more than 12. Over the last year, ACART has had 12 members then decreased to 11 members in January 2024 due to one member resigning.
3. While some of the positions can be filled fairly easily, others require greater effort to fill. For example, it can be more difficult to find members with expertise in ethics and human reproductive research, bearing in mind that the candidates also need to understand public policy making, legislative practice and stakeholder engagement.
4. The Ministry of Health provides the Minister responsible for appointments with recommendations to support their appointment decisions.
5. As of April 2024, ACART's membership is as set out in the following table.
6. Note that:
    a. Karen Reader and Sarah Wakeman are not eligible for reappointment (they will have both been on ACART for the maximum of 6 consecutive years by December 2024). By December 2024, Drs Reader and Wakeman will have been on ACART for 7 and 8 years respectively. The reason for this period (of more than 6 years), is due to the time taken for their reappointments to be made.
    b. s 9(2)(a)
    c. 

ACART's membership

	Name	Date first term began	Date of Reappointment	Current term expires	Lay-person	Area of expertise
1	Minu Punchihewa *Wellington*	3 July 2023	—	2 July 2026	✓	Interests of children
2	Neuton Lambert *Auckland*	3 July 2023	—	2 July 2026	✓	General Lay
3	Amanda Lees *Auckland*	3 July 2023	—	2 July 2026	✓	Ethics
4	Catherine Ryan *Auckland*	6 August 2020 (2 year term)	3 July 2023	2 July 2026	✓	General Lay
5	Edmond Fehoko *Auckland*	22 Dec' 2021	—	21 Dec 2024	✓	General Lay
6	Debra Wilson *Christchurch*	22 Dec' 2021	—	21 Dec 2024	✓	Legal
7	Karen Reader *Dunedin*	1 Dec' 2017	22 Dec' 2021	21 Dec 2024		Human reproductive research
8	Sarah Wakeman *Christchurch*	2 Dec' 2016	22 Dec' 2021	21 Dec 2024		Assisted reproductive technology
9	Calum Barrett ***Chair*** *Wellington*	31 May 2019	Second term and position as Chair began 21 Dec 2021.	21 Dec 2024	✓	Consumer
10	Karaitiana Taiuru *Christchurch* ***Deputy chair***	6 August 2020	—	5 August 2023	✓	Māori
11	Seth Fraser *Wellington*	6 August 2020	—	5 August 2023	✓	Disability

Appendix 3: ECART'S membership

	Name	Date first term began	Date of Reappointment	Current term expires	Lay-person	Area of expertise
1	Jeanne Snelling **Chair**	22/12/2021	—	21/12/2024	✓	Law
2	Judith Charlton	30/05/2016	22/12/2019	22/12/2022	✓	Disability perspectives
3	Mania Maniapoto-Ngaia	20/06/2019	28/11/2022	28/11/2025	✓	Māori customary and consumer perspectives
4	Mike Legge	20/06/2019	28/11/2022	28/11/2025		Human reproductive research
5	Emily Liu	22/12/2021	—	22/12/2024		Assisted reproductive procedures
6	Angela Ballantyne	22/12/2021	—	22/12/2024	✓	Ethics
7	Analosa Veukiso-Ulugia	22/12/2021	—	22/12/2024	✓	Community perspectives
8	Richard Ngatai	22/12/2021	—	22/12/2024	✓	Law
9	Lana Stockman	16/07/2022	—	16/07/2025	✓	Consumer perspectives
10	Annabel Ahuriri-Driscoll	28/11/2022	—	28/11/2025		Health research
11	Simon McDowell	28/11/2022	—	28/11/2025		Assisted reproductive procedures
12	Peter Le Cren	03/07/2023	—	02/07/2026	✓	Law