Advisory Committee on
Assisted Reproductive Technology

Second Round of Consultation on the Proposed Donation and Surrogacy Guidelines: further changes since ACART's 2017 consultation

Consultation Document

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www.acart.health.govt.nz

Foreword

This document seeks public feedback on the proposal by the Advisory Committee on Assisted Reproductive Technology (ACART) to replace four separate guidelines with one set that covers the four procedures of: family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm), and clinic-assisted surrogacy. ACART is also seeking feedback on its advice to the Minister of Health about the scope of cases covered in the revised guidelines. The Human Assisted Reproductive Technology Act 2004 (HART Act) requires ACART to review its guidelines regularly and to consult the public on proposed changes and significant advice to the Minister.

This is a second round of consultation following our consultation in 2017 and the submissions ACART received. ACART is inviting submissions on three matters it has reconsidered since the first round of consultation.

Firstly, as a result of the consultation in 2017, ACART has confirmed its intention to progress the most significant policy shift, which is to rescind the mandatory biological link requirement. As a result of the submissions it was apparent that not all people had the same understanding of consent under the new regime. ACART is now presenting a fuller explanation of when consent would be needed to gauge whether people understand and agree with our proposal.

Second, ACART is re-consulting on the provisions for family gamete donations. ACART initially proposed that all cases involving family gamete donations should be subject to approval by ECART. As a result of the submissions, ACART has agreed that only certain risk factors should be considered by ECART when it assesses cases involving family gamete donations, and it is seeking public input on its amended provisions.

Thirdly, ACART is re-consulting on the provisions for surrogacy, having now proposed a new way of ensuring that all clinic assisted surrogacies be subject to ECART consideration. ACART also proposes reinstating a provision for the residency of the parties to a surrogacy and that surrogates be aware of the risks to their fertility.

ACART recognises the possible impacts of such a change, particularly for consumers, and seeks your views on the proposal. ACART appreciates the efforts many people and organisations make to provide valuable feedback to our public consultations and looks forward to receiving your submission.

Dr Kathleen Logan
Acting Chair

How to have your say

Your feedback is important in helping ACART finalise its guidelines for family gamete donation, embryo donation, use of donated eggs with donated sperm, and surrogacy and decide any advice to the Minister of Health about amendments to the HART regulatory framework.

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

1. e-mailing a completed feedback form or your comments to acart@moh.govt, or

2. using the online feedback form in this link:
   https://consult.health.govt.nz/acart/donation-surrogacy-guidelines

3. posting a completed feedback form or your comments to:
   ACART Secretariat
   PO Box 5013
   Wellington 6140.

ACART welcomes your views on any or all of the issues raised.

Publishing submissions

ACART may publish all submissions, or a summary of submissions on the Ministry of Health's website, unless you have asked us not to. If you are submitting as an individual, ACART will automatically remove your personal details and any identifiable information. You can also choose to have your personal details withheld if your submission is requested under the Official Information Act 1982.

Where feedback is given on behalf of an organisation, the Ministry will release the name and contact details of the submitter and the organisation unless there are other reasons for withholding the information in accordance with the Official Information Act. If you consider that your own and/or your organisation's name(s) and/or contact details should be withheld under the Official Information Act, please make this clear on your feedback form, noting the reasons.

Further guidance on releasing information under the Official Information Act is available from the Ombudsman's website, at: www.ombudsman.parliament.nz/resources-and-publications

The closing date for feedback is Monday, 25 March 2019.

Contents

Executive summary

This is a second round of consultation, following our consultation in 2017, on ACART's proposed changes to the guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm) and clinic-assisted surrogacy (collectively, the Donation Guidelines review). ACART is inviting submissions on three matters it has reconsidered since the first round of consultation.

Although ACART has confirmed its intention to rescind the mandatory biological link requirement, it was apparent from the submissions that not all people had the same understanding of consent under the new regime. Consequently, ACART has amended the consent provisions to ensure they are clear and unambiguous. In this consultation document, ACART presents a full and clear explanation of when consent would be needed, to gauge whether people understand and agree with our proposal. ACART has also made amendments to the provisions for family gamete donations and for surrogacy.

Following consultation, some of ACART's policy proposals will require changes to the HART Order. The specific changes relating to this consultation are that the HART Order would need amendments to enable the prohibition of certain family gamete donations and to require clinic assisted surrogacies to be subject to the guidelines.

The closing date for feedback is **Monday, 25 March 2019**.

Summary of proposals

Please refer to text for full proposals, rationales and effects.

Proposals	
1	The provisions about consent should be amended.
2	A new provision for re-donating embryos in a particular situation is proposed.
3	The list of family gamete donations that are prohibited should be extended to include the specified close genetic relationships and the HART Order would be amended to make this the case.
4	ACART no longer proposes that all family gamete donations should be subject to ECART consideration.
5	New provisions are proposed for the risks ECART must evaluate when considering cases involving family gamete donations.
6	In surrogacy cases, rather than requiring surrogates to have finished their families before acting as surrogates they should be required to be aware of the risks to their future reproductive capacity.
7	The residency of the parties to a surrogacy should be taken into account when clinic assisted surrogacies are being considered.
8	All clinic assisted surrogacies would need to go to ECART and the HART Order would be amended to make this the case.

1 Introduction

1. This chapter covers:
   - the purpose of this public consultation
   - the proposed amended guidelines
   - why and how ACART is reviewing the guidelines
   - the process after this consultation.

1.1 Purpose of this second consultation

2. This document seeks public feedback on three aspects of ACART's proposed combined guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm) and clinic-assisted surrogacy.

3. These aspects are:
   - clarification of the proposed consent regime with particular attention to embryo donations
   - provisions that prohibit certain family gamete donations and provisions that outline the considerations ECART must consider with respect to family gamete donations that are not prohibited
   - changes to three provisions for clinic assisted surrogacy.

4. ACART's further amendments (since its consultation in 2017) are significant enough that it is re-consulting to obtain public input. Given the significant change from the position consulted on for the family gamete donations, ACART must ensure that it meets its statutory consultation requirements before advising the Minister.

5. Notably, the amendments to the general provisions for consent are significant enough that readers might now form a different opinion about them than they did in the initial consultation. It is also possible that people who did not submit to ACART on these provisions would wish to do so now.

6. In the case of the proposed changes to the provisions for clinic assisted surrogacy, ACART believes these are unlikely to raise concerns, but it would be prudent to ensure that interested parties are aware of them.

7. This process is in accord with section 36(1) of the HART Act, which requires ACART to consult the public before issuing guidelines. ACART must:

on the basis of a discussion paper or an outline of the proposed guidelines, give interested parties and members of the public a reasonable opportunity to make submissions and take any such submissions into account.

ACART's 2017 consultation

8. In ACART's 2017 consultation, it explained the proposal to combine three donation guidelines and the surrogacy guidelines and the reasons for these changes. The proposed changes may require amendments to the Human Assisted Reproductive Technology Act 2004 (HART Act) or the Human Assisted Reproductive Technology Order 2005 (HART Order).

1.2 The proposed amended guidelines

9. The proposed amended guidelines, with ACART's recent extra revisions, are set out below. We discuss the proposed amendments in later chapters.

10. ACART's amendments, since the 2017 consultation, are presented using a) underlined red for new text, and b) red with strike through for text that would be removed. These amendments are in the provisions for:

    a) consent in the Provisions that apply to all procedures covered in these guidelines

    b) the Use of gametes donated between certain family gamete donations

    c) Embryo donation and use

    d) Clinic-assisted surrogacy.

11. For (a) above, ACART presents the proposed new text in the draft guideline (below) but the text consulted on in 2017 is presented in Appendix 1. The material is presented in this way to make the draft guidelines as easy to read as possible.

Proposed guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy

Preamble
ACART can issue guidelines
ACART is appointed by the Minister of Health, and one if its functions is to issue guidelines on any matter relating to any kind of assisted reproductive procedure (s.35(1)(a) of the HART Act).
Guidance on terms used
In these guidelines, unless the context indicates otherwise, words should be interpreted in accordance with definitions given in the HART Act and the HART Order.
Principles
When considering an application to carry out any of the following procedures ECART must be guided by the principles of the HART Act. The principles state: All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function: (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure: (b) the human health, safety, and dignity of present and future generations should be preserved and promoted: (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures: (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent: (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins: (f) the needs, values, and beliefs of Māori should be considered and treated with respect: (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.
Scope of the guidelines
In these guidelines, ACART sets out the requirements for assisted reproductive procedures that require a party other than the intended parents (third party assistance) to contribute to family formation and where a fertility services provider is involved.

PROVISIONS THAT APPLY TO ALL PROCEDURES COVERED IN THESE GUIDELINES
General requirements
ECART must be satisfied that: 1. full genetic siblings are produced in no more than two families (this does not preclude a donor from donating sperm or eggs separately to another couple or person) 2. the parties have not been subjected to any coercion or pressure 3. the procedure is the best or only opportunity for intending parents to have a child 4. the intending parents are not using the procedures for social or financial convenience or gain 5. the potential genetic, social, cultural and intergenerational aspects of the proposed arrangement safeguard the wellbeing of all parties and especially any resulting child 6. any relationships between the parties safeguard the wellbeing of all parties and especially any resulting children.
Counselling requirements
ECART must be satisfied that counselling: 7. has been received by each party in accordance with the current Fertility Services Standard 8. will be available throughout the donation/treatment process 9. is culturally appropriate 10. has provided for whānau or extended family involvement 11. has provided for the inclusion of any existing children of the parties 12. has addressed any matters raised by donation(s) between family members 13. has included implications counselling for all parties, and parties have considered, and in the opinion of the counsellor have understood: a. the rights of offspring, including their rights to obtain information about their genetic origins and to contact donors b. each other's needs and plans for continuing contact and information sharing c. any specific issues that might affect the health and wellbeing of all parties and especially the offspring d. the implications if offspring have medical conditions, disabilities or genetic disorders e. each other's attitudes to openness about donation, especially with the offspring f. the possibility of a termination of the pregnancy by the birth mother (whether she is the intending mother or a surrogate) g. issues related to use, storage and disposal of gametes and embryos h. requirements for information sharing under the HART Act i. their reasons for wishing to donate or receive gametes or embryos j. their feelings now and possible feelings in the future about donations k. the possibility of future contact with offspring, for themselves and their families, including any resulting children.

Consent requirements

ECART must be satisfied that:

14. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) consented to the use of their gametes at the time of donation
15. implications counselling about the potential use of gametes was provided before the gamete donor consented
16. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)
17. where a procedure will involve the use of a donated embryo, consent to the use of that embryo must have been given by the people who originally had the embryo created for themselves
    - at the time of donation, or
    - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated[1]
18. where a procedure will involve the use of a re-donated embryo, consent to the use of the embryo must have been given:
    - at the time of donation, or
    - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated

    by

    a. the people who originally had the embryo created for themselves whether or not they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and by

    b. the first recipient(s) of the donated embryos if they have already had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated

    but

    a re-donation can only be made if either the original intending parent(s) or the first recipients have not had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos (i.e. the limit of two families that can have full genetic siblings applies)
19. all parties understand that, once an embryo is created, the authority to vary or withdraw consent up to the time the embryo is transferred to the uterus remains with the person(s) for whom the embryos were created. However, if the original intending parents have no gametes in the embryos and they did not have a child(ren) using embryos that would be full siblings to those that would be born from the embryos being donated and the first recipients did have a child(ren) using embryos that would be full siblings to a child(ren) that would be born from the embryos being donated then the authority to consent is with the first recipients.

[1] This provision does **not** mean that gamete donors (or any other parties) have to give consent every time a recipient has an embryo transferred (after the whole embryo donation has been agreed to).

Legal advice requirements
ECART must be satisfied that: 20. where an application includes a surrogacy arrangement, each party has received independent legal advice 21. where an application does not include a surrogacy arrangement, each party has considered the option of seeking independent legal advice 22. any legal reports show that parties understand the legal implications of the procedure(s).
Health advice requirements
ECART must be satisfied that: 23. all parties have received independent medical advice 24. health reports show the parties understand the health implications of the procedure(s).

ADDITIONAL PROVISIONS THAT APPLY TO SPECIFIC PROCEDURES
Use of gametes donated between certain family members
Notes Ethical approval is not required for the following family donations: 1. in the case of donated eggs, the donor is a sister or cousin of the recipient woman (where both are 20 years or older) 2. in the case of donated sperm, the donor is a brother or cousin of the recipient woman's spouse or partner (where both are 20 years or older) 3. in the case of a procedure that involves the use of the eggs of the female partner of the recipient woman and donated sperm, the sperm donor is a brother or cousin of the recipient woman (where both are 20 years or older). If clinics are unsure about cases they can request a non-binding opinion from ECART. **The HART Order defines a family member for the purposes of donation as:** 1. any other person who is or has been related to the person by blood, marriage, civil union, de facto relationship or adoption 2. any other person who is a member of the person's whānau or other culturally recognised family group.
Use of embryos created from donated eggs in conjunction with donated sperm
Note Although donated eggs and donated sperm from the same two people may be used together to produce full genetic siblings in up to two families, neither donor is precluded from separately donating sperm or eggs to another couple or person.

Embryo donation and use
Notes 1. Embryo donation includes: a. the agreement to donate a stated number of surplus embryos b. the transfer of control of the embryo(s) to the intending parent(s) c. the transfer of an embryo into the uterus of the gestating woman (intending parent or surrogate). ~~2. Donated embryos:~~ ~~a. can be relinquished back to the original intending parent(s) for a second donation ('re-donation'). This requires a new application to ECART~~ ~~b. may not be donated by the recipient parent(s) ('on-donated') to any other party except as specified in Note 4.~~ 2. Donated embryos may be re-donated by the people who originally had the embryos created for themselves if: a. they have not had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, **and** the first recipient(s) of the donated embryos have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos, **or** b. they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and the first recipient(s) of the donated embryos have not had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos, **or** c. neither they nor the first recipients have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos 3. Donated embryos may be re-donated by the first recipients only if: a. the original intending parents have no gametes in the embryos **and** b. the original intending parents did not have a child(ren) using embryos that would be full siblings to those that would be born from the embryos being donated **and** c. the first recipients have had a child(ren) using embryos that would be full siblings to a child(ren) that would be born from the embryos being donated**.** 4. Any donation or re-donation requires an application to ECART.

~~Additional~~ Requirements

ECART must be satisfied that:

1. all affected parties understand that embryo donors can withdraw or vary consent up to the point of placing the embryo in the gestating mother's uterus
2. the embryo donors and recipients have received joint counselling relating to the implications of embryo donation
3. there has been discussion, understanding and agreement between all affected parties on matters relating to the use and storage of embryos and disposal of any unused embryos
4. if embryos are being donated by the original intending parents for the first time they:
   - have been created for the donors' own fertility treatment
   - are surplus to the needs of the donor(s); that is, the donors have completed their family or no longer intend to have children
5. if embryos are being re-donated they are within the circumstances specified in Notes 2 to 4 above
6. recipients have been vetted by the Police.

Clinic-assisted surrogacy

Notes

1. For the purpose of these guidelines:
   - surrogacy describes a procedure facilitated by a New Zealand fertility clinic where a woman gestates an embryo for intending parent(s)
   - a surrogate is a woman who becomes pregnant, carries and delivers a child on behalf of another couple (intended ~~or commissioning~~ parents).
2. Commercial surrogacy is prohibited under the HART Act.
3. A surrogacy arrangement is not enforceable by or against any person.

Requirements

ECART must be satisfied that:

1. there has been discussion, understanding and declared intentions between the affected parties about the day-to-day care, guardianship and adoption of any resulting child and any ongoing contact
2. the risks associated with a surrogacy for the adult parties and any resulting child are justified in the proposal. These risks are:
   a. risks to the health and wellbeing of the intending surrogate, including:
      - risks associated with pregnancy, childbirth and relinquishment of a resulting child to the intending parent(s)
      - the risk that the intending parent(s) may change their mind about parenting a resulting child
      - risks to the future reproductive capacity of the surrogate.

   b. risks to the health and wellbeing of the intending parent(s), (and embryo donor if applicable) including that the surrogate may change her mind about relinquishing a resulting child

   c. risks to the health and wellbeing of a resulting child, including becoming the subject of a dispute if the relationship between the surrogate and intending parents breaks down
3. the residency status and plans of the surrogate and intending parent(s) safeguard the health and wellbeing of the child, particularly in relation to being born in New Zealand.

~~the surrogate has completed her family before becoming a surrogate for others.~~

4. all affected parties have received joint counselling
5. in the opinion of the counsellor the health and wellbeing of the intending surrogate and any resulting offspring is safeguarded
6. all affected parties have considered, and in the opinion of the counsellor, have understood:
   a. each other's needs and plans for continuing contact
   b. specific issues that might affect the health and wellbeing of all affected parties
7. counselling will be made available to all parties before and after pregnancy is achieved.

1.3 Why and how ACART is reviewing the guidelines

12. In this section, ACART summarises information provided in the 2017 consultation document on this matter. In particular, ACART notes:

    - ACART's statutory role in regard to issuing guidelines to ECART and providing advice to the Minister of Health
    - the origins of this project
    - matters ACART has considered in developing the proposals in this document.

ACART's statutory role

13. ACART has a statutory role under the Human Assisted Reproductive Technology Act 2004 (HART Act) to issue guidelines to the Ethics Committee on Assisted Reproductive Technology (ECART) on matters that require case-by-case ethical review.

14. ACART's role under the HART Act is to:

    - issue guidelines and advice to ECART on any matter relating to any kind of assisted reproductive procedure, human reproductive research and extended storage of gametes and embryos
    - advise the Minister of Health on aspects of, or issues arising out of, different kinds of assisted reproductive procedures or human reproductive research
    - monitor the application and health outcomes of assisted reproductive procedures and established procedures and developments in human reproductive research.

15. More information about ACART and the current guidelines can be found on ACART's website at: www.acart.health.govt.nz

The origins of this project — a summary

16. In the 2017 consultation ACART explained that it had issued separate guidelines from 2008 to 2010 to cover family gamete donation, embryo donation, the use of donated eggs with donated sperm and surrogacy. ACART issued new surrogacy guidelines to ECART in 2013, allowing ECART to approve applications by single men and male couples to use surrogacy to become parents. At the same time, ACART issued new family gamete donation guidelines to provide for cases where a family member was the source of the necessary donated eggs for a single man or male couple. ACART wanted to ensure that provisions in the family gamete donation guidelines were consistent with the new surrogacy guidelines, which no longer required a medical reason to justify a surrogacy.

17. Under section 35(1)(a) of the HART Act, ACART is required to review its guidelines regularly. ACART decided to review the two other donation guidelines to ensure that they were consistent, where appropriate, with the guidelines issued in 2013. ACART also decided to consider the feasibility of having one set of guidelines to cover all four procedures.

Matters ACART has taken into account when developing the proposals in this document

18. In developing the proposed guidelines and advice, ACART has taken into account:

    - the principles of the HART Act
    - other common ethical principles, including autonomy, wellbeing of offspring and families/whānau and transparency
    - wider legal and public policy considerations, including the right to informed consent to health care under the Code of Health and Disability Services Consumers' Rights (the Code)
    - feedback from public consultation on related matters
    - evidence and information from local and international sources.

19. When considering these matters, ACART referred to its ethical framework, which incorporates the principles of the HART Act and generally accepted ethical principles. The ethical framework considers the welfare of those affected by the procedure and the autonomy of those involved, as well as altruism, social trust and responsibility, the special status of the embryo, justice and equality.[2]

20. The recognition of the importance of relatedness and connection to others expressed through values such as whānau, whakapapa and whanaungatanga, is relevant to gamete and embryo donation. Māori have been influential in shaping non-Māori views on the significance of whakapapa, and this has arguably led to a more open attitude to the knowledge of genetic parentage than exists in some countries.[3]

21. Principle 4(f) of the HART Act requires that the needs, values and beliefs of Māori should be considered and treated with respect. This is further developed in the New Zealand Fertility Services Standard (1.1.2), which requires that consumers who identify as Māori have their health and disability needs met in a manner that respects their individual values and beliefs. This recognises that while there may be viewpoints shared by many Māori, individuals and whānau will have their own preferences and practices.

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[2] For a copy of ACART's ethical framework, go to the ACART website: www.acart.health.govt.nz

[3] Dyall L, Keith J. 1994. Analysis of written submissions made to Ministerial Committee on Assisted Reproductive Technologies. In B Atkin and P Reid, Assisted Human Reproduction: Navigating Our Future, Wellington: Ministry of Justice. URL: www.moh.govt.nz/notebook/nbbooks.nsf/0/8E8C59B6E4F845EE4C2565D70018BEB1 (accessed 27 July 2017).

22. Nonetheless, the concept of Te Ao Māori (Māori world view) will have implications for the way we should consider these matters. For example, in developing these guidelines, ACART has considered the concept of whakapapa and the way in which this concept defines and identifies elements around family relationships that are of importance to Māori.

23. ACART has also considered that Pasifika communities have a holistic perspective of health and wellbeing – this includes an interconnectedness between spiritual/ religious, cultural, emotional and social dimensions and that health and wellbeing are often heavily influenced by family and community.

24. The 2013 census found that just over one-quarter of people living in New Zealand were born in another country.[4] Principle 4(g) of the HART Act recognises the diversity resulting from migration and a pluralistic, multicultural society, and requires the different ethical, spiritual and cultural perspectives to be considered and treated with respect in the context of assisted reproduction.

25. The Human Rights Act 1993 prohibits discrimination against individuals on the basis of disability, and New Zealand is a signatory to the United Nations Convention on the Rights of Persons with Disabilities. People with disabilities have equal rights to autonomous decisions over reproduction. Clinics must ensure, where practicable, that clients with disabilities are provided with services and information in an appropriate manner, including accessible formats.

1.4 The process after this consultation

26. Following this consultation, ACART will consider public feedback and decide if any amendments should be made to the proposed guidelines. ACART will then consult the Minister of Health on the finalised guidelines as required under section 41(2) of the HART Act and issue the guidelines to ECART.[5] ACART will also decide if it needs to recommend to the Minister any amendments to the HART Act or the HART Order and associated further changes to the guidelines.

Interim guidelines will be published

27. In December 2018, ACART agreed it would publish interim guidelines to enable ECART to consider more applications for donations and surrogacy. ACART reconsidered its earlier position, to not publish interim guidelines, on learning that ECART had recently had applications that could have been considered, and potentially approved, if amended guidelines were in place. Such interim guidelines do not require changes to the HART Order.

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4 Statistics New Zealand. 2013 Census QuickStats about culture and identity. URL: www.stats.govt.nz/Census/2013-census/profile-and-summary-reports/quickstats-culture-identity/birthplace.aspx (accessed 27 July 2017).

5 http://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart/advice-applications-fall-under-more

28. ACART also noted that interim guidelines would be useful as it could take a significant time before the fully amended guidelines would be available due to the standard process that must be followed after ACART advises the Minister about the planned new guidelines. That process would involve the Ministry of Health advising the Minister about ACART's recommendations, followed by changes to the HART Order, if the Minister and Cabinet agree. The publication of the final amended guidelines would only happen once Cabinet agreed to amend the HART Order.

Applications that fall under more than one of the guidelines

29. ACART issued advice to ECART in 2013 on applications that fall under more than one of the guidelines issued by ACART to ECART. When new guidelines are issued, ACART will decide if any changes need to be made to that advice.

30. A feedback form is provided separately. The consultation period ends on Monday, 25 March 2019.

2 Background: the regulatory setting for the guidelines

31. ACART's guidelines must be consistent with the HART Act and other relevant law. ACART can recommend to the Minister of Health that the HART Act or other enactment be amended if appropriate.[6] ACART can also recommend the Minister of Health change the status of procedures in the HART Order.[7]

32. This chapter describes and summarises the HART Act,[8] the HART Order,[9] the Code,[10] and the New Zealand Fertility Services Standard.[11] The chapter also notes other relevant legislation.

2.1 The HART Act

33. The HART Act is the key law regulating human assisted reproductive technology and human reproductive research in New Zealand. The HART Act aims to enable the appropriate use of assisted reproductive technology by providing a robust and flexible regulatory framework that protects the health, safety, dignity and rights of individuals (in particular women and children).[12]

34. The HART Act requires all assisted reproductive procedures to be approved by ECART on a case-by-case basis, unless the procedure is an 'established procedure'. Established procedures are listed in the HART Order.[13] ECART can only consider assisted reproductive procedures if guidelines issued by ACART relating to the procedure exist, and in accordance with any such guidelines.[14]

35. Part 3 of the HART Act sets out the information that must be collected about donors and the rights of donor offspring to access identifying information about donors held on the HART registers.

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6 HART Act section 5(1)(b)(i). Note that while the Minister of Justice is responsible for the HART Act, any ACART advice about the HART Act must go to the Minister of Health who is the Minister responsible for appointing ACART members.

7 HART Act section 6 and section 35(1)(b)(iii).

8 www.legislation.govt.nz/act/public/2004/0092/latest/whole.html

9 www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html

10 www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-(full)

11 www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/services-standards#fertility

12 HART Act section 3.

13 www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html

14 HART Act section 18(2) and section 19(2).

Principles of the HART Act

36. The HART Act contains important principles that guide the actions of everyone involved with human assisted reproductive technology and human reproductive research.[15] Anyone exercising powers or performing functions under the HART Act must be guided by each of the following principles, relevant to the particular power or function:

    a) the health and wellbeing of children born as a result of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure

    b) the human health, safety and dignity of present and future generations should be preserved and promoted

    c) while all types of individuals are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and wellbeing of women must be protected in the use of these procedures[16]

    d) no assisted reproductive procedure nor human reproductive research should be performed on an individual unless the individual has made an informed choice and given informed consent

    e) donor offspring should be made aware of their genetic origins and be able to access information about those origins

    f) the needs, values and beliefs of Māori should be considered and treated with respect

    g) the different ethical, spiritual and cultural perspectives in society should be considered and treated with respect.

Prohibited actions

37. One of the HART Act's purposes is to prohibit unacceptable assisted reproductive procedures and certain commercial transactions relating to human reproduction.[17] This is reflected in a number of specific prohibitions. These include sex selection of an embryo,[18] commercial surrogacy arrangements,[19] the commercial supply of human gametes and embryos[20] and the use of minors' gametes.[21] Schedule 1 of the HART Act lists other prohibited actions, including creating and using a cloned embryo.

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15 HART Act section 4.

16 This includes women who are surrogates.

17 HART Act section 3(b) and (c).

18 HART Act section 11.

19 HART Act section 14.

20 HART Act section 13.

21 HART Act section 12.

2.2 The HART Order

38. The HART Order identifies and describes the procedures that have been declared to be 'established procedures'. These are generally procedures that are done routinely during the course of fertility treatment and do not require ECART approval. Examples include in-vitro fertilisation (IVF) and collecting of sperm for donation purposes. There is no requirement that established procedures be reviewed by ECART, although a clinic can request a non-binding ethical view from ECART on cases involving an established procedure.

39. Part 2 of the HART Order excludes some procedures from being established procedures. This means that some procedures, which would otherwise be established procedures, require ECART approval. This is because such procedures are generally seen to be more ethically complex. They include:

- donations of gametes between certain family members
- family donations involving donors or patients under the age of 20 years
- the use of donated eggs in conjunction with donated sperm.

2.3 Code of Health and Disability Services Consumers' Rights

40. The Code applies to any person or organisation providing or receiving health and disability services in New Zealand. Rights 5, 6 and 7 of the Code give every consumer the right to effective communication, to be fully informed, to make an informed choice and to give informed consent.

41. While the Code does not address all aspects of assisted reproductive technology, any regulations or guidelines must be consistent with it.[22] ACART's 2016 advice to the Minister of Health (*Informed Consent and Assisted Reproductive Technology)* included recommendations that:

- consent, variation of consent and withdrawal of consent to an assisted reproductive process should be recorded in writing, where practicable and in accordance with best practice
- gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation or insemination
- gamete donors should continue to be allowed to place conditions on their donations
- the consent of a partner or family/whānau should not be required for gamete donation

[22] HART Act section 76.

- any amended and new requirements for informed consent in the context of human assisted reproductive technology should be included in the Fertility Services Standard.[23]

2.4 The New Zealand Fertility Services Standard

42. Providers of fertility services in New Zealand must operate in accordance with the safety and quality of fertility services requirements listed in the New Zealand Fertility Services Standard (the Standard). The Standard reflects the requirements contained in the HART Act. It is a form of regulation issued under the Health and Disability Services (Safety) Act 2001, against which providers are audited and certified.

2.5 Other relevant legislation

43. The legal status of children born as a result of assisted reproductive technology procedures is governed by the Status of Children Act 1969.[24] Under this Act, the woman who gives birth to a child is regarded in law as the child's mother. If that woman has a partner, the partner is regarded as a parent to the child. This means gamete and embryo donors do not have parental rights and obligations. Because the Act is focussed on the birth mother and her relationships, the legislation does not provide for single men or male couples becoming parents in this way. Their only means of becoming parents in the eyes of the law is by adopting the child. The same is true for heterosexual couples who become parents by means of surrogacy.[25]

44. The law also means that a child born from surrogacy is, in law, the child of the surrogate, regardless of whose gametes were used to create the embryo that the surrogate gestated. The Family Court must issue an adoption order under the Adoption Act 1955[26] to enable the intending parents to assume legal parenthood of a child born from surrogacy.

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[23] See: http://acart.health.govt.nz/system/files/documents/publications/informed_consent_and_assisted_reproductive_technology-oct16.pdf

[24] Status of Children Act 1969, section 13. The Act was amended in 2004 to extend the status of parent to a woman living as a de facto partner of the birth mother. The birth mother and her male or female partner will be the legal parents, even if neither person has a biological connection to the child. (See: www.legislation.govt.nz/act/public/2004/0091/latest/whole.html).

[25] Peart N. 2015. Alternative Means of Reproduction. In Skegg and Paterson (eds) *Health Law in New Zealand*, Wellington: Thomson Reuters (page 537).

[26] www.legislation.govt.nz/act/public/1955/0093/32.0/DLM292661.html

3 The biological link and consenting

45. In the 2017 consultation, ACART proposed removing the mandatory biological link and, having consulted the public, the intention is still to rescind it.

46. However, it was apparent from the submissions that some people had interpreted the consent provisions in ways ACART had not anticipated. Consequently, ACART has further amended the general consent requirements. ACART draws readers' attention to the implications of these changes.

47. In this chapter, ACART first summarises the rationale for removing the mandatory biological link, and the benefits and risks of doing so. ACART presents this explanation again as it is important that there is a common understanding of both the consent processes and the way in which the removal of the mandatory biological link affects those consent points.

3.1 The mandatory biological link was unjustified

48. The biological link policy requires that a child born from an assisted reproductive procedure must have at least one biological link (either genetic or gestational) to an intending parent.

- A *genetic* link means that the embryo used must be created by the sperm and/or eggs of the intending parents.
- A *gestational* link means that an embryo is gestated by a woman who is an intending parent.

49. The biological link policy was potentially discriminatory, in the sense that some people wishing to use certain procedures may have been unable to do so because of their biological or social circumstances.

50. While some forms of discrimination can be justified, ACART had concluded that the biological link policy would most likely fail the test of potentially being justified discrimination because the negative effects are disproportionate to the policy intent. (The policy intent being to protect a child's biological connection to its parents.) ACART considered that the guidelines should enable donation of surplus embryos created from donated gametes, provided ECART takes into account the potential complexity (especially for the offspring to navigate) of resulting relationships and that the gamete donors have consented to the donation.

51. ACART proposed changes to the guidelines to provide for the donation of surplus embryos created from donated gametes and for the re-donation of unused donated embryos. In addition, ACART proposed that the regulatory framework be amended to (i) ensure that all embryo donations be regulated by guidelines and (ii) clarify what counts as embryo donation.

52. The removal of the link means a greater range of donations could be made. Before consenting (or choosing not to consent) participants would need to understand a greater range of donation scenarios that might arise.

3.2 The donation scenarios that could occur

53. Rescinding the biological link policy means that, in addition to the cases it can already consider, ECART will be able to consider cases where:

- donated embryos would be used in surrogacy arrangements
- embryos created using donated eggs with donated sperm would be used in surrogacy arrangements (including embryos that were created without gametes from either intending parent)
- embryos are re-donated. This means that the embryos may be returned to the embryo donors, in accordance with earlier agreements between the affected parties, and donated to another party. The recipients of donated embryos could also donate the embryos if the original intending parents have no gametes in the embryos and no child(ren) using these embryos, and the recipients do have a child(ren) using the embryos. Any re-donation would require an application to ECART.

54. In all cases, gamete donors would need to have consented to the procedures.

55. In practice, these changes would mean that single people and same sex couples who are currently unable to gestate a baby themselves or to provide their own gametes will be able to use embryo donation, or donated eggs with donated sperm, with surrogates.

56. In many cases, the provision that limits full genetic siblings to no more than two families will preclude re-donation, because the first donation would have resulted in full genetic siblings in two families (i.e. the embryo donors and the first recipients). However, in cases where that hasn't happened, the proposal will provide for re-donation if the donors and/or recipients agree, at the time of donation or subsequently, to donate the surplus embryos.

Re-donation would be permitted

57. In 2017, ACART's consultation noted that rescinding the mandatory biological link policy raised the possibility that recipients of donated embryos might wish to 'on-donate' embryos they have not used. ACART proposed that on-donation would be precluded, even if the two families limit would not be breached. However, we now propose that the recipients of donated embryos can on-donate the embryos if the original intending parents have no gametes in the embryos and no child(ren) using these embryos, and the recipients do have a child(ren) using the embryos. The reasons for not allowing on-donation, in most cases, are as follows.

- On-donation would unduly compound the complexity of resulting relationships.
- The original embryo donors had the embryos created for themselves and therefore have a special interest in them. The original donors would select recipients who they believe are suitable potential parents of children who would be full genetic siblings of their own children. Conversely, if on-donation were possible, the original embryo donors might have little or no say in the choice of subsequent recipients.
- On-donation could result in offspring having concerns about their origins and identity.
- In contrast, in cases of **re**-donation the original embryo donors would continue to choose who receives their surplus embryos.

3.3 The benefits, risks and how they will be managed

58. With ACART removing the mandatory biological link, ECART is likely to receive an increase in more ethically complex applications than under the current guidelines. Having one set of guidelines will simplify the ethical review process and help clinics prepare applications to ECART.

59. Evidence indicates that, in general, people prefer to have as close as possible biological relationship to their children.[27] However, some medical or social circumstances will mean that the only way for an individual or couple to have a child is to use a surrogate mother in conjunction with a donated embryo or donated eggs/donated sperm.

Benefits

60. ACART considers that people who need or want to use an assisted reproductive procedure should be entitled to have their case considered by ECART. The change will give more options to people who wish to use ART.

61. Single people and same-sex couples also tend to prefer a child who is created using the sperm or eggs of the individual or one member of the couple. The use of third-party assistance to have a child is either a second choice or the only realistic option.

62. In addition, rescinding the biological link policy may encourage some people, who are currently excluded from fertility treatment in New Zealand, to remain in this country for their treatment. Treatment here offers the following advantages.

[27] See discussion about preferences in Van den Akker O. 2007. Psychological aspects of surrogate motherhood. *Human Reproduction* 13(1) 53–62. URL: https://academic.oup.com/humupd/article-lookup/doi/10.1093/humupd/dml039 (accessed 27 July 2017).

- The HART Act's provisions protect intending parents and resulting children.
- The intending parents can remain close to family and friend support networks.
- The intending parents do not incur overseas travel costs.[28]

Risks and their management

63. In the 2017 consultation, ACART noted that the HART Act includes the principle that children's health and wellbeing should be an important consideration. ACART also noted that children born from cases where there is no genetic link with the intending parents will have access to their genetic history on the HART register. In New Zealand, children born from surrogacy will have access to information about the surrogate mother under the provisions of the Adult Adoption Information Act 1985. Children who are born from surrogacy with no genetic link to their intending parents would need to access their full history using both the HART Act and the Adult Adoption Information Act because surrogates are not recorded on the HART register.

64. Whether a case includes a genetic or gestational link is only one of the factors that ECART will consider in making decisions on such cases. In making their decisions, ECART will consider all provisions in guidelines and information provided in applications.

65. Allowing procedures in which there would be no genetic or gestational link between the intending parents and offspring is likely to increase the social complexity and in cases involving surrogacy, also the legal complexity. It will also increase the number and complexity of relationships for all parties involved including any resulting children. These risks are intended to be managed through counselling and ethical oversight of the circumstances.

66. ACART anticipates that the number of applications to ECART that do not include either a genetic or gestational link will be low, given that most people's first choice is to have a genetic link to their children.

67. For these reasons, ECART must be satisfied that any application that does not include a genetic or gestational link is the best or only opportunity to have a child. ACART discusses the issue of justification to use a procedure later in this document.

3.4 ACART's proposed new provisions for consenting

68. All participants will need to understand a greater range of situations to which they could be asked to consent. Participants will have the same authority to choose whether or not to consent to specific procedures as they do now.

69. The amended guidelines would require gamete donors to always give informed consent to the procedures in which their gametes are to be or might be used. The

[28] http://acart.health.govt.nz/advice-minister-health-requirements-importing-and-exporting-vitro-gametes-and-embryos-human

consent may be at the time of donation or any time before the gametes or embryos created from the gametes are used in a specific procedure.

70. Related to the concept of biological link is the "two family limit" where full genetic siblings are produced in no more than two families. ACART proposes to continue to adopt the "two family limit" in the revised guidelines.

71. ACART also proposes that donated embryos must not be used in any procedure unless the person(s) for whom the embryos were originally created gives consent to that specific procedure at the time of donation or before donated embryos are used in the procedure, except where the donation is an on-donation in specific circumstances explained in the paragraphs 76 and again in paragraph 81.

Donors to consider how their gametes may be used

72. Where donated gametes are used, the donors become part of these relationships. ACART considers that gamete donors should make an informed choice about the specific use of their gametes, taking into account the long-term implications for themselves and their families.

73. In many cases, the specific consent ACART is proposing will already occur, for instance where a family or friend is donating sperm or eggs for an embryo to be used in a surrogacy. In other situations, a gamete donor may give consent to donate without considering the implications of the specific use. ACART's proposal will mean that:

    - donors would need to consent to specific uses at the time of donation, after receiving counselling about the implications; or
    - where consent is not given for a specific use at the time of donation, a clinic would need to contact the donor(s) to obtain specific consent to use an embryo created from their gametes in the planned procedure.

74. As is the case now, gamete donors will be able to change or withdraw their consent up to the point the gametes are used.

75. It is important that gamete donors be aware that an embryo might be donated and possibly re-donated and that they will have no say in any donation (other than through conditions they might have placed before their gametes are used).

First embryo donation

76. The original intending parents would have authority over the embryos that are created for them even when they have donated the embryos to recipients. This applies even if the original intending parents have no gametes in the embryos. This is the same as under the current guidelines. There is one exception to this position:

    - if the donated embryo was made from donated eggs and sperm, and
    - the original intending parents did not have a child from donated eggs and sperm from the same donors, and

- the first recipients did have a child from the donated eggs and sperm from the same donors.

77. In this case, the authority over the embryos shifts to the first recipients. In this situation, ACART considers the fact that the first recipients already have a child that will be a genetic sibling to any child born from the donated embryo gives them a stronger interest in what happens to it. Embryo donors will need to be aware of this when they consent to embryo donation.

Embryo re-donation — a new proposal

78. If the original intending parents:

- already **had** a child that would be a genetic sibling to a child born from the donated embryo and
- had donated their unused embryos and
- the first recipients did **not** have a child that would be so related

then the original intending parents can re-donate to second recipients. The original intending parents have authority over the embryos because they were created for them and they have a child who could have a full genetic sibling in a new recipient family. We expect this would be explained to any recipients of donations, so they understand the full implications in the consenting process.

79. If the original intending parents:

- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and
- had donated the unused embryos, and
- the first recipients also did **not** have a child that would be so related

then the original intending parents can re-donate to second recipients. Again, the original intending parents have authority over the embryos, because they were created for them.

80. If the original intending parents:

- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and
- the first recipients **did** have a child that would be so related

then both the first recipients *and* the original intending parents must consent to any re-donation because the original intending parents have authority over the embryos and the first recipients would potentially have a child with a full genetic sibling in another family.

81. If the original intending parents:

- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and

- did **not** have any **gametes** in the embryos, and
- the first recipients **did** have a child that would be so related,

then the authority to consent to re-donation should lie with the first recipients. This reflects their stronger interest in the embryos, as a result of the genetic relationship that would exist between their existing children and any child born from those embryos. This proposal is a new position for ACART and we invite comments.

82. Note that there will not be any cases of re-donation in which both the original intending parents and the first recipients have had children using full sibling embryos, because full siblings will not be permitted in more than two families.

3.5 Advice to the Minister of Health

83. In the event that ACART confirms its intention to amend the guidelines as described above, ACART would advise the Minister about the reasons for the amendments, as explained, such as the potentially discriminatory nature of some of the provisions in the current guidelines. ACART would also explain how the review and revision were conducted to ensure ACART's work is transparent.

Question 1: ACART proposes the following provisions for consent by gamete and embryo donors.

ECART must be satisfied that:

1. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) has given consent to the use of their gametes at the time of donation
2. implications counselling about the potential use of gametes was provided before the gamete donor gave consent
3. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)
4. where a procedure will involve the use of a donated embryo, consent to the use of that embryo must have been given by the people who originally had the embryo created for themselves:
   a) at the time of donation, or
   b) if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated
5. where a procedure will involve the use of a re-donated embryo, consent to the use of the embryo must have been given:
   - at the time of donation, or

- if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated

by

a) the people who originally had the embryo created for themselves whether or not they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and by

b) the first recipient(s) of the donated embryos if they have already had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated

but

a re-donation can only be made if either the original intending parent(s) or the first recipients have not had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos (i.e. the limit of two families that can have full genetic siblings applies)

6. all parties understand that, once an embryo is created, the authority to vary or withdraw consent up to the time the embryo is transferred to the womb remains with the person(s) for whom the embryos were created. However, **if** the original intending parents have no gametes in the embryos **and** they did not have a child(ren) using embryos that would be full siblings to those that would be born from the embryos being donated **and** the first recipients **did** have a child(ren) using embryos that would be full siblings to a child(ren) that would be born from the embryos being donated **then** the authority to consent is with the first recipients.

Do you agree with the proposed consent provisions?

Yes / No

Please give reasons for your views.

Question 2: ACART proposes a new position, in which the interest in and authority over embryos would switch to the first recipients of donated embryos if a) they have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated and b) the original donors do not have any gametes in the embryo(s) to be donated and c) the original embryo donors do not have a child(ren) using embryos that would be full siblings of the embryos.

Do you agree with this proposed provision for re-donation by recipients?

Yes / No

Please give reasons for your views.

4 Provisions applying to family gamete donation

84. In the 2017 consultation, ACART noted that New Zealand is unique in having guidelines about family gamete donations. ACART sought views about proposed advice that all family gamete donation cases should be subject to an ECART decision.

85. ACART understands from its first consultation that there is a clear preference that not all family gamete donations should be subject to ECART consideration.

86. ACART has concluded the inclusion of this proposed provision was disproportionate to the risk, has amended the proposal, and presents it for further comment by the public.

4.1 The current regulatory situation

87. Part 2(1)(a) of the HART Order says that where donors of eggs or sperm are family members, the procedure is not an established procedure. This reflects a general assumption that gamete donations between family members, while having benefits, also involve some particular risks.

88. The definition of 'family members' in clause 3 Interpretation of the HART Order is broad, interpreted as:

- any other person who is or has been related to the person by blood, marriage, civil union, de facto relationship, or adoption
- any other person who is a member of the person's whānau or other culturally recognised family group.

89. However, Part 2(2) of the HART Order sets out some family relationships that are not to be treated as a donation made by a family member. In summary, depending on whether eggs or sperm are donated and who is using the gametes, brother/sister/cousin gamete donations are established procedures.[29] The only exception is where, at the time of donation, the donor or the patient is younger than 20 years of age (Part 2(2A)). In these cases, ECART must decide all applications regardless of the family relationships involved.

[29] The summary reference to brother or sister donations should not be understood to mean that an embryo can be created from the gametes of a brother and sister. Part 2(2) of the HART Order sets out the details of brother/sister/cousin gamete donation. The guidelines include relationships from which an embryo must not be created. Note that, despite the wording in Part 2(c) of the HART Order that refers to donation of gametes by a patient's partner, a partner who contributes gametes is *not* a donor according to clause 3 (Interpretation) of the HART Order.

90. These regulations exist because family gamete donations can be ethically complex and some require ECART approval before proceeding.

4.2 ACART's proposal in 2017

91. In the 2017 proposal, ACART suggested that in cases involving the donation of gametes between family members that there should be three classes of donations. These classes were:

- prohibited donations, which would be determined by the HART Order
- established procedures, also determined by the HART Order
- assisted reproductive procedures i.e. procedures that would be subject to the guidelines.

92. For procedures that would be subject to guidelines ACART proposed one simple provision, that "Any other proposal for donating eggs or sperm between family members requires ethical approval."

4.3 Proposed change since the 2017 consultation

93. Having received submissions, ACART now proposes amendments to the original proposal for the provisions for family gamete donations. ACART particularly notes the points raised in the submissions that in many cases families would be able to manage risks while in other cases the clinics could manage risks.

94. ACART also concluded that there will still be some matters that should be subject to ECART consideration as they present certain risks. The provision for these matters needed to be amended.

Prohibited donations

95. The first amendment would be to extend the list of prohibited family gamete donations so that embryos cannot be created using the gametes of the specified closely genetically related family members. (See the proposed list of prohibited family gamete donations, under the heading "ECART must not approve," on page 6 of this document in the revised draft guidelines.)

Matters subject to ECART consideration

96. The second provision ACART has amended since the 2017 consultation is for cases involving donations of gametes between family members. In that provision ACART had suggested all such donations should be subject to ECART consideration.

97. ACART has now amended this provision so that the same cases of donation would be subject to ECART consideration as now. We no longer propose to remove the exception in the HART Order for brothers, sisters and cousins. This is a significant change from ACART's initial proposal and ACART would like to know if you agree (see question 4).

98. To be clear, ACART's position is that ethical approval will not be required for the following family donations.

- In the case of donated eggs, the donor is a sister or cousin of the recipient woman (where both are 20 years or older).
- In the case of donated sperm, the donor is a brother or cousin of the recipient woman's spouse or partner (where both are 20 years or older).
- In the case of a procedure that involves the use of the eggs of the female partner of the recipient woman and donated sperm, the sperm donor is a brother or cousin of the recipient woman (where both are 20 years or older).

99. The amended provision states that ECART must be satisfied that a) the parties are not subject to undue influence, and b) the health and wellbeing of the offspring and any other parties to the donation are not compromised by the procedure, including intergenerational complexity. This second provision is consistent with the existing provision for intergenerational concerns. (See provision 2 in the "Requirement" section for family gamete donations, on page 6 of this document.)

100. Intergenerational complexities include, but are not limited to:

- identity and psychological effects on the parties, especially
  - the offspring and the risk that the offspring will be uncertain about the generation which he or she belongs
  - how parties will relate to one another in the event a child is born with a substantial age difference to other siblings
  - the complexities of relationships that the child must navigate in the family
- interdependency between parents and children (e.g. mother and daughter)
- health and wellbeing of all parties (especially the offspring and birth mother)
- how the parties consent to procedures
- inheritance and property rights of the various parties.

4.4 Rationale for ACART's new position

101. ACART maintains its 2017 position that family gamete donations can pose risks as well as benefits for participating parties and the offspring. However ACART recognises feedback that ethical review of *all* family gamete donations would be disproportionate. Therefore, ACART does not propose changing that part of the HART Order.

102. ACART proposes extending the list of prohibited donations between specific family members who have a close genetic relationship (the specific members are listed in the provision). These additional prohibitions are made in order to minimise the risk of consanguinity (blood relationships) and allow for the management of cases that might contain such risks.

Risks and benefits associated with family gamete donations

103. Benefits of gamete donation between family members include a known donor, strengthening of family relationships, and maintaining whakapapa or ancestry within a family.

104. Risks include consanguinity and inheritance of family genetic conditions, confusion about relationships, and potential undue influence or emotional pressure.

105. Family gamete donations, regardless of the relationship between family members or whether the family members are of the same or different generations, can carry risks for the affected parties and resulting children. When the risks are significant, they are most appropriately managed by ECART's review and decision.

No increase in applications to ECART

106. ECART considers approximately five to ten cases a year involving family gamete donations. Under the revised guidelines, the number of cases involving family gamete donations needing ECART approval is likely to be the same as at present because ACART does not now propose changes to the Order that would result in more cases being subject to ECART consideration. This means that the guidelines would be applied to the same types of applications as they are now.

4.5 Advice to the Minister of Health

107. If ACART confirms its view that amendments are needed it would need to recommend to the Minister of Health, that the HART Order[30] be amended. The amendments would expand the list of prohibited family donations.

[30] HART Act section 35(1)(b)(iii).

Question 3: ACART proposes to extend the list of prohibited family gamete donations.

ACART proposes to extend the list of prohibited family gamete donations so that none of the specified closely genetically related family members can use ART.

Do you agree? Yes / No

Please give reasons for your views.

Question 4: ACART proposes not to amend the Order so that ECART is required to consider all between family donations.

Do you agree? Yes / No

Please give reasons for your views.

Question 5: ACART proposes that the guidelines should include the new requirements for cases involving donations of family gametes, in place of the provision that was consulted on in 2017.

ACART is of the view that, when ECART considers cases involving donations of family gametes, ECART should consider if there is evidence that a) parties are being subject to undue influence, or b) that the health and wellbeing of the offspring and any other parties to the donation are compromised by the procedure, including, for example, by intergenerational complexities.

Do you agree? Yes / No

Please give reasons for your views.

5 Clinic assisted surrogacy

5.1 The current situation

108. Neither the HART Act nor the HART Order defines the procedure of surrogacy. The HART Act defines a 'surrogacy arrangement' but refers to a legal agreement that is not enforceable,[31] rather than the procedure itself, facilitated by a fertility services provider where a woman gestates an embryo for intending parents.

109. The current guidelines clarify in the Preamble that the criteria apply only where a surrogacy involves an assisted reproductive procedure. Surrogacies currently requiring ECART approval are those that involve a clinic, where the embryo transferred to the surrogate has been created from:

- gametes (eggs and sperm) of two intending parents
- gametes of one intending parent (male or female) and a donor who is not an intending parent
- gametes of two donors, neither of whom is an intending parent (not currently allowed under the guidelines).

110. Importantly for this discussion, surrogacies in a clinic where the surrogate uses her own eggs (traditional surrogacies) are not subject to ECART approval. If a woman agrees to be a surrogate, using her own eggs and the sperm of the intending father or another man, the arrangement is an established procedure under the HART Order. Likewise, if the surrogate uses donated eggs and the sperm of her partner, such a surrogacy is also not subject to ECART approval.

111. If the eggs as well as the sperm are donated, as is often the case, it is an assisted reproductive procedure and therefore requires ECART approval. The reason for this is that an intending parent who contributes sperm or eggs to the gestated embryo is technically donating gametes to the surrogate.

5.2 ACART's proposal in 2017

112. ACART's 2017 consultation recommended that *all* clinic assisted surrogacies be subject to the guidelines and noted that definitions in the HART Order would need to be amended so that when one partner gives egg or sperm to the other partner this act would be a "donation" and therefore subject to the guidelines.

[31] HART Act section 14(1).

5.3 ACART's new proposals

113. ACART now intends to recommend a change to the Order to enable all clinic assisted surrogacies be deemed subject to the guidelines (rather than changing the definitions of who is a donor).

114. Also, ACART's 2017 draft guidelines had a provision stating that "the surrogate has completed her family before becoming a surrogate for others." ACART now proposes to remove this provision and instead include a provision that ECART be satisfied that the parties have considered the risks arising from the surrogacy including any risks to the future reproductive capacity of the surrogate.

115. Finally, ACART now proposes that the guidelines should include a provision about the residency of the parties being sufficient to protect the well-being of the offspring and the adult parties. This provision will give ECART the scope to consider whether the residency plans will make such protections available.

5.4 Rationale for ACART's new proposal

Make all clinic assisted surrogacies subject to ECART consideration

116. ACART maintains the position, stated in the 2017 consultation document, that all clinic assisted surrogacies should be subject to ECART consideration. To recap the reasoning:

- all surrogacies can be ethically complex
- the wellbeing of offspring depends on the relationship between the surrogate and intending parents proceeding as expected, and intending parents adopting the child
- surrogacy involves both a woman's choices about her body and the sometimes conflicting interests of the potential child and the intending parents
- surrogates could be subject to coercion or undue influence, particularly if the surrogacy occurs within a close family relationship between intending parents and the surrogate.

117. In addition to these observations, ACART also notes that if clinic assisted surrogacies were not subject to ECART approval, the management of those surrogacies would lie entirely with the clinics.

118. Using these new requirements, ECART will be able to manage risks consistently across all those surrogacies and will be able to focus on the ethical considerations in accord with the HART Act principles.[32]

[32] ACART notes that ECART is able to provide clinics with non-binding ethical advice about individual cases and has done so on occasions in regard to traditional surrogacies.

Replace "finish family" requirement with a requirement about risk awareness

119. A requirement that a woman must have finished her family before acting as a surrogate is not actually enforceable or measurable – a woman might have another child for herself after being a surrogate.

120. Having said this, ACART believes a woman should have *considered* the implications of not having finished her own family. Such a provision makes it clear that there are important matters for the parties to consider but at the same time it does not prohibit a woman from being a surrogate without first finishing her family.

121. The risks or factors ACART considered when reaching this position were:

- risks to the surrogate, in particular to her own health and wellbeing and the risk of not being able to have her own family, after being a surrogate, if being a surrogate leaves her infertile
- risks associated with pregnancy, childbirth and relinquishment of a resulting child to the intending parent(s)
- the risk that the intending parent(s) may change their mind about parenting a resulting child
- risks to the surrogate, offspring and intending parents, if the surrogate has not given birth before, and does not know how she will respond to pregnancy and birth
- undue influence
- differences in different family/friend circumstances
- informed consent and autonomy.

122. Consequently, ACART has proposed a provision that the surrogate should be aware of these risks.

123. ECART had stated its preference for a provision that gives a strong indication that it would be ideal to have finished one's own family first, but also gives ECART some discretion.

Include a residency provision

124. ACART proposes to include a provision about the parties having made plans that take into account the residency of those parties. The provision will require that these plans should be sufficient to protect the well-being of the offspring and the adult parties. The provision will give ECART the scope to consider whether the residency plans will make such protections available.

125. ACART decided to include this provision when confirming that it would rescind the mandatory biological link, because it noted the possibility that some children born to overseas surrogates could, in theory, be stateless.

126. Although ACART concluded that the removal of the mandatory biological link could in fact reduce the risk of statelessness, situations could still arise in which the offspring, intending parent(s) and surrogate could have limited, or no, ability to interact with one another.

127. ACART proposes that the "residency" provision should state that the residency plans of the parties should be a consideration for ECART to take into account rather than a requirement.

5.5 Impacts of ACART's new proposals

128. The new proposal, to replace the requirement that the surrogate have completed her family with a requirement that the risks be considered and regarded as justified, gives surrogates and the other parties to surrogacy, greater autonomy while still ensuring that risks are taken into account. From a practical perspective, the new wording is unlikely to change the number of people acting as surrogates.

129. ACART's new proposal to include a residency provision is also unlikely to have a bearing on the number of surrogacies, but it will give ECART an additional means for assessing the potential risks of the case.

5.6 Advice to the Minister of Health

130. If ACART confirms its view that these changes for clinic assisted surrogacy are needed, ACART would explain to the Minister of Health why they are being amended. ACART would also explain that the HART Order[33] should be amended to ensure that traditional surrogacies at clinics would be subject to ECART approval. The amendment will be to add to the Order that all clinic-assisted surrogacy arrangements are not established procedures.

[33] HART Act section 35(1)(b)(iii).

Question 6: ACART proposes that a change to the HART Order is the best way to ensure all clinic-assisted surrogacies be subject to ECART consideration.

ACART is of the view that the Order should be amended to state that all clinic assisted surrogacies should be subject to ECART consideration.

Do you agree? Yes / No

Please give reasons for your views.

Question 7: ACART proposes to remove the phrase "the surrogate has completed her family" and replace it with the phrase that asks parties to "consider the risks to the future reproductive capacity of the surrogate".

ACART is of the view that the revised provision manages the risks and does not contain the problematic (unenforceable) provision of requiring family completion.

Do you agree? Yes / No

Please give reasons for your views.

Question 8: ACART proposes to include a provision that ECART can take into account the participants' residency status and plans.

ACART is of the view that the revised provision gives greater protections to all parties involved.

Do you agree? Yes / No

Please give reasons for your views.

6 Glossary

This glossary relates solely to terms used in this document and defines those terms in relation to discussions in this document only. For this reason, it 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 HART Act. Members are appointed by the Minister of Health. For more information, see ACART's website at: acart.health.govt.nz
Assisted reproductive procedure	Under the HART Act, 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.
Clinic-assisted surrogacy	A procedure facilitated by a fertility clinic where a woman gestates an embryo for an intending parent.
Donated embryo	An in-vitro human embryo that is donated for reproductive purposes.
Donor	A person whose gametes or embryo are given to another person for use in assisted reproduction. See section 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.
Established procedure	Procedures declared in the Human Assisted Reproductive Technology Order 2005 (HART Order) that do not require ECART review and approval.
Ethics Committee on Assisted Reproductive Technology (ECART)	The Ethics Committee established under New Zealand's HART Act. 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. ECART members are appointed by the Minister of Health. For more information, see ECART's website at: 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 is available on ACART's website.

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.
Genetic link	A link created when the embryo used is created by the sperm and/or eggs of the intending parents.
Gestational link	A link created when the embryo used is gestated by a woman who is an intending parent.
Gestational surrogacy	A surrogacy where an embryo is transferred into the uterus of the surrogate and has no genetic link to the surrogate.
HART Act (2004)	The *Human Assisted Reproductive Technology Act (2004)* is 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.
HART Order (2005)	The *Human Assisted Reproductive Technology Order (2005)* is an Order in Council stating regulations associated with the HART Act.
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).
On-donation	A situation in which the recipients of donated embryos would donate surplus embryos to other recipients.
Re-donation	A situation in which surplus embryos are returned, by the recipients of those donated embryos, to the original intending parents and then donated by those original intending parents to a new intending parent or parents.
Surrogate	A woman who becomes pregnant, carries and delivers a child on behalf of another person or couple (intended parent(s)).
Te Ao Māori	A Māori world view or the Māori dimension of understanding.
Third-party assistance	Assisted reproductive procedures that require a party other than the intended parents to contribute to family formation and where a fertility services provider is involved.
Traditional surrogacy	Surrogacy where the eggs of the surrogate mother are used in conception (by in-vitro fertilisation or insemination).
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 kinship ties to other members.
Whanaungatanga	A relationship, kinship, sense of family connection, through shared experiences of working together, which provides a sense of belonging.

Appendix 1

Consent requirements proposed in the "Provisions that apply to all procedures covered in these guidelines" section of the draft guidelines presented in the 2017 consultation document

The numbering for these provisions in the draft guidelines began at number 12.

"ECART must be satisfied that:

12. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) has given consent to that specific use of their gametes:
    a. at the time of donation, or
    b. when a procedure using such an embryo is contemplated

13. in either case, implications counselling about the potential use of gametes was provided before the gamete donor gave specific consent

14. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)

15. in addition, where a procedure will involve the use of a donated embryo, the person(s) for whom the embryo was created must have given consent to the specific use of the donated embryo:
    a. at the time of donation, or
    b. when a procedure using such a donated embryo is contemplated

16. all parties understand that, once an embryo is created, the authority to vary or withdraw consent up to the time the embryo is transferred to the womb remains with the person(s) for whom the embryos were created."

Feedback form

Please provide your contact details below.

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

Privacy

We may publish all submissions, or a summary of submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

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

☐ Do not publish this submission.

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

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

If your submission contains commercially sensitive information, please tick this box:

☐ This submission contains commercially sensitive information.

Question 1: ACART proposes the following provisions for consent by gamete and embryo donors.

ECART must be satisfied that:

1. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) has given consent to the use of their gametes at the time of donation
2. implications counselling about the potential use of gametes was provided before the gamete donor gave consent

3. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)

4. where a procedure will involve the use of a donated embryo, consent to the use of that embryo must have been given by the people who originally had the embryo created for themselves:
   a. at the time of donation, or
   b. if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated

5. where a procedure will involve the use of a re-donated embryo, consent to the use of the embryo must have been given:
   - at the time of donation, or
   - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated

   by

   a. the people who originally had the embryo created for themselves whether or not they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and by
   b. the first recipient(s) of the donated embryos if they have already had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated

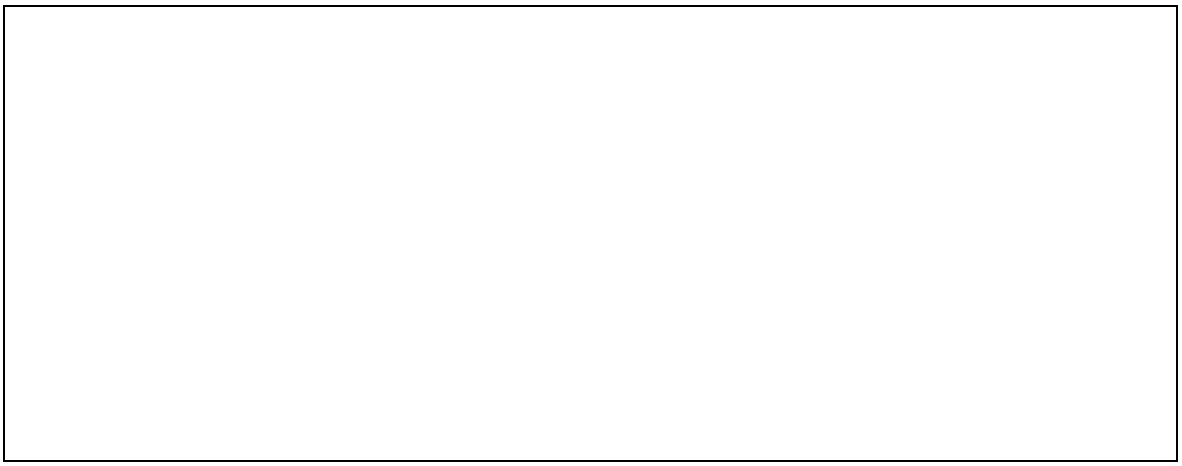
   but

   a re-donation can only be made if either the original intending parent(s) or the first recipients have not had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos (i.e. the limit of two families that can have full genetic siblings applies)

6. all parties understand that, once an embryo is created, the authority to vary or withdraw consent up to the time the embryo is transferred to the womb remains with the person(s) for whom the embryos were created. However, **if** the original intending parents have no gametes in the embryos **and** they did not have a child(ren) using embryos that would be full siblings to those that would be born from the embryos being donated **and** the first recipients **did** have a child(ren) using embryos that would be full siblings to a child(ren) that would be born from the embryos being donated **then** the authority to consent is with the first recipients.

Do you agree with the proposed consent provisions? Yes ☐ No ☐

Please give reasons for your views.



Question 2: ACART proposes a new position, in which the interest in and authority over embryos would switch to the first recipients of donated embryos if a) they have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated <u>and</u> b) the original donors do not have any gametes in the embryo(s) to be donated <u>and</u> c) the original embryo donors do not have a child(ren) using embryos that would be full siblings of the embryos.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 3: ACART proposes to extend the list of prohibited family gamete donations.

ACART proposes to extend the list of prohibited family gamete donations so that none of the specified closely genetically related family members can use ART.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 4: ACART proposes not to amend the Order so that ECART is required to consider all between family donations.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 5: ACART proposes the guidelines should include the new requirement, for cases involving donations of family gametes, in place of the provision that was consulted on in 2017.

Refer to section 4.

ACART is of the view that, when ECART considers cases involving donations of family gametes, ECART should consider if there is evidence that a) parties are being subject to undue influence, or b) that the health and wellbeing of the offspring and any other parties to the donation are compromised by the procedure, including, for example, by intergenerational complexities.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 6: ACART proposes that a change to the HART Order is the best way to ensure all clinic-assisted surrogacies be subject to ECART consideration.

Refer to section 5.

ACART is of the view that the Order should be amended to state that all clinic assisted surrogacies should be subject to ECART consideration.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 7: ACART proposes to remove the phrase "the surrogate has completed her family" and replace it with the phrase that asks parties to "consider the risks to the future reproductive capacity of the surrogate".

Refer to section 5.

ACART is of the view that the revised provision manages the risks and does not contain the problematic (unenforceable) provision of requiring family completion.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 8: ACART proposes to include a provision that ECART can take into account the participants' residency status and plans.

Refer to section 5.

ACART is of the view that the revised provision gives greater protections to all parties involved.

Do you agree? Yes ☐ No ☐

Please give reasons for your views.

Question 9: Do you have any other comments about the proposals in this document?