



**Advisory Committee on
Assisted Reproductive Technology**

**Proposed Donation Guidelines:
for family gamete donation, embryo
donation, use of donated eggs with
donated sperm and surrogacy**

Consultation Document

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www.acart.health.govt.nz





Foreword

This document seeks public feedback on the Advisory Committee on Assisted Reproductive Technology's (ACART's) proposal 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. We also seek feedback on ACART's 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.

In 1997, the then National Ethics Committee on Assisted Human Reproduction (NECAHR) introduced New Zealand's first guidelines for ethical review of clinic-assisted surrogacy. In the ensuing 20 years, the surrogacy guidelines have been revised and guidelines for sperm, egg and embryo donation have been introduced. The proposed new guidelines seek to reflect the 'robust and flexible' approach set out in the HART Act as well as society's acceptance of developments in assisted reproduction. Our proposals aim to balance the benefits and manage the risks with necessary safeguards for all parties, including any resulting children.

The most significant policy shift in the proposed guidelines is to rescind the biological link requirement currently in all four donation guidelines. ACART proposes that the guidelines no longer require intending parents to have a genetic or gestational link to a resulting child. Instead, we propose that where there is no such genetic or gestational link, the Ethics Committee on Assisted Reproductive Technology (ECART) must be satisfied that the procedure is justified based on the criteria set out in the guidelines. As a result of the proposed change, ECART could approve a surrogacy arrangement involving a donated embryo, or a donated embryo created from donated eggs and/or donated sperm. Despite this change, we consider that most intending parents will prefer to have a genetic or gestational link to resulting children.

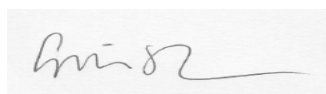
ACART has previously advised the Minister of Health on the issue of importing and exporting gametes and embryos. Broadening the scope of available assisted reproduction procedures will encourage New Zealanders to access such procedures in this country, with better safeguards and outcomes for resulting children. Treatment in New Zealand also avoids the pitfalls of trans-border reproduction such as difficulty in bringing offspring back to New Zealand.

This document also proposes expanding the scope of the guidelines. At present, not all family gamete donations, embryo donations and clinic-assisted surrogacies require ethical approval. It is our view that the potential ethical complexity of these procedures requires all cases involving these procedures to be subject to approval by ECART. We recognise the possible impacts of such a change, particularly for consumers, and seek your views on the proposal.

We appreciate the efforts many people and organisations make to provide valuable feedback to our public consultations and look forward to receiving your submission.



Alison Douglass
Outgoing Chair



Gillian Ferguson
Incoming 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. emailing a completed feedback form or your comments to acart@moh.govt, or
2. 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

We 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, we 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, 13 November 2017.

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Executive summary

1. The Advisory Committee on Assisted Reproductive Technology (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. This document seeks public feedback on ACART's proposed amended guidelines: replacing the four separate guidelines of family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm) and clinic-assisted surrogacy with a single set of guidelines that cover all four procedures.
2. The proposed guidelines include rescinding ACART's biological link policy, which requires that a child born from an assisted reproductive procedure must have at least one biological (genetic or gestational) link 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 must be gestated by a woman who is an intending parent.
3. Rescinding the policy would enable ECART to approve a surrogacy procedure involving a donated embryo, or an embryo created from donated eggs/donated sperm. The proposed guidelines require ECART to be satisfied that the circumstances of a case justify using the procedures in question, given the complexity of resulting relationships for the adult parties and any resulting children.
4. Another significant proposed change is to the criteria to use an assisted reproductive procedure. Embryo donation and donated eggs/donated sperm both currently require a medical reason to use the procedures. We propose that for all four procedures ECART should be satisfied that the procedure is the best or only opportunity for the intending parents to have a child and the intending parents are not using the procedure for social or financial convenience or gain.
5. Many provisions in the current guidelines are not changed in substance although wording may be amended.
 - Proposed consent provisions are more detailed.
 - Some substantial changes are proposed for embryo donation, enabling:
 - donation of embryos created from donated gametes
 - donors to re-donate to other intending parents any surplus embryos returned from initial intending parents.
6. ACART's role also extends to advising the Minister of Health about the regulatory status of procedures. We are inviting feedback about potential advice by ACART to the Minister of Health about the scope of cases covered by the family gamete donation, embryo donation and surrogacy guidelines. Some family gamete donations, embryo donations and surrogacy procedures within clinics currently do not require ethical approval. We are inviting feedback about our view that all cases involving

family gamete donation, embryo donation and surrogacy procedures within a clinic should be subject to approval by ECART in accord with ACART's guidelines.

7. In addition, we invite views about ways to enhance access by donor offspring to genetic history.
8. A feedback form is provided separately. The consultation period ends on **Monday, 13 November 2017**. ACART will consider public feedback in deciding what amendments should be made to the proposed guidelines. We will then consult the Minister of Health on the finalised guidelines as required by section 41(2) of the HART Act and then issue the amended guidelines to ECART. We will also decide if we will recommend to the Minister any changes that may require amending the HART Act or the Human Assisted Reproductive Technology Order 2005.

Summary of proposals (please refer to text for full proposals, rationales and impacts)

Proposals	
1	The guidelines should no longer require a gestational or genetic link between intending parents and a resulting child.
2	Options should be considered for ways to strengthen access by donor offspring to information about their origins held on birth certificates.
3	There should be one set of guidelines encompassing family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy.
4	ECART should be satisfied that a proposed procedure is the best or only opportunity for intending parents to have a child.
5	Where a procedure involves using an embryo created from donated eggs and/or sperm, the gamete donor must give consent to that specific use of their gametes.
6	ECART should take account of any factors in a relationship that might give rise to coercion.
7	There should be full genetic siblings in no more than two families.
8	For surrogacy, each party must receive independent legal advice. For other procedures, each party must have considered seeking independent legal advice.
9	All family gamete donation cases through a fertility services provider should be regulated by guidelines and thus require ECART approval.
10	ECART should be able to approve the donation of embryos created from donated gametes.
11	Surplus donated embryos should not be able to be on-donated by the recipients but can be returned to the donors for re-donation to another party, with a new application to ECART.
12	The regulatory framework should clarify that: <ul style="list-style-type: none"> • all embryo donation cases are regulated by guidelines and thus require ECART approval • embryo donation does not include cases where an embryo created for a couple is used by one of the couple in a new relationship with the informed consent of the previous partner.
13	All surrogacies through fertility services providers should be regulated by guidelines and thus require ECART approval.
14	Further comments are invited about any proposal in the document.

1 Introduction

9. 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 the consultation

10. This document seeks public feedback on 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. Our proposed guidelines comprise provisions applying to all the procedures, together with provisions specific to each procedure.
11. The guidelines we propose to amend and combine are:
- *Guidelines on donation of eggs or sperm between certain family members (2013)*
 - *Guidelines on embryo donation for reproductive purposes (2008)*
 - *Guidelines on the creation and use, for reproductive purposes, of an embryo created from donated eggs in conjunction with donated sperm (2010)*
 - *Guidelines on surrogacy involving assisted reproductive procedures (2013).*
12. The document also seeks feedback about what potential advice ACART should give to the Minister of Health about the scope of cases covered by the family gamete donation, embryo donation and surrogacy guidelines. Some family gamete donations, embryo donations and surrogacy procedures within clinics do not require ethical approval. We are inviting feedback about our view that all family gamete donation cases, embryo donation cases and surrogacies within a clinic should be subject to approval by ECART in accord with ACART's guidelines. Our 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).
13. In addition, we seek feedback on ways to enhance access by donor offspring to their genetic history.

14. We invite feedback on our proposals from interested parties using the separate feedback form. 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.

1.2 The proposed amended guidelines

15. The proposed amended guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy are set out below. We discuss the proposed format and amendments in later chapters.

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, with one function being 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.

Counselling requirements

ECART must be satisfied that counselling:

5. has been received by each party in accordance with the current Fertility Services Standard
6. will be available throughout the donation/treatment process
7. is culturally appropriate
8. has provided for whānau or extended family involvement
9. has provided for the inclusion of any existing children of the parties
10. has addressed any matters raised by donation(s) between family members
11. 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
- l. whether the potential genetic, social, cultural and intergenerational aspects of the proposed arrangement safeguard the wellbeing of all parties and especially any resulting child
- m. whether any relationships between the parties safeguard the wellbeing of all parties and especially any resulting children.

Consent requirements

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:
 - at the time of donation, or
 - 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:
 - at the time of donation, or
 - 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.

Legal advice requirements

ECART must be satisfied that:

- 17. where an application includes a surrogacy arrangement, each party has received independent legal advice
- 18. where an application does not include a surrogacy arrangement, each party has considered the option of seeking independent legal advice
- 19. any legal reports show that parties understand the legal implications of the procedure(s).

Health advice requirements
<p>ECART must be satisfied that:</p> <p>20. all parties have received independent medical advice</p> <p>21. health reports show the parties understand the health implications of the procedure(s).</p>

ADDITIONAL PROVISIONS THAT APPLY TO SPECIFIC PROCEDURES
Use of gametes donated between certain family members¹
<p>ECART must not approve:</p> <p>1. an application for donation where any resulting child would be formed by eggs and sperm respectively donated from:</p> <ul style="list-style-type: none"> • father and daughter • mother and son • brother and sister • grandfather and granddaughter • grandmother and grandson. <p>Notes</p> <p>Ethical approval is not required for the following family donations:</p> <p>a. in the case of donated eggs, the donor is a sister or cousin of the recipient woman (where both are 20 years or older)</p> <p>b. 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)</p> <p>c. 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).</p> <p>The HART Order defines a family member for the purposes of donation as:</p> <p>a. any other person who is or has been related to the person by blood, marriage, civil union, de facto relationship or adoption</p> <p>b. any other person who is a member of the person's whānau or other culturally recognised family group.</p> <p>Any other proposal for donating eggs or sperm between family members requires ethical approval.</p> <p>Additional requirements</p> <p>ECART must be satisfied that:</p> <p>2. affected parties have received joint counselling</p> <p>3. the relationship between the intending parent(s) and the other family members safeguards the wellbeing of all parties and especially any resulting offspring.</p>

¹ Our view, as discussed on pages 37 to 39, is that all family gamete donations through a fertility services provider should be regulated by guidelines. This would require additional changes to the guidelines.

Use of embryos created from donated eggs in conjunction with donated sperm
<p>Note</p> <p>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.</p>
Embryo donation and use
<p>Note</p> <ul style="list-style-type: none"> • Embryo donation includes: <ul style="list-style-type: none"> – the agreement to donate a stated number of surplus embryos – the transfer of control of the embryo(s) to the intending parent(s) – the transfer of an embryo into the uterus of the gestating woman (intending parent or surrogate). • Donated embryos: <ul style="list-style-type: none"> – can be relinquished back to the original intending parent(s) for a second donation ('re-donation'). This requires a new application to ECART – may not be donated by the recipient parent(s) ('on-donated') to any other party. <p>Additional requirements</p> <p>ECART must be satisfied that:</p> <ol style="list-style-type: none"> 1. all affected parties understand that 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. embryos being donated: <ul style="list-style-type: none"> • have been created for the donors' own fertility treatment • are surplus to the needs of the donor(s). 5. recipients have been vetted by the Police 6. the donors have completed their family or do not intend to have children.
Clinic-assisted surrogacy
<p>Notes</p> <ul style="list-style-type: none"> • For the purpose of these guidelines: <ul style="list-style-type: none"> – 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). • Commercial surrogacy is prohibited under the HART Act. • A surrogacy arrangement is not enforceable by or against any person.

Additional 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
 - 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 surrogate has completed her family before becoming a surrogate for others.

Additional counselling requirements

ECART must be satisfied that:

4. all affected parties have received joint counselling
5. in the opinion of the counsellor the wellbeing and welfare 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

16. In this section, we explain:

- 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.

1.3.1 ACART's statutory role

17. 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.
18. More information about ACART and the current guidelines can be found on ACART's website at: www.acart.health.govt.nz

1.3.2 The origins of this project

19. ACART issued separate guidelines from 2008 to 2010 to cover family gamete donation, embryo donation, the use of donated eggs with donated sperm and surrogacy. This followed the pattern established by the former National Ethics Committee on Assisted Human Reproduction (NECAHR) before the HART Act came into force in 2004.
20. In 2011, ACART received a complaint through the Human Rights Commission that the surrogacy guidelines discriminated on the basis of sex and sexual orientation. 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.
21. Under section 35(1)(a) of the HART Act, ACART is required to review its guidelines regularly. Thus 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.

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

22. In developing the proposed guidelines and advice, we have taken into account:
 - the principles of the HART Act, including the health and wellbeing of women and children; the right of donor offspring to access information about their genetic origins and the needs, values and beliefs of Māori

- other common ethical principles, including autonomy, wellbeing of families/whānau and transparency
 - wider 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, including on proposed surrogacy guidelines (in 2012) and on proposed advice on informed consent (in 2015)
 - evidence and information from local and international sources.
23. When considering these matters, we referred to ACART's 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

1.3.4 Cultural dimension

24. Compared with many countries, New Zealand has a strong commitment to enabling access to identifying information about gamete and embryo donors.³ From the late 1980s, well before the HART Act, fertility services providers began a policy of openness by requiring all sperm donors to be identifiable. Providers were also counselling intending parents who were using donated gametes about the importance of children knowing about their origins. This approach reflected changes in adoption legislation (the Adult Adoption Information Act 1985) and what had been learnt from the era of closed adoption: that it is important for people to have the option of accessing identifying information about their genetic origins.
25. The recognition of the centrality and 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.⁴

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

³ Daniels K, Douglass A. 2008. Access to genetic information by donor offspring and donors: medicine, policy and law in New Zealand. *Medicine and Law* 27 131–46.

⁴ Dyllal 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).

26. ACART makes no assumptions, however, that knowledge of a person's genetic origins requires that the offspring born from gamete and embryo donation need be genetically related to their intended parents. Children born through assisted reproductive technology may still learn their whakapapa and whanaungatanga through gamete and embryo donation without the need for a biological connection. The 'donation' may also be the gift of carrying a child for another by means of surrogacy, which has parallels with the Māori customary practice of whāngai.
27. 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. There is rarely one single viewpoint representative of Māori concerns, any more than there is a single religious or social viewpoint.
28. Nonetheless, the concept of Te Ao Māori (Māori world view) will have implications for the way we should consider these matters. For example, we have 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, in developing these guidelines.
29. The 2013 census found that just over one-quarter of people living in New Zealand were born in another country.⁵ 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. For example, we have 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.

1.3.5 Disability perspective

30. The Human Rights Act 1993 prohibits discrimination against individuals on the basis of disability. In addition, the United Nations Convention on the Rights of Persons with Disabilities, to which New Zealand is a signatory, requires that people with disabilities have access to information on the same basis as other members of society. Failure to provide information in accessible formats to people with disabilities may therefore be seen as a form of discrimination. Assumptions that people with disabilities are unable to cope with parenting may also constitute discrimination.

⁵ 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).

1.4 The process after this consultation

31. Following this consultation, ACART will consider public feedback and decide if any amendments should be made to the proposed guidelines. We 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.⁶ We will also decide if we need to recommend to the Minister any amendments to the HART Act or the HART Order and associated further changes to the guidelines.
32. 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.

⁶ <http://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart/advice-applications-fall-under-more>

2 The regulatory setting for the guidelines

33. 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.⁷ ACART can also recommend the Minister of Health change the status of procedures in the HART Order.⁸
34. This chapter describes and summarises the HART Act,⁹ the HART Order,¹⁰ the Code,¹¹ and the New Zealand Fertility Services Standard.¹² The chapter also notes other relevant legislation.

2.1 The HART Act

35. 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).¹³
36. 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.¹⁴ ECART can decide only cases involving assisted reproductive procedures, in accord with guidelines issued by ACART.¹⁵
37. 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.

⁷ 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.

⁸ HART Act section 6 and section 35(1)(b)(iii).

⁹ www.legislation.govt.nz/act/public/2004/0092/latest/whole.html

¹⁰ www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html

¹¹ [www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-\(full\)](http://www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-(full))

¹² www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/services-standards#fertility

¹³ HART Act section 3.

¹⁴ www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html

¹⁵ HART Act section 18(2) and section 19(2).

2.1.1 Principles of the HART Act

38. The HART Act contains important principles that guide the actions of everyone involved with human assisted reproductive technology and human reproductive research.¹⁶ 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 procedures¹⁷
 - 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.

2.1.2 Prohibited matters

39. One of the HART Act's purposes is to prohibit unacceptable assisted reproductive procedures and certain commercial transactions relating to human reproduction.¹⁸ This is reflected in a number of specific prohibitions. These include sex selection of an embryo,¹⁹ commercial surrogacy arrangements,²⁰ the commercial supply of human gametes and embryos²¹ and the use of minors' gametes.²² Schedule 1 of the HART Act lists other prohibited actions, including creating and using a cloned embryo.

¹⁶ HART Act section 4.

¹⁷ This includes women who are surrogates.

¹⁸ HART Act section 3(b) and (c).

¹⁹ HART Act section 11.

²⁰ HART Act section 14.

²¹ HART Act section 13.

²² HART Act section 12.

2.2 The HART Order

40. 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. ECART does not have a role in deciding established procedures, although a clinic can request a non-binding ethical view from ECART on cases involving an established procedure.
41. Part 2 of the HART Order excludes some procedures from being established procedures. This means that some the procedures, which would otherwise be established procedures, still 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

42. The Code extends 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.
43. While the Code does not address all aspects of assisted reproductive technology, any regulations or guidelines must be consistent with it.²³ 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 accord 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

²³ 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.²⁴

2.4 The New Zealand Fertility Services Standard

44. 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

45. The legal status of children born as a result of assisted reproductive technology procedures is governed by the Status of Children Act 1969.²⁵ 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.²⁶
46. 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 1955²⁷ to enable the intending parents to assume legal parenthood of a child born from surrogacy.

²⁴ See:
http://acart.health.govt.nz/system/files/documents/publications/informed_consent_and_assisted_reproductive_technology-oct16.pdf

²⁵ 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).

²⁶ Peart N. 2015. Alternative Means of Reproduction. In Skegg and Paterson (eds) *Health Law in New Zealand*, Wellington: Thomson Reuters (page 537).

²⁷ www.legislation.govt.nz/act/public/1955/0093/32.0/DLM292661.html

3 Proposed changes to the biological link policy

47. There are two overarching matters that ACART has considered in this review of guidelines: whether the guidelines should continue to incorporate a biological link policy and the format of proposed amended guidelines. We consider the biological link issue first because our views on that matter have contributed to the proposed new format for the guidelines.
48. As noted earlier, in 2013, ACART issued new surrogacy and family gamete donation guidelines. Both guidelines no longer require intending parents to have a medical reason for using the procedure, and the surrogacy guidelines no longer refer to an 'intending mother'. This approach has broadened the eligibility criteria for those wishing to apply for ECART approval. Now, ECART must be satisfied that the planned procedure is justified under the criteria in the guidelines.
49. Following this change, ACART then considered whether to amend the criteria for intending parents to use embryo donation and donated eggs/donated sperm. As part of this work, ACART has noted a source of potential discrimination in the guidelines: the biological link policy. This is an ACART policy and is not required by either the HART Act or the HART Order.
50. 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.
51. The policy is explicitly expressed in the surrogacy guidelines by the requirement that at least one intending parent must be the genetic parent of any resulting child. This means that surrogacy cannot take place with either embryo donation or donated eggs/donated sperm. Both of those procedures involve using an embryo that is created from gametes of two people who are not the intending parents. Therefore for embryo donation and donated eggs/donated sperm, an intending mother must gestate the embryo used.
52. ACART's proposed new guidelines no longer incorporate the biological link policy. Our view is that there are potentially two factors more significant for the wellbeing of children born from third-party assistance than how an embryo is created or gestated.

- Preparation before fertility treatment, when an individual or couple is looking at the implications for themselves and the child of having a child through gamete or embryo donation or using surrogacy.
- Once a child is born, the way in which the family deals with the child's identity.

3.1 The rationale for change

3.1.1 The guidelines exclude some individuals and couples from using assisted reproductive procedures to create a family

53. Evidence indicates that, in general, people prefer to have as close as possible biological relationship to their children.²⁸ 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.
54. Impacts of the biological link policy.
- Single men and male couples may not use embryo donation or donated eggs/donated sperm because they would require a surrogate mother.
 - Single women and partnered women (same sex or heterosexual) who are unable to gestate a pregnancy are also precluded from using embryo donation and donated eggs/donated sperm.
55. In such cases, people may decide to go overseas to use surrogacy in combination with an embryo created from donated eggs together with donated sperm.

3.1.2 There have been changes in technology, science and society

56. The reproductive technologies have expanded the opportunities for human reproduction. Until comparatively recently, adoption or other arrangements, such as whāngai, were the only options to parents where one of the couple was infertile. It is now possible to use donated eggs, sperm and embryos as well as surrogacy to create a family. As with adoption, these procedures separate genes from biological and gestational relationships. However, assisted reproduction can create relationships that bring increased complexity, depending on the number of parties involved in creating and gestating an embryo, further challenging the traditional concepts of family.

²⁸ 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).

57. While adoption is intended to meet the needs of an existing child, assisted reproduction may involve deliberately creating a child who will have no genetic link to one or both parents (in the case of a couple), and who may also have no gestational link to an intending mother. The changing biological and social factors brought about by using reproductive technologies have become intertwined. New ways of family formation are bringing complexity to how kinship and parent-child relationships are defined and experienced, for the parties involved and resulting children and within the wider culture.

3.1.3 The significance of biological relations varies according to circumstances and culture

58. There are debates about the meaning and significance of biological relationships for how families are created and children are raised. For instance, the European Society of Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law has argued:

The rights and obligations connected to a genetic connection is a matter to be decided by society, usually by means of legislation. Given the absence of a fixed meaning, it is ethical to enable families to be created in this way [gamete and embryo donation].²⁹

59. United Kingdom research found that different weight was given to genetic relationships in adoption and embryo donation.³⁰ While embryo donation parents viewed the donors as relatively unimportant to family life, the adoptive parents considered the birth parents to be important. The researcher concluded that the difference perspectives linked to the role of pregnancy and birth in the family's creation. With parents who had used a donated embryo, the mother was able to gestate the embryo. The adoptive parents were also raising a child who was not genetically theirs, but in contrast, the mother had not gestated the pregnancy. Australian research indicated that genetics was underplayed by women using donated eggs, while women who used a surrogate mother emphasised the importance of genetic kinship.³¹
60. In contrast, New Zealand research found that embryo donation parents are highly sensitive to the impact of their children's genetic history. This finding indicates that the cultural environment and regulatory requirements have an impact on the way genetic history and donors are considered.³²

²⁹ ESHRE Task Force on Ethics and Law. 2002. Gamete and embryo donation. *Human Reproduction* 17(5) 1407–8.

³⁰ MacCallum F. 2008. Embryo donation parents' attitudes towards donors: comparison with adoption. *Human Reproduction* 24(3) 517–23.

³¹ Kirkman M. 2008. Being a 'real' mum: motherhood through donated eggs and embryos. *Women's Studies International Forum* 31: 1241–8.

³² Goedeke S. 2014. Understandings and experiences of embryo donation in the New Zealand context. Unpublished PhD thesis, AUT University.

61. Kinship is significant in determining relationships and responsibilities, and may also bring customary and legal rights. New Zealand research relating to Māori reproduction, sexuality, maternity and adoption identified that the concept of whānau often transcends whakapapa and may include non-kin aligned through shared experience.³³
62. In 2005, the New Zealand Law Commission identified that bloodlines are important in many tribal or customary situations, rather than foster or adoptive lines, in determining status or tribal connection. As a result of statutory and judicial intervention, the default position was that the genetic line must be proven in order to gain identity as Māori and to gain rights in respect of significant resources.³⁴
63. It is likely that Māori who are closely related to their iwi already take into account any implications that arise from using assisted reproduction to create a family. To preserve the integrity of whakapapa, many Māori are likely to make arrangements from within their own environments. Informants in the New Zealand Law Commission's research told of lesbian couples who they believed used sperm from a whānau member of the partner to achieve a pregnancy.
64. A South African writer, critiquing the South African requirement for at least one intending parent to be a genetic parent, argues that there is no evidence of harm to children conceived using donated gametes and that communal relationships are of more importance than genetic relationships.³⁵

3.1.4 Children have interests to be protected

65. Children's welfare: The HART Act includes the principle that children's health and wellbeing should be an important consideration. A growing number of children are being born through the donation of gametes (sperm or egg) or embryos, or a surrogate carrying a pregnancy for another woman, thus creating families in which the children lack a gestational and/or genetic relationship with one or both parents. Research on these families suggests that concerns about adverse outcomes for parenting and child development are largely unfounded. Although less is known about non-traditional families formed through reproductive donation than about traditional families, it is believed that these new family types are not at any greater risk of parenting or child-adjustment problems than the traditional family make-up.³⁶

³³ Le Grice J. 2014. Māori and reproduction, sexuality education, maternity and abortion. PhD thesis, University of Auckland. URL: <https://researchspace.auckland.ac.nz/handle/2292/23730> (accessed 27 July 2017).

³⁴ New Zealand Law Commission. 2005. *New Issues in Legal Parenthood*. Wellington: Law Commission. URL: www.nzlii.org/nz/other/nzlc/report/R88/R88.pdf (accessed 27 July 2017).

³⁵ Metz T. 2014. Questioning South Africa's 'genetic link' requirement for surrogacy. *SAJBL* 7(1): 34–9.

³⁶ Golombok S. 2013. Families created by reproductive donation: issues and research. *Child Development Perspectives* 7(1): 61–5.

66. Access to information by donor offspring: Another HART Act principle is that donor offspring should be made aware of their genetic origins and be able to access identifying information. We recognise our proposals might introduce added complexity in some cases. However, we believe the process can be managed by intending parents and other parties considering the implications carefully before proceeding and the resulting child learning about their history at an early age. Research from the United Kingdom concluded that early age and the process of disclosure were likely to be critical factors in a child accepting their history.³⁷
67. Children born from cases where there is no genetic link with the intending parents will have access to their genetic history, which will be held on the HART register, as provided for Part 3 of the HART Act. This is already the case for children born from embryo donation and donated eggs/donated sperm.
68. 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.
69. Intending parents generally appreciate the importance of their children knowing about their history. However, while the HART Act principle says that donor offspring should have access to information about their origins, it is not possible to enforce the principle without unduly intruding on the rights of parents to make decisions about what their children are told.
70. The question of access to information was considered by the New Zealand Law Commission in its 2005 report *New Issues in Legal Parenthood*.³⁸ The Law Commission considered ways of enhancing donor offspring's access to information without intruding on family life. They recommended all birth certificates be amended to include a statement indicating that the Births, Deaths and Marriages register contains other information that may be accessed by the certificate's owner. In addition, Births, Deaths and Marriages should consider allowing parents to choose to have an annotation stating that the certificate's owner was born by 'donor'.
71. The Government of 2005 felt that further policy work was needed on this recommendation.³⁹ However, the Government has not progressed consideration of the recommendation.

³⁷ Ilioi EC, Golombok S. 2015. Psychological adjustment in adolescents conceived by assisted reproductive techniques: a systematic review. *Human Reproduction Update* 21(1): 84–96.

³⁸ New Zealand Law Commission. 2005. *New Issues in Legal Parenthood*. Wellington: Law Commission. URL: www.nzlii.org/nz/other/nzlc/report/R88/R88.pdf (accessed 27 July 2017).

³⁹ Government Response to Law Commission Report on New Issues in Legal Parenthood. URL: <https://www.justice.govt.nz/assets/Documents/Publications/Government-Response-to-Law-Commission-Report-on-New-Issues-in-Legal-Parenthood.pdf> (accessed 28 July 2017).

72. ACART is interested in your feedback on potential strategies to strengthen offspring access to information about their origins. We will then consider whether to provide advice to the Minister of Health on the issue, in accord with our statutory role of providing advice to the Minister on aspects of, or issues arising out of, kinds of assisted human procedure or human reproductive research.⁴⁰

3.1.5 Other jurisdictions that provide for surrogacy using an embryo created from donated gametes

73. The regulatory frameworks for assisted reproduction in the United Kingdom and Victoria, Australia, are based on similar principles to the HART Act. In the United Kingdom, a surrogate can gestate an embryo created from donated eggs and donated sperm. Where the intending parents are the genetic parents of a resulting child born to a surrogate, the intending parents may apply for a parental order. If the intending parents are not the genetic parents of a resulting child, the intending parents must apply for an adoption order.
74. In Victoria, Australia, a surrogate can gestate a donated embryo or an embryo created from donated eggs and donated sperm.

3.1.6 The policy is discriminatory, and the discrimination is not justified

75. Infertility, and the state of unwanted childlessness, is a form of disability. If ACART wished to retain the biological link policy in any or all of the guidelines that involve third-party assistance to have a child, it would need to consider the justification in accordance with the New Zealand Bill of Rights Act 1990 (NZBORA). The NZBORA applies to the government and also people and bodies that perform lawful public functions, powers or duties (section 3). The NZBORA therefore applies to ACART guidelines.
76. We have 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 negative effects include precluding infertile men (single or male couple) from surrogacy, which may be their only opportunity to have a child. Moreover, infertility is a disability, and the policy exacerbates the effects of the disability.

⁴⁰ HART Act section 35(1)(b).

3.2 Impacts of rescinding the biological link policy

77. The key impact will be the potential for ECART to approve applications that involve combinations of procedures that ECART cannot currently approve. These include applications for:
- surrogacy using a donated embryo
 - surrogacy using an embryo created from donated eggs/donated sperm.

3.2.1 Benefits

78. Most heterosexual couples who want to become parents want to have a child who is created from their genes and is gestated by the mother. Single people and same-sex couples also want a child who is created using the sperm or eggs of the individual or one of the couple. The use of third-party assistance to have a child is either a second choice or the only realistic option.
79. We consider that it is fair to enable all people who need or want to use an assisted reproductive procedure to have their case considered by ECART. There is no evidence that groups that are currently excluded from using assisted reproduction in certain circumstances (eg, male couples or single men who are unable to use their own sperm; heterosexual couples who are unable to use their own gametes and women who are unable to carry a pregnancy) pose a risk to the health and wellbeing of children. If the biological link policy is rescinded, ECART will be able to approve cases that involve surrogacy and embryo donation or donated eggs/donated sperm, provided they are satisfied that the circumstances of the specific case justify using the procedures in question.
80. 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 in New Zealand, as noted in ACART's 2015 *Import/Export Advice*, offers the following advantages.
- 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.⁴¹

⁴¹ <http://acart.health.govt.nz/advice-minister-health-requirements-importing-and-exporting-vitro-gametes-and-embryos-human>

3.2.2 Risks

81. All cases subject to ECART approval are already ethically complex. Allowing procedures that provide no genetic or gestational link between the intending parents and offspring will increase the ethical complexity and introduce legal complexity, in particular in cases using surrogacy.
82. Such procedures will also increase the number and complexity of relationships for all parties involved and any resulting children.
83. The HART Act prohibits valuable consideration for surrogates and gamete donors. However, commodification can occur without valuable consideration being involved. There is a risk that children could be seen/treated as commodities to be created from eggs, sperm and a uterus outside the context of an ongoing relationship between parties.⁴²
84. For these reasons, ECART must be satisfied that any application that does not include a genetic or gestational link is justified. We discuss the issue of justification to use a procedure later in this document.

3.2.3 ECART decisions

85. The matter of whether a case includes a genetic or gestational link between intending parents and a resulting child 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.
86. We anticipate 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.

3.2.4 ACART advice to ECART

87. When issuing new guidelines, ACART will review their 2013 advice to ECART on *Applications that fall under more than one of the guidelines issued by the Advisory Committee on Assisted Reproductive Technology*.⁴³ This will not require public consultation since such advice does not create new policy but clarifies existing policy.

⁴² Legge M, Fitzgerald R. 2016. Valuing embryos as both commodities and singularities. *New Zealand Medical Journal* 129 (1431). URL: <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1431-11-march-2016/6835> (accessed 28 July 2017).

⁴³ ACART. 2013. *Applications that fall under more than one of the guidelines issued by the Advisory Committee on Assisted Reproductive Technology*. Wellington: ACART. URL: <http://acart.health.govt.nz/publications-and-resources/guidelines-and-advice-issued-ecart/advice-applications-fall-under-more> (accessed 28 July 2017).

Question 1: Rescinding the biological link policy

ACART is proposing that:

- the guidelines should no longer require intending parents to have a genetic or gestational link to a resulting child
- instead the guidelines should require ECART to be satisfied that where intending parents will have neither a genetic nor a gestational link to a resulting child, the lack of such links is justified.

Do you agree? Yes/No

Do you believe there are any cultural implications associated with the proposed removal of the biological link policy? If so, please describe these implications.

Please give reasons for your views.

Question 2: Access to information held on birth certificates

ACART is interested in hearing views about potential strategies to strengthen access by donor offspring to information about their origins, which is held on their birth certificates.

Do you have suggestions? Yes/No

Please give reasons for your views.

4 Common provisions in the new guidelines

88. Since 2008 ACART has issued separate guidelines for each assisted reproductive procedure, following the pattern established by the former NECAHR. The HART Act, however, does not require ACART to issue separate guidelines. Instead, the Act refers to ACART issuing 'guidelines ... to ECART relating to any kind of assisted reproductive procedure'.⁴⁴
89. We propose to bring four procedures under one set of guidelines: family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy.
90. In this chapter, we discuss the proposed provisions that are common to all four procedures. In subsequent chapters, we discuss provisions that apply to only one of the procedures.
91. Please note that, while ACART is proposing some amendments to matters outside the guidelines, the proposed guidelines are consistent with the current HART Act and HART Order.

4.1 Rationale for the proposed change to the format of guidelines

92. **Increasingly complex cases:** ACART and ECART's work began in late 2005. At that stage, the procedures were distinct, with little overlap apart from all guidelines recognising the principles of the HART Act. Even counselling, while a shared feature, has different requirements for the different procedures. However, it soon became apparent that some cases coming to ECART fell across more than one procedure: for instance, a family gamete donation might be part of a surrogacy. ACART addressed these situations by advising ECART that the provisions in the relevant guidelines should apply when ECART considered cases involving more than one procedure, for example, a surrogacy where the gestated embryo used eggs or sperm donated by a family member (where the relationship falls under the scope of the family gamete donation guidelines).

⁴⁴ HART Act section 35(1)(a).

93. If the biological link is rescinded, ECART is likely to receive some applications which are more complex in terms of the procedures and resulting relationships. For instance, they could receive an application that involves surrogacy, donated eggs/donated sperm and family gamete donation. We believe one set of guidelines will simplify the ethical review process and help clinics prepare applications to ECART.
94. **Inconsistent language:** In some cases, the separate guidelines have similar provisions that use different words to describe processes and ethical issues. A single set of guidelines allows us to identify core provisions that apply to all procedures and develop a level of common language to be used in those provisions that are specific to particular procedures.

4.1.1 Impacts of the proposed format

95. ECART will still need to consider an extensive range of matters. However, the guidelines will be easier to manage as cases that involve more than one procedure will no longer need to cross-reference to separate guidelines.
96. ECART publishes application forms on its website and, as with any new guidelines, will need to design a new application form for clinics to use.

Question 3: Format of the proposed guidelines

ACART is proposing to issue one set of guidelines to ECART that encompass family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy.

Do you agree with the format of the proposed guidelines? Yes/No

Please give reasons for your views.

4.2 Provisions applying to all procedures

97. The proposed provisions that will be applicable to all procedures include counselling provisions that do not substantially differ from the counselling provisions in current guidelines. The 'residency' requirement in two of the current guidelines has been replaced by the provision in the current surrogacy and family gamete donation guidelines which focuses on future contact. This shifts the emphasis to the long-term relationship, regardless of geographic proximity.
98. In the rest of this chapter, our discussion focuses on provisions that are substantially changed or where clarification is needed. This includes:
- justification to use a procedure
 - consent by gamete donors

- potential coercion
- number of families with full genetic siblings.

4.2.1 Justification to use a procedure

99. ECART should feel assured that the proposed procedure is the best or only opportunity for intending parents to have a child and that the intending parents are not using the procedures for social or financial convenience or gain.
100. In 2013, ACART amended the surrogacy and family gamete donation guidelines to remove medical criteria for intending parents. In contrast, the current embryo donation and donated eggs/donated sperm guidelines have medical criteria for the use of the procedures. We are of the view that those procedures should be consistent with the eligibility criteria for the surrogacy and family gamete donation.
101. The new guidelines criteria recognise that there is not always a medical need for following a particular procedure. It makes all four guidelines consistent in terms of the justification for using a particular procedure. However, ECART must still be satisfied that the use of the procedures is justified.

4.2.2 Rationale for our proposal

102. The proposed rescinding of the biological link policy allows the guidelines to take account of the diversity of circumstances that may necessitate third-party assistance to have a child and the potential combinations of procedures that may be involved in a case.

4.2.3 Impacts of the proposal

103. **Justification to use a procedure:** ECART would still need to decide that the use of a procedure is justified, whatever the stated need. In making its decisions, ECART takes account of all provisions in the guidelines.
104. **Provide for cases where donated sperm was not available:** The removal of the medical criteria for using a donated embryo would provide for any cases where a lesbian couple or a single woman could not access donated sperm through a clinic but was offered a donated embryo. Embryo donation for these women might, in some cases, reduce the incentive to use donated sperm outside a clinic setting.
105. **Provide for cases where intending parents are currently excluded from using embryo donation:** Single men and male couples would also be able to seek ECART approval to use embryo donation and donated eggs/donated sperm because such parties would need to use surrogacy in order to use a donated embryo or an embryo created through donated eggs/donated sperm.

106. **Donated eggs/donated sperm would continue to be used for medical reasons:**
We have not been able to identify any scenarios where individuals or couples would seek to use the procedure without a medical reason. For example:
- a. a single man would need a surrogate to gestate an embryo created from donated eggs in conjunction with donated sperm. Presumably he would use his own sperm, if possible. Medical reasons that might mean the man was unable to use his own sperm include infertility, inheritable genetic condition, etc
 - b. a male couple would also need a surrogate to gestate an embryo created from donated eggs in conjunction with donated sperm. And as with a single man, the couple would presumably want to use their own sperm unless there were a medical reason why neither could do so
 - c. the removal of the biological link policy will mean that there is potential for women (whether single or in a couple) to use a surrogacy with donated eggs/donated sperm if the women are unable to gestate the pregnancy themselves.
107. ACART has taken into account both the broader question of consistency across guidelines and the interrelationships between guidelines in rescinding the biological link. Moreover, we recognise that regardless of the reasons people wish to use any procedure, ECART makes an ethical decision based on all the circumstances for each case.

Question 4: Justification to use a procedure

ACART is proposing that ECART should be satisfied the proposed procedure is the best or only opportunity for intending parents to have a child and the intending parents are not using the procedures for social or financial convenience or gain.

Do you agree? Yes/No

Please give reasons for your views.

4.3 Consent by gamete donors

108. We are proposing, in accordance with our advice to the Minister of Health on informed consent,⁴⁵ that the guidelines should require gamete donors to always give informed consent to the specific procedures in which their gametes are to be or might be used. The 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.

⁴⁵ See:

http://acart.health.govt.nz/system/files/documents/publications/informed_consent_and_assisted_reproductive_technology-oct16.pdf (accessed 28 July 2017).

109. We also propose 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.

4.3.1 Rationale for our proposal

110. Donated gametes can already be used in different procedures. However, rescinding the biological link policy expands the potential combination of procedures. Rescinding the policy will also enable ECART to decide cases where a donated embryo is to be used with surrogacy. In some cases, the donated embryo could have been created from donated eggs and/or donated sperm.
111. Third-party assistance to have a child creates potentially long-lasting relationships between the parties concerned and resulting children. Where donated gametes are used, the donors become part of these relationships. Our proposed guidelines may result in children being born as a result of increasingly complex procedures, for instance surrogacy using donated eggs/donated sperm.
112. Our proposal is consistent with a provision in the Fertility Services Standard requiring potential donors to be informed of the options of placing boundaries on the use of their gametes (section 1.11.1(j)). We consider 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.

4.3.2 Impacts of our proposal

113. **Donors to consider how their gametes may be used:** In many cases, the specific consent we are 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. Our 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.

Question 5: Consent by gamete and embryo donors

ACART is proposing that where a procedure will involve the use of an embryo created from donated eggs and/or donated sperm, the gamete donor(s) must have given consent to the specific use of their gametes:

- at the time of donation; or
- when a procedure using such an embryo is contemplated.

In either case, the affected parties should receive counselling, on the implications of using gametes, before the gamete donor gives consent.

If consent is given, the gamete donor can vary or withdraw their consent only up until an embryo is created (in cases where consent is given before the embryo is created).

In addition, where a procedure will involve the use of a donated embryo, the person(s) for whom the embryo was created must give consent to the specific use of the donated embryo:

- at the time of donation; or
- when a procedure using such a donated embryo is contemplated.

Once an embryo is created, the decision to vary or withdraw consent up to the time the embryo is transferred to the womb should remain with the people for whom the embryos were created.

Do you agree? Yes/No

Please give reasons for your views.

4.4 Potential coercion

114. We propose to strengthen the guidelines by explicitly requiring ECART to take account of any factors in a relationship that might lead to coercion or unduly influence the consent of a party to a procedure.

115. Most cases will not involve coercion. Some circumstances, however, could contribute to individuals feeling obliged to donate gametes or be a surrogate in order to help a family member or other person/s to have a child. Examples are:

- a daughter donating eggs to a mother who is no longer fertile but wants to have a child with a new partner (as has been the case in some applications to ECART). (If the daughter is fairly young, she may still be dependent on her mother for financial support and/or accommodation)
- where there are no clinic donations by donors from particular cultural groups, and the extended family appears to be the only potential source of donated gametes
- where an intending parent and a donor are in an employment or other contractual relationship.

4.4.1 Rationale for the proposal

116. The current family gamete donation and embryo donation guidelines both refer to the risk of coercion. An important aspect of informed consent regarding donation between family members is that the decision to donate is made voluntarily. While all current guidelines require ECART to consider the matter of informed consent, we believe the guidelines should go further to require consideration of any circumstances that may have unduly influenced a donor or surrogate.
117. Our proposal is consistent with Right 2 of the Code (Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation). Right 2 says that every consumer has the right to be free from discrimination, coercion, harassment and sexual, financial or other exploitation.⁴⁶

4.4.2 Impact of the proposal

118. Applications to ECART already include considerable information about the relationship between the parties involved. The provision would signal that applications should explicitly address any circumstances that might give rise to a person feeling obliged to be a donor or surrogate.

Question 6: Taking account of potential coercion

ACART is proposing that ECART should take account of any factors in a relationship that might give rise to coercion or unduly influence the consent of a donor or surrogate to a procedure.

Do you agree? Yes/No

Please give reasons for your views.

4.5 Number of families with full genetic siblings

119. The current embryo donation guidelines and the guidelines for the use of donated eggs with donated sperm both require that full genetic siblings be limited to no more than two families. Section 1.11.1(i) of the Fertility Services Standard requires that donated gametes and the embryos created from them shall not be used for treatment once children have been born to the number of families specified in the relevant guidelines or legislation.⁴⁷

⁴⁶ Code of Health and Disability Services Consumers' Rights Regulation 1996. URL: www.hdc.org.nz/the-act-code/the-code-of-rights (accessed 28 July 2017).

⁴⁷ www.health.govt.nz/system/files/documents/pages/nzs_8181-2007.pdf

120. Our proposal to rescind the biological link policy, coupled with our proposal (discussed later) that ECART should be able to approve the donation of embryos created with donated gametes, has the potential to increase the complexity of resulting relationships. Therefore, we propose a general provision requiring full genetic siblings should exist in no more than two families.

4.5.1 Rationale for the proposal

121. The current provisions that limit full genetic siblings to a maximum of two families exist to manage the number and complexity of relationships between parties and to ensure the risk of consanguinity (blood relationships) is minimised. The proposed changes noted above mean that the issue should be considered for all applications where embryos are to be or have been created.

4.5.2 Impact of change

122. Applications to ECART, where relevant, will need to include information about any existing children who would be full genetic siblings of any children born from a procedure.

Question 7: Limit to number of families with full genetic siblings

ACART is proposing that full genetic siblings should continue to be limited to no more than two families.

Do you agree? Yes/No

Please give reasons for your views.

4.6 Legal advice to parties

123. The current surrogacy and embryo donation guidelines both require affected parties to have received independent legal advice. We are now proposing that independent legal advice must be received by the affected parties only where a case involves surrogacy. Where a procedure does *not* involve surrogacy, we are proposing that ECART should take account of whether each affected party has considered seeking independent legal advice. It is not uncommon for ECART to request further information or reports from the various professionals involved. In some cases, ECART may request that the parties obtain legal advice before proceeding further with their application.

4.6.1 Rationale for the proposal

124. When a child is born from a surrogacy, the surrogate is the legal mother and the transfer of legal parenthood to the intending parents will be by an adoption order issued by the Family Court. It is therefore important that all affected parties understand the legal implications of surrogacy and adoption, given the interface with the Adoption Act 1955 and the Adult Adoption Information Act 1985.
125. Where a surrogacy arrangement is not part of a case, the legal parenthood issues are more straightforward. An intending mother who gives birth to a child is a legal parent, in accord with the Status of Children Act 1969. We consider, however, that when surrogacy is not part of a case, each affected party should have considered the merits of receiving independent legal advice. There may be particular circumstances where a party wishes to consider any legal issues associated with a procedure, for example, implications for estate planning.

4.6.2 Impacts of our proposal

126. Applications to ECART for cases involving surrogacy will continue to include independent legal reports for the parties, indicating that they understand the legal implications of the procedure. Where the case does not involve surrogacy, ECART must be satisfied that the affected parties have considered seeking legal advice.
127. We expect that in most cases that do not involve a surrogacy, the affected parties will not wish to seek legal advice. When considering an application, if ECART is of the view that a party's interests would be better served by receiving legal advice, members could request a report of such advice. Section 19(4) of the HART Act requires ECART to impose any conditions to ensure that the informed consent of any person is obtained before a procedure takes place.

Question 8: Legal advice

ACART is proposing that ECART must be satisfied that:

- where an application includes a surrogacy arrangement, each affected party has received independent legal advice
- where an application does not include a surrogacy arrangement, each affected party has considered seeking independent legal advice
- any legal reports show that all affected parties understand the legal implications of the procedure(s).

Do you agree? Yes/No

Please give reasons for your views.

5 Provisions applying to family gamete donation

128. New Zealand is unique in having guidelines about family gamete donations. We are not proposing any substantial amendments to the family gamete donation guidelines. The *Guidelines on Donation of Gametes between Certain Family Members* were amended in 2013, as discussed in the Introduction. However, we are seeking views about proposed advice that *all* family gamete donation cases should be subject to an ECART decision.

5.1 The current situation

129. 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.

130. 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 whanau or other culturally recognised family group.

131. However, Part 2(2) of the HART Order sets out some family relationships that are not regarded 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.⁴⁸ 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.

132. ACART does not know why the HART Order makes a distinction between the family relationship involved in the gamete donation.

⁴⁸ 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 where 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).

133. We believe that all family gamete donations have the potential to be ethically complex and should require ECART approval before proceeding.

5.2 Rationale for the proposal

134. All family gamete donations can pose risks as well as benefits for all participating parties.
135. Benefits of gamete donation between family members include a known donor, strengthening of family relationships and not having to wait for a suitable clinic donor.
136. Risks include confusion about relationships, potential coercion and inheritance of family genetic conditions. For example, a child born to a woman who has used her uncle's sperm to conceive might be uncertain who their 'real' father is.⁴⁹
137. The wellbeing of offspring, including knowing about their genetic heritage and understanding their identity, is an important factor when considering whether the donation of gametes within a family should be permitted. An additional risk to be considered is that some gamete donations may give the appearance of incest even though the relationships are not any of those excluded by the HART Order.
138. All family gamete donations, regardless of the relationship between family members or whether the family members are of the same or different generations, carry risks for the affected parties and resulting children. The risks are most appropriately managed by ECART review and decision.
139. In addition, it is fair that all family gamete donation cases be treated the same. The current differentiation between types of family relationships does not appear to be logical and, as set out in Part 2(2) of the HART Order, is unduly complicated.

5.3 Impacts of our proposal

140. **Advice to the Minister of Health:** The Minister of Health is responsible for the HART Order. If ACART confirms its current view, we would need to recommend to the Minister that the HART Order⁵⁰ be amended to exclude all family gamete donations from the established procedures and thus be regulated by ACART guidelines.
141. **Increase in applications to ECART:** Clinic information indicates that there are around 100 cases of family gamete donations annually that currently do not require ECART approval. If all family gamete donation cases were regulated by guidelines, consumers would incur the costs of applications to ECART and would need to wait for ECART approval. ECART's workload would increase substantially.

⁴⁹ Ethics Committee of the American Society for Reproductive Medicine. 2012. Using family members as gamete donors or gestational carriers. *Fertility and Sterility* 98: 797–803.

⁵⁰ HART Act section 35(1)(b)(iii).

Question 9: Regulation of all family gamete donations

ACART is of the view that all family gamete donations through a fertility services provider should be regulated by guidelines and thus require ECART approval.

Do you agree? Yes/No

Please give reasons for your views.

6 Provisions applying to embryo donation

142. New Zealand is almost the only jurisdiction in the world that has specific requirements for the use of a donated embryo for human reproduction. Australia also has specific requirements, set out in its *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*.⁵¹ The Australian guidelines apply to clinics in all states, whether or not the state has its own assisted reproductive technology regulation.
143. ACART issued embryo donation guidelines in 2008, to replace the guidelines issued by the former National Ethics Committee on Assisted Human Reproduction (NECAHR). The current guidelines require a medical justification for the use of embryo donation and do not allow the donation of a surplus embryo created using donated gametes. A donated embryo must be created from the gametes of a donating couple.
144. We are now proposing some significant changes to the guidelines applying to embryo donation, to provide for the donation of surplus embryos created from donated gametes and for the re-donation of unused donated embryos.
145. In addition, we are proposing the regulatory framework be amended to (i) clarify that all embryo donations are regulated by guidelines and (ii) clarify what counts as embryo donation.

6.1 Donation of embryos created from donated gametes

146. The current guidelines require donated embryos to have been created from the gametes of the donating couple. ACART has received several requests in the past to amend the guidelines to enable ECART to approve the donation of surplus embryos where the embryos were created from donated gametes. Currently, any surplus embryos created from donated gametes must be destroyed. Yet people who have embryos created from donated gametes sometimes wish to enable another person or couple to use the surplus embryos.
147. We are now proposing that the guidelines not preclude the donation of surplus embryos created from donated gametes.

⁵¹ NHMRC. 2007. *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*. Canberra: National Health and Medical Research Council, Australian Government. URL: <https://www.nhmrc.gov.au/guidelines-publications/e78> (accessed 28 July 2017).

6.1.1 Rationale for the proposal

148. The current requirement that donated embryos must have been created from the gametes of a donating couple precludes some people from donating surplus embryos. We consider that the guidelines should enable donation of surplus embryos created from donated gametes, provided ECART takes into account the potential complexity of resulting relationships and that the gamete donors have consented to the donation, either at the time of donating or later (in accord with our proposed consent provision applying to all procedures).

6.1.2 Impacts of the proposal

149. The proposed provision would give another option to people who have surplus embryos created from donated gametes, including single people. Presently, the only option for people who are currently excluded from donating surplus embryos is to dispose of the embryos, in accord with section 10 of the HART Act.⁵²

150. The proposed provision will apply to embryos created from donated eggs or donated sperm, and also to embryos created using donated eggs with donated sperm.

Question 10: Donation of embryos created from donated gametes

ACART is proposing that the guidelines should enable ECART to approve the donation of embryos created from donated eggs and/or donated sperm, provided ECART takes account of the potential complexity of resulting relationships, and the gamete donors have given consent to the specific use.

Do you agree? Yes/No

Please give reasons for your views.

6.2 On-donation and re-donation of embryos

151. The proposed rescinding of the biological link policy raises the possibility that recipients of donated embryos might wish to 'on-donate' embryos they have not used. We propose to include a provision that precludes ECART approving the on-donation of a previously donated embryo by the recipients. Where donated embryos become surplus to the requirement of recipients, we propose that embryo 're-donation' should be permitted. 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.

⁵² The HART Act section 10 prohibits storing gametes and embryos longer than 10 years, or longer than an approved storage period, without ECART approval.

6.2.1 Rationale for the proposal

152. In many cases, the provision limiting full genetic siblings to no more than two families will preclude re-donation. On-donation would always be precluded, even if the two families requirement would not be breached. On-donation would unduly compound the complexity of resulting relationships. Embryo donors select recipients who they believe are suitable potential parents of children who would be full genetic siblings of their own children.
153. However, if on-donation were possible, the original embryo donors would have little or no say in the choice of subsequent recipients. In contrast, with re-donation the embryo donors would continue to choose who receives their surplus embryos.

6.2.2 Impacts of the proposal

154. In most cases, re-donation of surplus donated embryos will be precluded because the first donation would have resulted in full genetic siblings in two families. However, the proposal will provide for re-donation if the donors and recipients agree, at the time of donation or subsequently, to return surplus embryos.
155. A re-donation would require a new application to ECART.

Question 11: Embryo on-donation and re-donation

ACART is proposing that surplus donated embryos:

- should not be able to be on-donated by the recipients
- but can be returned to the donors, in accordance with any agreement between the parties, for re-donation to another party, subject to a new approval by ECART.

Do you agree? Yes/No

Please give reasons for your views.

6.3 Clarification of the status of embryo donation in the regulatory framework

156. In addition to our proposed changes to the guidelines, we are also proposing amendments to the regulatory framework (HART Act, HART Order or other instrument) to clarify that all embryo donation cases are regulated by guidelines and to clarify what counts as embryo donation.

6.3.1 Rationale for the proposal

Guidelines regulation for all embryo donation cases

157. As noted above, ACART followed NECAHR's lead in issuing guidelines for embryo donation. However, neither the HART Act nor the HART Order are clear about the status of embryo donation in the regulatory framework. While the HART Act includes a definition of 'donated embryo',⁵³ the HART Order does not refer to embryo donation at all.
158. We are inviting feedback on our view that all embryo donation cases should be regulated by guidelines. When the guidelines were issued, embryo donation was seen as one of the most ethically complex procedures.⁵⁴ Recent research has highlighted the challenges for the parties involved in embryo donation and for resulting and existing children. These challenges include:
- uncertainty about how the relationship between donors and recipients will unfold in the future and how the children involved will see it (embryo donation is a comparatively new procedure, and the New Zealand model is unique)
 - for donors, a sense of connection to a resulting child who is genetic sibling to their own child/ren but for whom they have no parental role
 - for recipients, recognising a resulting child will have links to another family and may want some degree of contact with the donor family.⁵⁵

What counts as embryo donation

159. ECART has received some applications under the embryo donation guidelines where an embryo that was created in one relationship is to be used by one of the partners from that relationship with a new partner. The former partner (whether deceased or still alive) has given their consent to that use. We are inviting feedback about our view that these cases should not be considered embryo donation under the guidelines.
160. In situations where a relationship has ended and one person wants to use an embryo created for that specific relationship with a new partner, one of the gamete providers would be a parent of any child born from use of the embryo. We consider that the use of embryos in these situations is appropriately covered by the requirements of informed consent.⁵⁶

⁵³ HART Act section 5.

⁵⁴ Goedeke S, Daniels K, Thorpe M. 2016. Embryo donation and counselling for the welfare of donors, recipients, their families and children. *Human Reproduction* 31(2) 412–18.

⁵⁵ Goedeke S. 2015. Thinking about embryo donation? *The Dandelion* February. URL: www.fertilitynz.org.nz/information/dandelion-newsletter/february-2015-dandelion/ (accessed 31 July 2017).

⁵⁶ ACART's view on this matter is stated in general terms, and ECART must consider the status of each case on its own facts.

6.3.2 Impact of the proposals

161. Amendments to the HART Order in accordance with ACART's recommendations would clarify the status of cases to be regulated by guidelines.


Question 12: Clarification of the status of embryo donation in the regulatory framework

ACART is of the view that the regulatory framework should clarify that:

- all embryo donation cases are regulated by guidelines and thus require approval by ECART
- embryo donation does not include cases where an embryo created for one couple is used by one of the couple in a new relationship with the informed consent of the previous partner.

Do you agree? Yes/No

Please give reasons for your views.



7 Provisions applying to the creation and use of an embryo created from donated gametes and donated sperm

162. New Zealand is unique in distinguishing the use of donated eggs with donated sperm as a separate procedure from embryo donation. Other jurisdictions appear to see it as a variation of embryo donation or of sperm *or* egg donation.
163. The current guidelines require a medical justification for the use of an embryo created from donated eggs with donated sperm. Where there are two intending parents, both must meet this criteria. As discussed earlier, we are proposing that the criteria for using any of the four procedures should be amended to focus on need, whether the need is medical or circumstantial.
164. The proposed specific guidelines applying to donated eggs with donated sperm now only comprise a note, because the provisions applying to all four procedures take account of the ethical and policy issues arising in using donated eggs with donated sperm.

7.1 Policy impacts of other proposed changes

165. Rescinding the biological link policy would mean that ECART could decide a case where an embryo created using donated eggs with donated sperm was used in a surrogacy arrangement.
166. We have proposed in the preceding chapter (6: Provisions applying to embryo donation) that ECART should be able to approve the donation of an embryo created from donated gametes. This proposal means that a surplus embryo created using donated eggs with donated sperm could be donated, provided the gamete donors had each given specific consent to the procedure.

8 Provisions applying to surrogacy involving assisted reproductive procedures

167. The proposed guidelines do not make substantial changes to the provisions applying to surrogacy, except in regard to rescinding the biological link policy. The rationale for and impacts of this change were discussed in chapter 3: Proposed changes to the biological link policy.

8.1 Background to the provisions and scope of the current guidelines

168. 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,⁵⁷ rather than the procedure itself, facilitated by a fertility services provider where a woman gestates an embryo for intending parents.

169. ACART made substantial changes to the surrogacy guidelines in 2013 on the eligibility criteria for intending parents (discussed in chapter 1: Introduction) and to the title of the guidelines. The current guidelines clarify in the Preamble that the criteria apply only where a surrogacy involves an assisted reproductive procedure.

170. Surrogacies currently requiring ECART approval in accordance with the guidelines 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).

171. Surrogacies in a clinic where the surrogate uses her own eggs (traditional surrogacies) are not subject to ECART approval.⁵⁸

⁵⁷ HART Act section 14(1).

⁵⁸ 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. However, 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. An intending parent who contributes sperm or eggs to the gestated embryo is technically donating gametes to the surrogate.

8.2 ACART's view: all clinic surrogacies in New Zealand should be subject to ECART approval

172. The Preamble and the body of the current guidelines set out the risks associated with surrogacy. In developing proposed new guidelines, we concluded that the risks associated with surrogacy are generally well managed in New Zealand⁵⁹ through the following requirements and processes:
- the HART Act prohibits surrogacy for commercial gain⁶⁰
 - surrogacy in New Zealand is not based on legal agreements but on discussion between the parties, with an arrangement being non-binding. The guidelines require surrogates and intending parents to take part in joint counselling on the implications of parenting under a surrogacy arrangement
 - most clinic-assisted surrogacies in New Zealand are followed by adoption through the Family Court under the Adoption Act 1955. The surrogate mother is the legal mother (and any partner is the other legal parent) until an adoption order is made. The surrogate (birth mother) must not give consent to adoption until at least 10 days after the child's birth, in accord with the Adoption Act 1955.
173. Until the revision of the surrogacy guidelines in 2013, the requirement for ethical approval of *all* clinic-assisted surrogacies had been in place since 1997 when guidelines for surrogacy carried out in a fertility clinic were first issued in New Zealand.⁶¹ Since revision of the guidelines in 2013, not all clinic-assisted surrogacies have required ECART approval, as traditional surrogacy and the use of the surrogate's own eggs is not considered to be an 'assisted reproductive procedure' as defined in the HART Act.⁶²
174. As a matter of policy, ACART is of the view there should be a more consistent approach: all surrogacies that use a fertility clinic should require ECART approval. All surrogacies can be ethically complex. Surrogacy involves both a woman's choices about her body and the sometimes conflicting interests of the potential child and the intending parents. The procedure can raise issues of potential coercion of the surrogate mother, particularly if the surrogacy occurs within a close family relationship between intending parents and the surrogate. To that end, ACART has strengthened the requirement for ECART to take into account factors in a relationship that might give rise to coercion and thus influence the consent of a surrogate.

⁵⁹ Surrogacy arrangements by New Zealanders in other countries are outside the jurisdiction of the guidelines and ACART.

⁶⁰ HART Act section 14.

⁶¹ NECAHR issued the first surrogacy guidelines in 1997.

⁶² HART Act section 5 defines an assisted reproductive procedure as a procedure performed for the purpose of assisting human reproduction that does not include an established procedure. Established procedures are listed in the HART Order, together with some exceptions.

175. We also consider that this approach allows ECART to focus on the ethical considerations in accord with the HART Act principles when deciding these relatively few additional cases of traditional surrogacy.⁶³ This approach takes into account principle 4(e) of the HART Act, and that the ‘health and well-being of women must be protected’ in the use of any surrogacy procedures, whether by gestational or traditional surrogacy.⁶⁴
176. Our proposed change appears to require amending the HART Order, which is the responsibility of the Minister of Health.

8.2.1 Rationale for the proposal

177. Requiring ECART approval for all clinic-assisted surrogacies would ensure risks are managed consistently across all those surrogacies. The risks associated with a surrogacy for the adult parties and any resulting child, as set out in the guidelines, are:
- risks to the health and wellbeing of the intending surrogate, including risks associated with pregnancy, childbirth and relinquishing 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 health and wellbeing of the intending parent(s), including that the surrogate may change her mind about relinquishing a resulting child
 - 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.
178. Where a traditional surrogacy is between family members, there may be the additional risk of explicit or implicit coercion.

8.2.2 Impacts of change

179. **Some surrogacies in New Zealand would continue to be excluded from ECART review:** An unknown number of surrogacies in New Zealand do not use a clinic. Such arrangements would continue to be outside clinic or ECART oversight.

⁶³ 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.

⁶⁴ Henaghan M, Ballantyne R, Helm D. 2016. Genes versus gestation: protecting the interests of surrogate mothers. In M Henaghan and J Wall (eds) *Law, Ethics and Medicine: Essays in honour of Peter Skegg*. Wellington: Thomson Reuters.

180. **The number of surrogacy applications to ECART would increase:** Most surrogacies in New Zealand involve the use of an assisted reproductive procedure and are therefore reviewed by ECART. Any increase in the number of traditional surrogacy cases coming to ECART appears to be small.
181. **Risk of more surrogacies taking place outside a clinic:** If all clinic-assisted surrogacies must be reviewed by ECART, this might be an incentive for more traditional surrogacies to take place outside a clinic. However, such an impact is likely to be very small.

Question 13: Regulation of all clinic-assisted surrogacies by guidelines.

ACART proposes to recommend that all clinic-assisted surrogacy cases be regulated by guidelines and thus require ECART approval.

Do you agree? Yes/No

Please give reasons for your views.

9 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: <ul style="list-style-type: none">• the creation of an in-vitro human embryo, or• the storage, manipulation or use of an in-vitro human gamete or an in-vitro human embryo, or• the use of cells derived from an in-vitro 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 Order 2005 (HART Order) that do not require ECART review and approval. The Minister of Health is responsible for the HART Order.
Ethics Committee on Assisted Reproductive Technology (ECART)	The Ethics Committee established under New Zealand's 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)	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.
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. (ACART proposes to preclude this activity.)
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.
Tikanga Māori	The customary system of Māori values and practices that have developed over time.
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.
Whāngai	Customary Māori practice where a child is raised by someone other than their birth parents, usually a relative.

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: Rescinding the biological link policy

Refer to section 3.

ACART is proposing that:

- the guidelines should no longer require intending parents to have a genetic or gestational link to a resulting child
- instead the guidelines should require ECART to be satisfied that where intending parents will have neither a genetic nor a gestational link to a resulting child, the lack of such links is justified.

(a) Do you agree? Yes No

(b) Do you believe there are cultural implications associated with the proposed removal of the biological link policy? Yes No

If so, please describe these implications.

Please give reasons for your views.

Question 2: Access to information held on birth certificates

Refer to section 3.

ACART is interested in hearing views about potential strategies to strengthen a donor offspring's access to information about their origins, which is held on their birth certificate.

Do you have suggestions? Yes No

Please give reasons for your views.

Question 3: Format of the proposed guidelines

Refer to section 4.1.

ACART is proposing to issue one set of guidelines to ECART that encompass family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy.

Do you agree with the format of the proposed guidelines? Yes No

Please give reasons for your views.

Question 4: Justification to use a procedure

Refer to section 4.2.

ACART is proposing that ECART should be satisfied the proposed procedure is the best or only opportunity for intending parents to have a child and the intending parents are not using the procedures for social or financial convenience or gain.

Do you agree?

Yes No

Please give reasons for your views.

Question 5: Consent by gamete and embryo donors

Refer to section 4.3.

ACART is proposing that, where a procedure will involve the use of an embryo created from donated eggs and/or donated sperm, the gamete donor(s) must have given consent to the specific use of their gametes:

- at the time of donation; or
- when a procedure using such an embryo is contemplated.

In either case, the affected parties should receive counselling on the implications of using gametes before the gamete donor gives specific consent.

If consent is given, the gamete donor can vary or withdraw their consent only up until an embryo is created (in cases where consent is given before the embryo is created).

In addition, where a procedure will involve the use of a donated embryo, the person(s) for whom the embryo was created must give consent to the specific use of the donated embryo:

- at the time of donation; or
- when a procedure using such a donated embryo is contemplated.

Once an embryo is created, the decision to vary or withdraw consent up to the time the embryo is transferred to the womb should remain with the people for whom the embryos were created.

Do you agree?

Yes No

Please give reasons for your views.

Question 6: Taking account of potential coercion

Refer to section 4.4.

ACART is proposing that ECART should take account of any factors in a relationship that might give rise to coercion or unduly influence a donor's or surrogate's consent to take part in a procedure.

Do you agree?

Yes No

Please give reasons for your views.

Question 7: Limit to number of families with full genetic siblings

Refer to section 4.5.

ACART is proposing that full genetic siblings should continue to be limited to no more than two families.

Do you agree?

Yes No

Please give reasons for your views.

Question 8: Legal advice

Refer to section 4.6.

ACART is proposing that ECART must be satisfied that:

- where an application includes a surrogacy arrangement, each affected party has received independent legal advice
- where an application does not include a surrogacy arrangement, each affected party has considered seeking independent legal advice
- any legal reports show that all affected parties understand the legal implications of the procedure(s).

Do you agree?

Yes No

Please give reasons for your views.

Question 9: Regulation of all family gamete donations

Refer to section 5.

ACART is of the view that all family gamete donations through a fertility services provider should be regulated by guidelines and thus require ECART approval.

Do you agree?

Yes No

Please give reasons for your views.

Question 10: Donation of embryos created from donated gametes

Refer to section 6.1.

ACART is proposing that the guidelines should enable ECART to approve the donation of embryos created from donated eggs and/or donated sperm, provided ECART takes account of the potential complexity of resulting relationships and the gamete donors have given specific consent to the procedure.

Do you agree?

Yes No

Please give reasons for your views.

Question 11: Embryo on-donation and re-donation

Refer to section 6.2.

ACART is proposing that surplus donated embryos:

- should not be able to be on-donated by the recipients
- but can be returned to the donors, in accordance with any agreement between the parties, for re-donation to another party, subject to a new approval by ECART.

Do you agree?

Yes No

Please give reasons for your views.

Question 12: Clarification of the status of embryo donation in the regulatory framework

Refer to section 6.3.

ACART is of the view that the regulatory framework should clarify that:

- all embryo donation cases are regulated by guidelines and thus require approval by ECART
- embryo donation does not include cases where an embryo created for a couple is used by one of the couple in a new relationship with the informed consent of the previous partner.

Do you agree?

Yes No

Please give reasons for your views.

Question 13: Regulation of all clinic-assisted surrogacies by guidelines

Refer to section 8.

ACART proposes to recommend that all clinic-assisted surrogacy cases be regulated by guidelines and thus require ECART approval.

Do you agree?

Yes No

Please give reasons for your views.

Question 14: Any other comments

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