

Feedback form

Please provide your contact details below.

Name	Names of individuals withheld
If this feedback is on behalf of an organisation, please name the organisation	Department of Internal Affairs
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)	Responsibility for maintenance of information about donors and donor offspring in the Human Assisted Reproductive Technology (HART) Register

Privacy

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

ECART must be satisfied that:

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

3. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)
4. where a procedure will involve the use of a donated embryo, consent to the use of that embryo must have been given by the people who originally had the embryo created for themselves:
 - a. at the time of donation, or
 - b. if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated
5. where a procedure will involve the use of a re-donated embryo, consent to the use of the embryo must have been given:
 - at the time of donation, or
 - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated
 by
 - a. the people who originally had the embryo created for themselves whether or not they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and by
 - b. the first recipient(s) of the donated embryos if they have already had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated
 but

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

Do you agree with the proposed consent provisions?

Yes ☒ No ☐

Please give reasons for your views.

It is important that all donors understand the possible implications of re-donated embryos and gametes, in terms of additional parties involved. If there is a way to track this on the HART register, we would have no further concerns. Therefore, if there are situations where more than two parties are involved, i.e. the gamete donors, the original embryo recipients and the recipients from the re-donation, this should all be tracked on the HART register to identify any donor sibling relationships.

Question 2: ACART proposes a new position, in which the interest in and authority over embryos would switch to the first recipients of donated embryos if:

- a) they have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donated and**
- b) the original donors do not have any gametes in the embryo(s) to be donated and**
- c) the original embryo donors do not have a child(ren) using embryos that would be full siblings of the embryos.**

Do you agree?

Yes ☒ No ☐

Please give reasons for your views.

We agree with this, but our main interest is regarding the HART register. All the involved donors will need to be added to the HART register to ensure the integrity of the register is being maintained, and that donor offspring access rights are safeguarded.

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

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

The purpose of having an established list of prohibited family gamete ensures that no resulting off-spring will be formed from gametes donated by close relatives who are genetically related. Extending the list makes sense as it furthers that objective. The prohibited degrees of relationships in the extended list is consistent with the lists in [Schedule 2 of the Marriage Act 1955 - Prohibited degrees of marriage](#) and [Schedule 2 of the Civil Union Act 2005 - Prohibited degrees of Civil Union](#).

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

Family donations where there is no risk of consanguinity should be able to go through standard assisted reproductive procedures and should not require additional consideration by ECART.

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

Refer to section 4.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

We agree with this but do not have any interest in this in regard to the HART register.

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

Refer to section 5.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

It is appropriate that there is better visibility around ART involving surrogacy. It is ethically complex and therefore having regulations around the process will improve consistency in managing risks and better documentation of the donor relationships. With the proposed amendment ECART would be able to provide non-binding ethical advice around each individual case in accordance with the HART Act principles.

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

Refer to section 5.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

We agree that this gives a greater flexibility to the surrogate. The important issue here is risk awareness and we agree that the problematic (unenforceable) provision should be removed and replaced.

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

Refer to section 5. ✓

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

Do you agree?

Yes

☐

No

☒

Please give reasons for your views.

Currently there is no provision in the Act to ensure the donor updates details to allow for interaction with offspring/guardians in the future. Adding a residency provision for donors and recipients of donations will not guarantee that parties will change their plans at a later stage. Besides, this provision will not be enforceable.

In the case of an overseas based surrogate, the HART Act would not apply, as New Zealand legislation cannot be enforced in another country. There is provision in the Citizenship Act for [Citizenship by descent](#) if a link with a New Zealand citizen parent (either biological or through adoption) can be established, therefore avoiding the risk of offspring being stateless.

It does give provision for a more informed decision to be made by the donor which is a positive aspect. We would hope that if there are any questions raised about potential statelessness of donor offspring that ECART would contact the Department of Internal Affairs (the Department) to discuss these.

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

The Department holds information of both births and HART registration. Some of the BDM forms ask people if they are on the HART register so that their details can be updated, for example the name change application.

The BDMRRA allows BDM information to be used to update information on the HART register, see [section 85B](#).

**Advisory Committee on
Assisted Reproductive Technology**

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

Consultation Document

Citation: Advisory Committee on Assisted Reproductive Technology. 2019. *Second Round of Consultation on the Proposed Donation and Surrogacy Guidelines: Further changes since ACART's 2017 consultation*. Wellington: Advisory Committee on Assisted Reproductive Technology.

Published in February 2019 by the Advisory Committee on Assisted Reproductive Technology, PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-98-856835-5 (online)
HP 7004

This document is available on the ACART website:
www.acart.health.govt.nz





Foreword

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

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

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

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

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

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



Dr Kathleen Logan
Acting Chair



How to have your say

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

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

1. e-mailing a completed feedback form or your comments to acart@moh.govt, or
2. using the online feedback form in this link:
<https://consult.health.govt.nz/acart/donation-surrogacy-guidelines>
3. posting a completed feedback form or your comments to:
ACART Secretariat
PO Box 5013
Wellington 6140.

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

Publishing submissions

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

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

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

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



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Executive summary

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

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

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

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

Summary of proposals

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

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



1 Introduction

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

1.1 Purpose of this second consultation

2. This document seeks public feedback on three aspects of ACART's proposed combined guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm) and clinic-assisted surrogacy.
3. These aspects are:
 - clarification of the proposed consent regime with particular attention to embryo donations
 - provisions that prohibit certain family gamete donations and provisions that outline the considerations ECART must consider with respect to family gamete donations that are not prohibited
 - changes to three provisions for clinic assisted surrogacy.
4. ACART's further amendments (since its consultation in 2017) are significant enough that it is re-consulting to obtain public input. Given the significant change from the position consulted on for the family gamete donations, ACART must ensure that it meets its statutory consultation requirements before advising the Minister.
5. Notably, the amendments to the general provisions for consent are significant enough that readers might now form a different opinion about them than they did in the initial consultation. It is also possible that people who did not submit to ACART on these provisions would wish to do so now.
6. In the case of the proposed changes to the provisions for clinic assisted surrogacy, ACART believes these are unlikely to raise concerns, but it would be prudent to ensure that interested parties are aware of them.
7. This process is in accord with section 36(1) of the HART Act, which requires ACART to consult the public before issuing guidelines. ACART must:

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

ACART's 2017 consultation

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

1.2 The proposed amended guidelines

9. The proposed amended guidelines, with ACART's recent extra revisions, are set out below. We discuss the proposed amendments in later chapters.
10. ACART's amendments, since the 2017 consultation, are presented using a) underlined red for new text, and b) red with strike through for text that would be removed. These amendments are in the provisions for:
 - a) consent in the Provisions that apply to all procedures covered in these guidelines
 - b) the Use of gametes donated between certain family gamete donations
 - c) Embryo donation and use
 - d) Clinic-assisted surrogacy.
11. For (a) above, ACART presents the proposed new text in the draft guideline (below) but the text consulted on in 2017 is presented in Appendix 1. The material is presented in this way to make the draft guidelines as easy to read as possible.

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

Preamble
ACART can issue guidelines
ACART is appointed by the Minister of Health, and one of its functions is to issue guidelines on any matter relating to any kind of assisted reproductive procedure (s.35(1)(a) of the HART Act).
Guidance on terms used
In these guidelines, unless the context indicates otherwise, words should be interpreted in accordance with definitions given in the HART Act and the HART Order.
Principles
<p>When considering an application to carry out any of the following procedures ACART must be guided by the principles of the HART Act. The principles state:</p> <p>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:</p> <ul style="list-style-type: none"> (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
<p>ECART must be satisfied that:</p> <ol style="list-style-type: none"> 1. full genetic siblings are produced in no more than two families (this does not preclude a donor from donating sperm or eggs separately to another couple or person) 2. the parties have not been subjected to any coercion or pressure 3. the procedure is the best or only opportunity for intending parents to have a child 4. the intending parents are not using the procedures for social or financial convenience or gain 5. the potential genetic, social, cultural and intergenerational aspects of the proposed arrangement safeguard the wellbeing of all parties and especially any resulting child 6. any relationships between the parties safeguard the wellbeing of all parties and especially any resulting children.
Counselling requirements
<p>ECART must be satisfied that counselling:</p> <ol style="list-style-type: none"> 7. has been received by each party in accordance with the current Fertility Services Standard 8. will be available throughout the donation/treatment process 9. is culturally appropriate 10. has provided for whānau or extended family involvement 11. has provided for the inclusion of any existing children of the parties 12. has addressed any matters raised by donation(s) between family members 13. has included implications counselling for all parties, and parties have considered, and in the opinion of the counsellor have understood: <ol style="list-style-type: none"> a. the rights of offspring, including their rights to obtain information about their genetic origins and to contact donors b. each other's needs and plans for continuing contact and information sharing c. any specific issues that might affect the health and wellbeing of all parties and especially the offspring d. the implications if offspring have medical conditions, disabilities or genetic disorders e. each other's attitudes to openness about donation, especially with the offspring f. the possibility of a termination of the pregnancy by the birth mother (whether she is the intending mother or a surrogate) g. issues related to use, storage and disposal of gametes and embryos h. requirements for information sharing under the HART Act i. their reasons for wishing to donate or receive gametes or embryos j. their feelings now and possible feelings in the future about donations k. the possibility of future contact with offspring, for themselves and their families, including any resulting children.

Consent requirements

ECART must be satisfied that:

14. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) consented to the use of their gametes at the time of donation
15. implications counselling about the potential use of gametes was provided before the gamete donor consented
16. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)
17. where a procedure will involve the use of a donated embryo, consent to the use of that embryo must have been given by the people who originally had the embryo created for themselves
 - at the time of donation, or
 - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplated¹
18. where a procedure will involve the use of a re-donated embryo, consent to the use of the embryo must have been given:
 - at the time of donation, or
 - if consent was not obtained at the time of the donation then it must be obtained when a procedure using such a donated embryo is contemplatedby
 - a. the people who originally had the embryo created for themselves whether or not they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and by
 - b. the first recipient(s) of the donated embryos if they have already had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos that are now being donatedbut

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

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

Legal advice requirements
<p>ECART must be satisfied that:</p> <ul style="list-style-type: none"> 20. where an application includes a surrogacy arrangement, each party has received independent legal advice 21. where an application does not include a surrogacy arrangement, each party has considered the option of seeking independent legal advice 22. any legal reports show that parties understand the legal implications of the procedure(s).
Health advice requirements
<p>ECART must be satisfied that:</p> <ul style="list-style-type: none"> 23. all parties have received independent medical advice 24. health reports show the parties understand the health implications of the procedure(s).

ADDITIONAL PROVISIONS THAT APPLY TO SPECIFIC PROCEDURES

Use of gametes donated between certain family members

ECART must not approve:

an application for donation where any resulting child would be formed by eggs and sperm respectively donated from close relatives who are genetically related. These relatives are:

- father and daughter
- mother and son
- brother and sister
- grandfather and granddaughter
- grandmother and grandson
- half-brother and half-sister
- uncle and niece
- aunt and nephew
- uncle and half-niece
- aunt and half-nephew.

Requirements

ECART must be satisfied that:

1. the parties to the donation are not subject to undue influence
2. the health and wellbeing of the offspring and any other parties to the donation are not compromised by the procedure, including, for example, by intergenerational complexities
3. affected parties have received joint counselling
4. the relationship between the intending parent(s) and the other family members safeguards the wellbeing of all parties and especially any resulting offspring.

Notes

Ethical approval is not required for the following family donations:

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

If clinics are unsure about cases they can request a non-binding opinion from ECART.

The HART Order defines a family member for the purposes of donation as:

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

Use of embryos created from donated eggs in conjunction with donated sperm	
<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>Notes</p> <ol style="list-style-type: none"> Embryo donation includes: <ol 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: <ol 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 except as specified in Note 4. Donated embryos may be re-donated by the people who originally had the embryos created for themselves if: <ol style="list-style-type: none"> they have not had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and the first recipient(s) of the donated embryos have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos, or they have had a child that would be a full genetic sibling to a child that would be born from the embryos that are now being donated, and the first recipient(s) of the donated embryos have not had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos, or neither they nor the first recipients have had a child(ren) that would be a full genetic sibling to a child that would be born from the embryos Donated embryos may be re-donated by the first recipients only if: <ol style="list-style-type: none"> the original intending parents have no gametes in the embryos and the original intending parents did not have a child(ren) using embryos that would be full siblings to those that would be born from the embryos being donated and the first recipients have had a child(ren) using embryos that would be full siblings to a child(ren) that would be born from the embryos being donated. Any donation or re-donation requires an application to ECART. 	

Additional Requirements

ECART must be satisfied that:

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

Clinic-assisted surrogacy

Notes

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

Requirements

ECART must be satisfied that:

1. there has been discussion, understanding and declared intentions between the affected parties about the day-to-day care, guardianship and adoption of any resulting child and any ongoing contact
2. the risks associated with a surrogacy for the adult parties and any resulting child are justified in the proposal. These risks are:
 - a. risks to the health and wellbeing of the intending surrogate, including:
 - risks associated with pregnancy, childbirth and relinquishment of a resulting child to the intending parent(s)
 - the risk that the intending parent(s) may change their mind about parenting a resulting child
 - **risks to the future reproductive capacity of the surrogate.**
 - b. risks to the health and wellbeing of the intending parent(s), (and embryo donor if applicable) including that the surrogate may change her mind about relinquishing a resulting child
 - c. risks to the health and wellbeing of a resulting child, including becoming the subject of a dispute if the relationship between the surrogate and intending parents breaks down
3. **the residency status and plans of the surrogate and intending parent(s) safeguard the health and wellbeing of the child, particularly in relation to being born in New Zealand.**
~~the surrogate has completed her family before becoming a surrogate for others.~~
4. all affected parties have received joint counselling
5. in the opinion of the counsellor the health and wellbeing of the intending surrogate and any resulting offspring is safeguarded
6. all affected parties have considered, and in the opinion of the counsellor, have understood:
 - a. each other's needs and plans for continuing contact
 - b. specific issues that might affect the health and wellbeing of all affected parties
7. counselling will be made available to all parties before and after pregnancy is achieved.

1.3 Why and how ACART is reviewing the guidelines

12. In this section, ACART summarises information provided in the 2017 consultation document on this matter. In particular, ACART notes:
- ACART's statutory role in regard to issuing guidelines to ECART and providing advice to the Minister of Health
 - the origins of this project
 - matters ACART has considered in developing the proposals in this document.

ACART's statutory role

13. ACART has a statutory role under the Human Assisted Reproductive Technology Act 2004 (HART Act) to issue guidelines to the Ethics Committee on Assisted Reproductive Technology (ECART) on matters that require case-by-case ethical review.
14. ACART's role under the HART Act is to:
- issue guidelines and advice to ECART on any matter relating to any kind of assisted reproductive procedure, human reproductive research and extended storage of gametes and embryos
 - advise the Minister of Health on aspects of, or issues arising out of, different kinds of assisted reproductive procedures or human reproductive research
 - monitor the application and health outcomes of assisted reproductive procedures and established procedures and developments in human reproductive research.
15. More information about ACART and the current guidelines can be found on ACART's website at: www.acart.health.govt.nz

The origins of this project — a summary

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

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

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

18. In developing the proposed guidelines and advice, ACART has taken into account:
- the principles of the HART Act
 - other common ethical principles, including autonomy, wellbeing of offspring and families/whānau and transparency
 - wider legal and public policy considerations, including the right to informed consent to health care under the Code of Health and Disability Services Consumers' Rights (the Code)
 - feedback from public consultation on related matters
 - evidence and information from local and international sources.
19. When considering these matters, ACART referred to its ethical framework, which incorporates the principles of the HART Act and generally accepted ethical principles. The ethical framework considers the welfare of those affected by the procedure and the autonomy of those involved, as well as altruism, social trust and responsibility, the special status of the embryo, justice and equality.²
20. The recognition of the importance of relatedness and connection to others expressed through values such as whānau, whakapapa and whanaungatanga, is relevant to gamete and embryo donation. Māori have been influential in shaping non-Māori views on the significance of whakapapa, and this has arguably led to a more open attitude to the knowledge of genetic parentage than exists in some countries.³
21. Principle 4(f) of the HART Act requires that the needs, values and beliefs of Māori should be considered and treated with respect. This is further developed in the New Zealand Fertility Services Standard (1.1.2), which requires that consumers who identify as Māori have their health and disability needs met in a manner that respects their individual values and beliefs. This recognises that while there may be viewpoints shared by many Māori, individuals and whānau will have their own preferences and practices.

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

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

22. Nonetheless, the concept of Te Ao Māori (Māori world view) will have implications for the way we should consider these matters. For example, in developing these guidelines, ACART has considered the concept of whakapapa and the way in which this concept defines and identifies elements around family relationships that are of importance to Māori.
23. ACART has also considered that Pasifika communities have a holistic perspective of health and wellbeing – this includes an interconnectedness between spiritual/religious, cultural, emotional and social dimensions and that health and wellbeing are often heavily influenced by family and community.
24. The 2013 census found that just over one-quarter of people living in New Zealand were born in another country.⁴ Principle 4(g) of the HART Act recognises the diversity resulting from migration and a pluralistic, multicultural society, and requires the different ethical, spiritual and cultural perspectives to be considered and treated with respect in the context of assisted reproduction.
25. The Human Rights Act 1993 prohibits discrimination against individuals on the basis of disability, and New Zealand is a signatory to the United Nations Convention on the Rights of Persons with Disabilities. People with disabilities have equal rights to autonomous decisions over reproduction. Clinics must ensure, where practicable, that clients with disabilities are provided with services and information in an appropriate manner, including accessible formats.

1.4 The process after this consultation

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

Interim guidelines will be published

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

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

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

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

Applications that fall under more than one of the guidelines

29. ACART issued advice to ECART in 2013 on applications that fall under more than one of the guidelines issued by ACART to ECART. When new guidelines are issued, ACART will decide if any changes need to be made to that advice.
30. A feedback form is provided separately. The consultation period ends on Monday, 25 March 2019.

2 Background: the regulatory setting for the guidelines

31. ACART's guidelines must be consistent with the HART Act and other relevant law. ACART can recommend to the Minister of Health that the HART Act or other enactment be amended if appropriate.⁶ ACART can also recommend the Minister of Health change the status of procedures in the HART Order.⁷
32. This chapter describes and summarises the HART Act,⁸ the HART Order,⁹ the Code,¹⁰ and the New Zealand Fertility Services Standard.¹¹ The chapter also notes other relevant legislation.

2.1 The HART Act

33. The HART Act is the key law regulating human assisted reproductive technology and human reproductive research in New Zealand. The HART Act aims to enable the appropriate use of assisted reproductive technology by providing a robust and flexible regulatory framework that protects the health, safety, dignity and rights of individuals (in particular women and children).¹²
34. The HART Act requires all assisted reproductive procedures to be approved by ECART on a case-by-case basis, unless the procedure is an 'established procedure'. Established procedures are listed in the HART Order.¹³ ECART can only consider assisted reproductive procedures if guidelines issued by ACART relating to the procedure exist, and in accordance with any such guidelines.¹⁴
35. Part 3 of the HART Act sets out the information that must be collected about donors and the rights of donor offspring to access identifying information about donors held on the HART registers.

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

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

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

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

¹⁰ [www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-\(full\)](http://www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-(full))

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

¹² HART Act section 3.

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

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

Principles of the HART Act

36. The HART Act contains important principles that guide the actions of everyone involved with human assisted reproductive technology and human reproductive research.¹⁵ Anyone exercising powers or performing functions under the HART Act must be guided by each of the following principles, relevant to the particular power or function:
- a) the health and wellbeing of children born as a result of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure
 - b) the human health, safety and dignity of present and future generations should be preserved and promoted
 - c) while all types of individuals are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and wellbeing of women must be protected in the use of these procedures¹⁶
 - d) no assisted reproductive procedure nor human reproductive research should be performed on an individual unless the individual has made an informed choice and given informed consent
 - e) donor offspring should be made aware of their genetic origins and be able to access information about those origins
 - f) the needs, values and beliefs of Māori should be considered and treated with respect
 - g) the different ethical, spiritual and cultural perspectives in society should be considered and treated with respect.

Prohibited actions

37. One of the HART Act's purposes is to prohibit unacceptable assisted reproductive procedures and certain commercial transactions relating to human reproduction.¹⁷ This is reflected in a number of specific prohibitions. These include sex selection of an embryo,¹⁸ commercial surrogacy arrangements,¹⁹ the commercial supply of human gametes and embryos²⁰ and the use of minors' gametes.²¹ Schedule 1 of the HART Act lists other prohibited actions, including creating and using a cloned embryo.

¹⁵ HART Act section 4.

¹⁶ This includes women who are surrogates.

¹⁷ HART Act section 3(b) and (c).

¹⁸ HART Act section 11.

¹⁹ HART Act section 14.

²⁰ HART Act section 13.

²¹ HART Act section 12.

2.2 The HART Order

38. The HART Order identifies and describes the procedures that have been declared to be 'established procedures'. These are generally procedures that are done routinely during the course of fertility treatment and do not require ECART approval. Examples include in-vitro fertilisation (IVF) and collecting of sperm for donation purposes. There is no requirement that established procedures be reviewed by ECART, although a clinic can request a non-binding ethical view from ECART on cases involving an established procedure.
39. Part 2 of the HART Order excludes some procedures from being established procedures. This means that some procedures, which would otherwise be established procedures, require ECART approval. This is because such procedures are generally seen to be more ethically complex. They include:
- donations of gametes between certain family members
 - family donations involving donors or patients under the age of 20 years
 - the use of donated eggs in conjunction with donated sperm.

2.3 Code of Health and Disability Services Consumers' Rights

40. The Code applies to any person or organisation providing or receiving health and disability services in New Zealand. Rights 5, 6 and 7 of the Code give every consumer the right to effective communication, to be fully informed, to make an informed choice and to give informed consent.
41. While the Code does not address all aspects of assisted reproductive technology, any regulations or guidelines must be consistent with it.²² ACART's 2016 advice to the Minister of Health (*Informed Consent and Assisted Reproductive Technology*) included recommendations that:
- consent, variation of consent and withdrawal of consent to an assisted reproductive process should be recorded in writing, where practicable and in accordance with best practice
 - gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation or insemination
 - gamete donors should continue to be allowed to place conditions on their donations
 - the consent of a partner or family/whānau should not be required for gamete donation

²² HART Act section 76.

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

2.4 The New Zealand Fertility Services Standard

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

2.5 Other relevant legislation

43. The legal status of children born as a result of assisted reproductive technology procedures is governed by the Status of Children Act 1969.²⁴ Under this Act, the woman who gives birth to a child is regarded in law as the child's mother. If that woman has a partner, the partner is regarded as a parent to the child. This means gamete and embryo donors do not have parental rights and obligations. Because the Act is focussed on the birth mother and her relationships, the legislation does not provide for single men or male couples becoming parents in this way. Their only means of becoming parents in the eyes of the law is by adopting the child. The same is true for heterosexual couples who become parents by means of surrogacy.²⁵
44. The law also means that a child born from surrogacy is, in law, the child of the surrogate, regardless of whose gametes were used to create the embryo that the surrogate gestated. The Family Court must issue an adoption order under the Adoption Act 1955²⁶ to enable the intending parents to assume legal parenthood of a child born from surrogacy.

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

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

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

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

3 The biological link and consenting

45. In the 2017 consultation, ACART proposed removing the mandatory biological link and, having consulted the public, the intention is still to rescind it.
46. However, it was apparent from the submissions that some people had interpreted the consent provisions in ways ACART had not anticipated. Consequently, ACART has further amended the general consent requirements. ACART draws readers' attention to the implications of these changes.
47. In this chapter, ACART first summarises the rationale for removing the mandatory biological link, and the benefits and risks of doing so. ACART presents this explanation again as it is important that there is a common understanding of both the consent processes and the way in which the removal of the mandatory biological link affects those consent points.

3.1 The mandatory biological link was unjustified

48. The biological link policy requires that a child born from an assisted reproductive procedure must have at least one biological link (either genetic or gestational) to an intending parent.
 - A *genetic* link means that the embryo used must be created by the sperm and/or eggs of the intending parents.
 - A *gestational* link means that an embryo is gestated by a woman who is an intending parent.
49. The biological link policy was potentially discriminatory, in the sense that some people wishing to use certain procedures may have been unable to do so because of their biological or social circumstances.
50. While some forms of discrimination can be justified, ACART had concluded that the biological link policy would most likely fail the test of potentially being justified discrimination because the negative effects are disproportionate to the policy intent. (The policy intent being to protect a child's biological connection to its parents.) ACART considered that the guidelines should enable donation of surplus embryos created from donated gametes, provided ECART takes into account the potential complexity (especially for the offspring to navigate) of resulting relationships and that the gamete donors have consented to the donation.
51. ACART proposed changes to the guidelines to provide for the donation of surplus embryos created from donated gametes and for the re-donation of unused donated embryos. In addition, ACART proposed that the regulatory framework be amended to (i) ensure that all embryo donations be regulated by guidelines and (ii) clarify what counts as embryo donation.

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

3.2 The donation scenarios that could occur

53. Rescinding the biological link policy means that, in addition to the cases it can already consider, ECART will be able to consider cases where:
- donated embryos would be used in surrogacy arrangements
 - embryos created using donated eggs with donated sperm would be used in surrogacy arrangements (including embryos that were created without gametes from either intending parent)
 - embryos are re-donated. This means that the embryos may be returned to the embryo donors, in accordance with earlier agreements between the affected parties, and donated to another party. The recipients of donated embryos could also donate the embryos if the original intending parents have no gametes in the embryos and no child(ren) using these embryos, and the recipients do have a child(ren) using the embryos. Any re-donation would require an application to ECART.
54. In all cases, gamete donors would need to have consented to the procedures.
55. In practice, these changes would mean that single people and same sex couples who are currently unable to gestate a baby themselves or to provide their own gametes will be able to use embryo donation, or donated eggs with donated sperm, with surrogates.
56. In many cases, the provision that limits full genetic siblings to no more than two families will preclude re-donation, because the first donation would have resulted in full genetic siblings in two families (i.e. the embryo donors and the first recipients). However, in cases where that hasn't happened, the proposal will provide for re-donation if the donors and/or recipients agree, at the time of donation or subsequently, to donate the surplus embryos.

Re-donation would be permitted

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

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

3.3 The benefits, risks and how they will be managed

58. With ACART removing the mandatory biological link, ECART is likely to receive an increase in more ethically complex applications than under the current guidelines. Having one set of guidelines will simplify the ethical review process and help clinics prepare applications to ECART.
59. Evidence indicates that, in general, people prefer to have as close as possible biological relationship to their children.²⁷ However, some medical or social circumstances will mean that the only way for an individual or couple to have a child is to use a surrogate mother in conjunction with a donated embryo or donated eggs/donated sperm.

Benefits

60. ACART considers that people who need or want to use an assisted reproductive procedure should be entitled to have their case considered by ECART. The change will give more options to people who wish to use ART.
61. Single people and same-sex couples also tend to prefer a child who is created using the sperm or eggs of the individual or one member of the couple. The use of third-party assistance to have a child is either a second choice or the only realistic option.
62. In addition, rescinding the biological link policy may encourage some people, who are currently excluded from fertility treatment in New Zealand, to remain in this country for their treatment. Treatment here offers the following advantages.

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

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

Risks and their management

63. In the 2017 consultation, ACART noted that the HART Act includes the principle that children's health and wellbeing should be an important consideration. ACART also noted that children born from cases where there is no genetic link with the intending parents will have access to their genetic history on the HART register. In New Zealand, children born from surrogacy will have access to information about the surrogate mother under the provisions of the Adult Adoption Information Act 1985. Children who are born from surrogacy with no genetic link to their intending parents would need to access their full history using both the HART Act and the Adult Adoption Information Act because surrogates are not recorded on the HART register.
64. Whether a case includes a genetic or gestational link is only one of the factors that ECART will consider in making decisions on such cases. In making their decisions, ECART will consider all provisions in guidelines and information provided in applications.
65. Allowing procedures in which there would be no genetic or gestational link between the intending parents and offspring is likely to increase the social complexity and in cases involving surrogacy, also the legal complexity. It will also increase the number and complexity of relationships for all parties involved including any resulting children. These risks are intended to be managed through counselling and ethical oversight of the circumstances.
66. ACART anticipates that the number of applications to ECART that do not include either a genetic or gestational link will be low, given that most people's first choice is to have a genetic link to their children.
67. For these reasons, ECART must be satisfied that any application that does not include a genetic or gestational link is the best or only opportunity to have a child. ACART discusses the issue of justification to use a procedure later in this document.

3.4 ACART's proposed new provisions for consenting

68. All participants will need to understand a greater range of situations to which they could be asked to consent. Participants will have the same authority to choose whether or not to consent to specific procedures as they do now.
69. The amended guidelines would require gamete donors to always give informed consent to the procedures in which their gametes are to be or might be used. The

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

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

70. Related to the concept of biological link is the “two family limit” where full genetic siblings are produced in no more than two families. ACART proposes to continue to adopt the “two family limit” in the revised guidelines.
71. ACART also proposes that donated embryos must not be used in any procedure unless the person(s) for whom the embryos were originally created gives consent to that specific procedure at the time of donation or before donated embryos are used in the procedure, except where the donation is an on-donation in specific circumstances explained in the paragraphs 76 and again in paragraph 81.

Donors to consider how their gametes may be used

72. Where donated gametes are used, the donors become part of these relationships. ACART considers that gamete donors should make an informed choice about the specific use of their gametes, taking into account the long-term implications for themselves and their families.
73. In many cases, the specific consent ACART is proposing will already occur, for instance where a family or friend is donating sperm or eggs for an embryo to be used in a surrogacy. In other situations, a gamete donor may give consent to donate without considering the implications of the specific use. ACART’s proposal will mean that:
 - donors would need to consent to specific uses at the time of donation, after receiving counselling about the implications; or
 - where consent is not given for a specific use at the time of donation, a clinic would need to contact the donor(s) to obtain specific consent to use an embryo created from their gametes in the planned procedure.
74. As is the case now, gamete donors will be able to change or withdraw their consent up to the point the gametes are used.
75. It is important that gamete donors be aware that an embryo might be donated and possibly re-donated and that they will have no say in any donation (other than through conditions they might have placed before their gametes are used).

First embryo donation

76. The original intending parents would have authority over the embryos that are created for them even when they have donated the embryos to recipients. This applies even if the original intending parents have no gametes in the embryos. This is the same as under the current guidelines. There is one exception to this position:
 - if the donated embryo was made from donated eggs and sperm, and
 - the original intending parents did not have a child from donated eggs and sperm from the same donors, and

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

Embryo re-donation — a new proposal

78. If the original intending parents:
- already **had** a child that would be a genetic sibling to a child born from the donated embryo and
 - had donated their unused embryos and
 - the first recipients did **not** have a child that would be so related
- then the original intending parents can re-donate to second recipients. The original intending parents have authority over the embryos because they were created for them and they have a child who could have a full genetic sibling in a new recipient family. We expect this would be explained to any recipients of donations, so they understand the full implications in the consenting process.
79. If the original intending parents:
- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and
 - had donated the unused embryos, and
 - the first recipients also did **not** have a child that would be so related
- then the original intending parents can re-donate to second recipients. Again, the original intending parents have authority over the embryos, because they were created for them.
80. If the original intending parents:
- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and
 - the first recipients **did** have a child that would be so related
- then both the first recipients *and* the original intending parents must consent to any re-donation because the original intending parents have authority over the embryos and the first recipients would potentially have a child with a full genetic sibling in another family.
81. If the original intending parents:
- did **not** have a child that would be a genetic sibling to a child born from the donated embryo and

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

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

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

3.5 Advice to the Minister of Health

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

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

ECART must be satisfied that:

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

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

by

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

but

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

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

Do you agree with the proposed consent provisions?

Yes / No

Please give reasons for your views.

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

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

Yes / No

Please give reasons for your views.

4 Provisions applying to family gamete donation

84. In the 2017 consultation, ACART noted that New Zealand is unique in having guidelines about family gamete donations. ACART sought views about proposed advice that all family gamete donation cases should be subject to an ECART decision.
85. ACART understands from its first consultation that there is a clear preference that not all family gamete donations should be subject to ECART consideration.
86. ACART has concluded the inclusion of this proposed provision was disproportionate to the risk, has amended the proposal, and presents it for further comment by the public.

4.1 The current regulatory situation

87. Part 2(1)(a) of the HART Order says that where donors of eggs or sperm are family members, the procedure is not an established procedure. This reflects a general assumption that gamete donations between family members, while having benefits, also involve some particular risks.
88. The definition of ‘family members’ in clause 3 Interpretation of the HART Order is broad, interpreted as:
 - any other person who is or has been related to the person by blood, marriage, civil union, de facto relationship, or adoption
 - any other person who is a member of the person’s whānau or other culturally recognised family group.
89. However, Part 2(2) of the HART Order sets out some family relationships that are not to be treated as a donation made by a family member. In summary, depending on whether eggs or sperm are donated and who is using the gametes, brother/sister/cousin gamete donations are established procedures.²⁹ The only exception is where, at the time of donation, the donor or the patient is younger than 20 years of age (Part 2(2A)). In these cases, ECART must decide all applications regardless of the family relationships involved.

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

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

4.2 ACART's proposal in 2017

91. In the 2017 proposal, ACART suggested that in cases involving the donation of gametes between family members that there should be three classes of donations. These classes were:
- prohibited donations, which would be determined by the HART Order
 - established procedures, also determined by the HART Order
 - assisted reproductive procedures i.e. procedures that would be subject to the guidelines.
92. For procedures that would be subject to guidelines ACART proposed one simple provision, that "Any other proposal for donating eggs or sperm between family members requires ethical approval."

4.3 Proposed change since the 2017 consultation

93. Having received submissions, ACART now proposes amendments to the original proposal for the provisions for family gamete donations. ACART particularly notes the points raised in the submissions that in many cases families would be able to manage risks while in other cases the clinics could manage risks.
94. ACART also concluded that there will still be some matters that should be subject to ECART consideration as they present certain risks. The provision for these matters needed to be amended.

Prohibited donations

95. The first amendment would be to extend the list of prohibited family gamete donations so that embryos cannot be created using the gametes of the specified closely genetically related family members. (See the proposed list of prohibited family gamete donations, under the heading "ECART must not approve," on page 7 of this document in the revised draft guidelines.)

Matters subject to ECART consideration

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

97. ACART has now amended this provision so that the same cases of donation would be subject to ECART consideration as now. We no longer propose to remove the exception in the HART Order for brothers, sisters and cousins. This is a significant change from ACART's initial proposal and ACART would like to know if you agree (see question 4).
98. To be clear, ACART's position is that ethical approval will not be required for the following family donations.
- In the case of donated eggs, the donor is a sister or cousin of the recipient woman (where both are 20 years or older).
 - In the case of donated sperm, the donor is a brother or cousin of the recipient woman's spouse or partner (where both are 20 years or older).
 - In the case of a procedure that involves the use of the eggs of the female partner of the recipient woman and donated sperm, the sperm donor is a brother or cousin of the recipient woman (where both are 20 years or older).
99. The amended provision states that ECART must be satisfied that a) the parties are not subject to undue influence, and b) the health and wellbeing of the offspring and any other parties to the donation are not compromised by the procedure, including intergenerational complexity. This second provision is consistent with the existing provision for intergenerational concerns. (See provision 2 in the "Requirement" section for family gamete donations, on page 7 of this document.)
100. Intergenerational complexities include, but are not limited to:
- identity and psychological effects on the parties, especially
 - the offspring and the risk that the offspring will be uncertain about the generation which he or she belongs
 - how parties will relate to one another in the event a child is born with a substantial age difference to other siblings
 - the complexities of relationships that the child must navigate in the family
 - interdependency between parents and children (e.g. mother and daughter)
 - health and wellbeing of all parties (especially the offspring and birth mother)
 - how the parties consent to procedures
 - inheritance and property rights of the various parties.

4.4 Rationale for ACART's new position

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

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

Risks and benefits associated with family gamete donations

103. Benefits of gamete donation between family members include a known donor, strengthening of family relationships, and maintaining whakapapa or ancestry within a family.
104. Risks include consanguinity and inheritance of family genetic conditions, confusion about relationships, and potential undue influence or emotional pressure.
105. Family gamete donations, regardless of the relationship between family members or whether the family members are of the same or different generations, can carry risks for the affected parties and resulting children. When the risks are significant, they are most appropriately managed by ECART's review and decision.

No increase in applications to ECART

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

4.5 Advice to the Minister of Health

107. If ACART confirms its view that amendments are needed it would need to recommend to the Minister of Health, that the HART Order³⁰ be amended. The amendments would expand the list of prohibited family donations.

³⁰ HART Act section 35(1)(b)(iii).

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

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

Do you agree? Yes / No

Please give reasons for your views.

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

Do you agree? Yes / No

Please give reasons for your views.

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

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

Do you agree? Yes / No

Please give reasons for your views.

5 Clinic assisted surrogacy

5.1 The current situation

108. Neither the HART Act nor the HART Order defines the procedure of surrogacy. The HART Act defines a 'surrogacy arrangement' but refers to a legal agreement that is not enforceable,³¹ rather than the procedure itself, facilitated by a fertility services provider where a woman gestates an embryo for intending parents.
109. The current guidelines clarify in the Preamble that the criteria apply only where a surrogacy involves an assisted reproductive procedure. Surrogacies currently requiring ECART approval are those that involve a clinic, where the embryo transferred to the surrogate has been created from:
- gametes (eggs and sperm) of two intending parents
 - gametes of one intending parent (male or female) and a donor who is not an intending parent
 - gametes of two donors, neither of whom is an intending parent (not currently allowed under the guidelines).
110. Importantly for this discussion, surrogacies in a clinic where the surrogate uses her own eggs (traditional surrogacies) are not subject to ECART approval. If a woman agrees to be a surrogate, using her own eggs and the sperm of the intending father or another man, the arrangement is an established procedure under the HART Order. Likewise, if the surrogate uses donated eggs and the sperm of her partner, such a surrogacy is also not subject to ECART approval.
111. If the eggs as well as the sperm are donated, as is often the case, it is an assisted reproductive procedure and therefore requires ECART approval. The reason for this is that an intending parent who contributes sperm or eggs to the gestated embryo is technically donating gametes to the surrogate.

5.2 ACART's proposal in 2017

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

³¹ HART Act section 14(1).

5.3 ACART's new proposals

113. ACART now intends to recommend a change to the Order to enable all clinic assisted surrogacies be deemed subject to the guidelines (rather than changing the definitions of who is a donor).
114. Also, ACART's 2017 draft guidelines had a provision stating that "the surrogate has completed her family before becoming a surrogate for others." ACART now proposes to remove this provision and instead include a provision that ECART be satisfied that the parties have considered the risks arising from the surrogacy including any risks to the future reproductive capacity of the surrogate.
115. Finally, ACART now proposes that the guidelines should include a provision about the residency of the parties being sufficient to protect the well-being of the offspring and the adult parties. This provision will give ECART the scope to consider whether the residency plans will make such protections available.

5.4 Rationale for ACART's new proposal

Make all clinic assisted surrogacies subject to ECART consideration

116. ACART maintains the position, stated in the 2017 consultation document, that all clinic assisted surrogacies should be subject to ECART consideration. To recap the reasoning:
 - all surrogacies can be ethically complex
 - the wellbeing of offspring depends on the relationship between the surrogate and intending parents proceeding as expected, and intending parents adopting the child
 - surrogacy involves both a woman's choices about her body and the sometimes conflicting interests of the potential child and the intending parents
 - surrogates could be subject to coercion or undue influence, particularly if the surrogacy occurs within a close family relationship between intending parents and the surrogate.
117. In addition to these observations, ACART also notes that if clinic assisted surrogacies were not subject to ECART approval, the management of those surrogacies would lie entirely with the clinics.
118. Using these new requirements, ECART will be able to manage risks consistently across all those surrogacies and will be able to focus on the ethical considerations in accord with the HART Act principles.³²

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

Replace “finish family” requirement with a requirement about risk awareness

119. A requirement that a woman must have finished her family before acting as a surrogate is not actually enforceable or measurable – a woman might have another child for herself after being a surrogate.
120. Having said this, ACART believes a woman should have *considered* the implications of not having finished her own family. Such a provision makes it clear that there are important matters for the parties to consider but at the same time it does not prohibit a woman from being a surrogate without first finishing her family.
121. The risks or factors ACART considered when reaching this position were:
- risks to the surrogate, in particular to her own health and wellbeing and the risk of not being able to have her own family, after being a surrogate, if being a surrogate leaves her infertile
 - risks associated with pregnancy, childbirth and relinquishment of a resulting child to the intending parent(s)
 - the risk that the intending parent(s) may change their mind about parenting a resulting child
 - risks to the surrogate, offspring and intending parents, if the surrogate has not given birth before, and does not know how she will respond to pregnancy and birth
 - undue influence
 - differences in different family/friend circumstances
 - informed consent and autonomy.
122. Consequently, ACART has proposed a provision that the surrogate should be aware of these risks.
123. ECART had stated its preference for a provision that gives a strong indication that it would be ideal to have finished one’s own family first, but also gives ECART some discretion.

Include a residency provision

124. ACART proposes to include a provision about the parties having made plans that take into account the residency of those parties. The provision will require that these plans should be sufficient to protect the well-being of the offspring and the adult parties. The provision will give ECART the scope to consider whether the residency plans will make such protections available.
125. ACART decided to include this provision when confirming that it would rescind the mandatory biological link, because it noted the possibility that some children born to overseas surrogates could, in theory, be stateless.

126. Although ACART concluded that the removal of the mandatory biological link could in fact reduce the risk of statelessness, situations could still arise in which the offspring, intending parent(s) and surrogate could have limited, or no, ability to interact with one another.
127. ACART proposes that the “residency” provision should state that the residency plans of the parties should be a consideration for ECART to take into account rather than a requirement.

5.5 Impacts of ACART’s new proposals

128. The new proposal, to replace the requirement that the surrogate have completed her family with a requirement that the risks be considered and regarded as justified, gives surrogates and the other parties to surrogacy, greater autonomy while still ensuring that risks are taken into account. From a practical perspective, the new wording is unlikely to change the number of people acting as surrogates.
129. ACART’s new proposal to include a residency provision is also unlikely to have a bearing on the number of surrogacies, but it will give ECART an additional means for assessing the potential risks of the case.

5.6 Advice to the Minister of Health

130. If ACART confirms its view that these changes for clinic assisted surrogacy are needed, ACART would explain to the Minister of Health why they are being amended. ACART would also explain that the HART Order³³ should be amended to ensure that traditional surrogacies at clinics would be subject to ECART approval. The amendment will be to add to the Order that all clinic-assisted surrogacy arrangements are not established procedures.

³³ HART Act section 35(1)(b)(iii).

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

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

Do you agree? Yes / No

Please give reasons for your views.

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

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

Do you agree? Yes / No

Please give reasons for your views.

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

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

Do you agree? Yes / No

Please give reasons for your views.

6 Glossary

This glossary relates solely to terms used in this document and defines those terms in relation to discussions in this document only. For this reason, it should not be relied on as a legal interpretation of the terms listed.

Advisory Committee on Assisted Reproductive Technology (ACART)	The advisory committee established under New Zealand's HART Act. Members are appointed by the Minister of Health. For more information, see ACART's website at: acart.health.govt.nz
Assisted reproductive procedure	<p>Under the HART Act, a procedure performed for the purpose of assisting human reproduction that involves:</p> <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 Technology Order 2005 (HART Order) that do not require ECART review and approval.
Ethics Committee on Assisted Reproductive Technology (ECART)	The Ethics Committee established under New Zealand's HART Act. ECART reviews and decides case-by-case applications to undertake assisted reproductive procedures, human reproductive research and to extend the statutory storage period of gametes and embryos. ECART members are appointed by the Minister of Health. For more information, see ECART's website at: ecart.health.govt.nz
Fertility services provider	A fertility clinic.
Fertility Services Standard	A standard issued under the Health and Disability Services (Safety) Act 2001 that sets out the safety and quality measures that all New Zealand fertility services providers must meet. This standard came into force in 2009 and is available on ACART's website.

Gamete	An egg or sperm, whether mature or not, or any other cell (whether naturally occurring or artificially formed or modified) that (i) contains only one copy of all or most chromosomes and (ii) is capable of being used for reproductive purposes.
Genetic link	A link created when the embryo used is created by the sperm and/or eggs of the intending parents.
Gestational link	A link created when the embryo used is gestated by a woman who is an intending parent.
Gestational surrogacy	A surrogacy where an embryo is transferred into the uterus of the surrogate and has no genetic link to the surrogate.
HART Act (2004)	The <i>Human Assisted Reproductive Technology Act (2004)</i> is New Zealand's human assisted reproductive technology legislation, under which ACART and ECART were established. The Minister of Justice is responsible for the HART Act.
HART Order (2005)	The <i>Human Assisted Reproductive Technology Order (2005)</i> is an Order in Council stating regulations associated with the HART Act.
Informed consent	A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.
In-vitro fertilisation (IVF)	The uniting of egg and sperm outside the body (in the laboratory).
On-donation	A situation in which the recipients of donated embryos would donate surplus embryos to other recipients.
Re-donation	A situation in which surplus embryos are returned, by the recipients of those donated embryos, to the original intending parents and then donated by those original intending parents to a new intending parent or parents.
Surrogate	A woman who becomes pregnant, carries and delivers a child on behalf of another person or couple (intended parent(s)).
Te Ao Māori	A Māori world view or the Māori dimension of understanding.
Third-party assistance	Assisted reproductive procedures that require a party other than the intended parents to contribute to family formation and where a fertility services provider is involved.
Traditional surrogacy	Surrogacy where the eggs of the surrogate mother are used in conception (by in-vitro fertilisation or insemination).
Whakapapa	Genealogy, ancestral history, descent.
Whānau	Family group. In the modern context, the term is sometimes used to include friends who may not have any kinship ties to other members.
Whanaungatanga	A relationship, kinship, sense of family connection, through shared experiences of working together, which provides a sense of belonging.

Appendix 1

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

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

“ECART must be satisfied that:

12. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) has given consent to that specific use of their gametes:
 - a. at the time of donation, or
 - b. when a procedure using such an embryo is contemplated
13. in either case, implications counselling about the potential use of gametes was provided before the gamete donor gave specific consent
14. all parties understand that the gamete donor can vary or withdraw consent only up until an embryo is created (in cases where consent is given before the embryo is created)
15. in addition, where a procedure will involve the use of a donated embryo, the person(s) for whom the embryo was created must have given consent to the specific use of the donated embryo:
 - a. at the time of donation, or
 - b. when a procedure using such a donated embryo is contemplated
16. all parties understand that, once an embryo is created, the authority to vary or withdraw consent up to the time the embryo is transferred to the womb remains with the person(s) for whom the embryos were created.”

Feedback form

Please provide your contact details below.

Name	Alex Price
If this feedback is on behalf of an organisation, please name the organisation	Fertility Associates Holdings Limited (FA)
Please provide a brief description of the organisation (if applicable)	Provider of fertility services
Address/email	aprice@fertilityassociates.co.nz
Interest in this topic (eg, user of fertility services, health professional, researcher, member of public)	<ul style="list-style-type: none">• CEO of FA• Submission from the organisation

Privacy

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

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

☐ Do not publish this submission.

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

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

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

☐ This submission contains commercially sensitive information.

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

ECART must be satisfied that:

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

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

Do you agree with the proposed consent provisions?

Yes

☒

No

☐

Please give reasons for your views.

FA believes that general principles are more likely to have longevity in this space and should be the starting point for debate. The number of embryo donations is actually quite low in NZ – we believe that the number of “re-donations” will be correspondently extremely small and therefore clarity is of benefit to patients in considering their options.

We believe there are three stakeholders involved in embryo donation:

- 1) The providers of the original gametes who have a genetic investment and therefore need to provide consent
- 2) All of the original (first) recipients of embryos, as recorded in the original treatment consent, who have an emotional investment by dint of the embryos being created for their treatment
- 3) Those offspring by dint of genetic linkage, and if not yet at the age of consent (16 years), their parent/guardian/s who are full siblings to the potential child (embryo)

FA believes that the consent of all three stakeholders are necessary in re-donation.

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

Conversely stakeholders who do not meet the criteria of these three stakeholders may be consulted but their explicit consent is not required.

FA believes that the consent of the above three stakeholders provides the right balance between people being able to access treatment and ensuring the wellbeing of the potential child, all involved in the reproduction are supportive and have given consent, – first principle of the HART Act

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

Rationale as outlined in Ques 1

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

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

Do you agree?

Yes ☒ No ☐

Please give reasons for your views.

We support making this clear

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

Covered in original submission:

FA supports matching regulation to potential for coercion, rather considering that all within family donation has the same status. We support the need for ECART review of within-family donations when cross-generational donation is proposed, and in any planned donation where the clinic considered there is a higher risk or potential evidence of coercion.

If the current exception for donations by cousins and siblings continues, we would like to see the legal definitions widened to include in-law and step relationships.

All donation occurs within a framework of compulsory counselling by counsellors with training and experience in ART and gamete and embryo donation.

We would like to raise the concept of a framework for rating risk, and an ECART application being needed if the risk passed a threshold. This is an increasingly common approach in health and safety and other areas.

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

Refer to section 4.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

These inclusions are consistent with other areas of donation, with concern of undue influence, and with our original submission. Further, given the importance of the wellbeing and health of the potential child and women undergoing treatment (principles of the HART Act) that inter-generational complexities do need consideration.

FA supports strengthening this consideration. Coercion may be more probable with intergenerational donation. However, coercion is not limited to with-family donation. We would like the option of being able to submit any planned donation to ECART for advice, not just donation involving family members.

We also raise the concept of ACART providing voluntary guidelines for clinics and consumers in some areas where ECART approval is not required, for instance using embryos after a couple has separated.

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

Refer to section 5.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

This is consistent with our original submission that Crown Law's interpretation of IUI surrogacy as donor insemination needs to change.

FA clinics have a policy requiring ethical review of all surrogacy cases where the surrogate's own eggs are to be used, and a non-binding opinion is sought from ECART in these cases. FA supports regulation to strengthen this, making ECART approval a requirement for treatment. It is our view that cases where the surrogate's own eggs are used are amongst the most challenging and risky surrogacy cases.

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

Refer to section 5.

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

Do you agree?

Yes

☒

No

☐

Please give reasons for your views.

From our experience with surrogacy we consider that a further relevant consideration be:

'consider the risks to the future reproductive capacity of the surrogate, AND

'consider the physical and mental health of the surrogate' in her previous pregnancies'

Surrogates who have had a difficult pregnancy, including significant post-partum depression, do find being a gestational carrier more challenging and this needs to be a factor in the decision making.

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

Refer to section 5.

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

Do you agree?

Yes ☒ No ☐

Please give reasons for your views.

FA believes that we should be in a position to provide third-party reproduction to patients from other countries, including those where treatment options are not available, for example the South Pacific.

So, being a New Zealander (broadly by citizenship or residency) should not be a requirement for being a participant in third-party reproduction.

However, EACRT should take into account other countries laws/regulations to ensure there is a pathway to adoption or parentage of the child by the intending parents that ensures the wellbeing of the potential child is protected.

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

No

13 March 2019

Dr Kathleen Logan
Acting Chair
Advisory Committee on Assisted Reproductive Technology (ACART)
PO Box 5013
Wellington 6145

By email: acart@moh.govt.nz

Dear Kathleen

Thank you for the opportunity to comment on ACART's paper *Second Round of Consultation on the proposed Donation and Surrogacy Guidelines*.

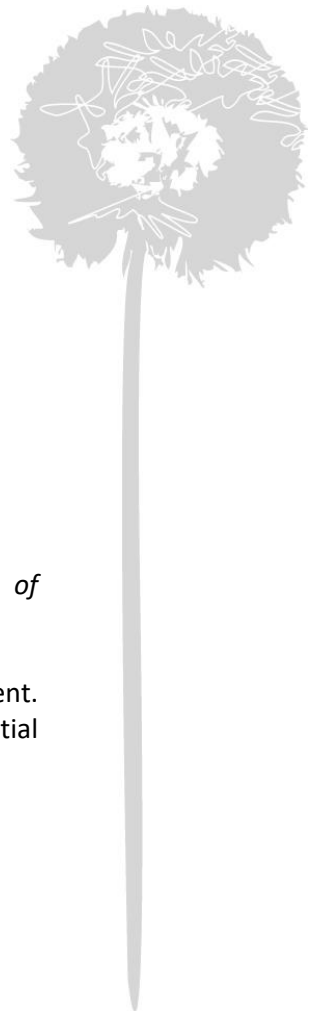
Fertility New Zealand's Executive Committee has discussed the consultation document. We are broadly supportive of it, and in particular the changes made since the initial consultation.

We would appreciate being kept informed as discussions progress.

Yours sincerely



Nicola Bitossi
CEO



29 March 2019



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Dr Kathleen Logan
Acting Chair
Advisory Committee on Assisted Reproductive Technology (ACART)
PO Box 5013
WELLINGTON

Dear Dr Logan

Proposed Donation and Surrogacy Guidelines: second round of consultation

Thank you for the opportunity to comment on the Advisory Committee on Assisted Reproductive Technology's (ACART) proposed guidelines for family gamete donation, embryo donation, the use of donated eggs with donated sperm and clinic-assisted surrogacy (the proposed guidelines).

As you are no doubt aware, the Health and Disability Commissioner is charged with promoting and protecting the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code).

The Health and Disability Commissioner provided a submission in November 2017 as part of the earlier consultation process on the proposed guidelines. The current consultation document seeks feedback on three aspects of the proposed guidelines that ACART has reconsidered since the consultation in 2017. As with the Commissioner's earlier submission, this response focuses on the elements that relate to the Code and informed consent. We also reiterate the comments made by the Commissioner in his earlier submission.

Consent provisions

The consent provisions in the proposed guidelines are essentially about identifying who will have the authority to consent to the use of gametes or embryos in each case.

In the Health and Disability Commissioner's earlier submission in the 2017 consultation round, he noted that, for the purposes of the Code, consent must always be informed. Under the Code, informed consent involves three essential elements - effective communication (Right 5), provision of information (Right 6), and making an informed choice and giving informed consent (Right 7). The Code applies to any individual or organisation that provides health services, including fertility services. In light of this, we restate the Commissioner's earlier recommendation that the term "informed consent" is used in the guidelines.

The consent provisions have implications for those who are contemplating donating, as well as those who are to receive donated gametes and embryos. The rules therefore need to be clear and accessible for all parties. Currently, the rules in the proposed guidelines are difficult to understand when seen on their own. Without further explanation or illustration of the consent rules, it may be

unclear to fertility service consumers how the rules may apply in their situation. For example, it is not clear what the implications of the second bullet point in rule 17 will be and what it adds to the first bullet point. We suggest consideration be given to further clarification within the guidelines, or explanatory material that can accompany the guidelines.

Family gamete donation

The consultation document rightly recognises the risk of undue influence or emotional pressure coming into play with gamete donation between family members. We support the inclusion of the requirement for ECART to be satisfied that parties to such donations are not subject to undue influence.

Conclusion

I trust that these comments are helpful. Please do not hesitate to contact Renay Duncalfe, Senior Legal Adviser, on (04) 494 7015 or renay.duncalfe@hdc.org.nz if you have any questions about this submission.

Yours sincerely



Jane King
Associate Commissioner, Legal

Response ID ANON-P1SY-P3WC-A

Submitted to **Second round of consultation on the proposed donation and surrogacy guidelines**

Submitted on **2019-03-25 14:05:01**

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

Do you agree with the proposed consent provisions?

No

Please give reasons for your views:

We agree in principle to the proposed consent provisions. However, we are concerned that consent of the gamete donors does not seem to be required in the case of re-donation of an embryo created using their gametes. We may have misunderstood this, however it seems as though once embryos have been created the gamete donors have no right to consider to whom these embryos are given. We believe that in the case of re-donation, the permission of the gamete donors as well as the original person/persons for whom the embryo was created must be given the opportunity to give or with-hold consent. Friends or family members may have donated gametes for a specific person or couple and may not be comfortable with an unknown third party/parties receiving an embryo that contains their genetic material.

Question 2: ACART proposes a new position on interest in and authority over embryos

Do you agree?

No

Please give reasons for your views:

Again, we agree to this proposed authorities but recommend that the original gamete donors must also be consulted and have the right to give or with-hold consent to the proposed re-donation.

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

Do you agree?

Yes

Please give reasons for your views:

This will help ensure that, (within the limits of existing knowledge of genetics and reproduction), children conceived using ARTs have the best opportunity of living without conditions and syndromes that are known to have a greater chance of being expressed in offspring of closely genetically related "parents".

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

Do you agree?

Yes

Please give reasons for your views:

We believe that this requirement provides an essential additional safeguard and opportunity for understanding of the implications of participating in ART, for all individuals involved in between family donations.

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

Do you agree?

Yes

Please give reasons for your views:

We believe that every possible method of ensuring that a) there has been no pressure put on potential gamete donors and b) that within limits of current knowledge, the health and wellbeing of the donor and the resulting child are understood and that informed consent has been obtained from all parties.

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

Do you agree?

Yes

Please give reasons for your views:

Again, we agree that it is necessary to put in place any practicable safeguard to the wellbeing of all parties involved in a surrogacy arrangement. It is neither safe, nor appropriate, for clinic, owners or operators (who may benefit financially from surrogacy arrangement) to be given authority to assist surrogate pregnancies, without recourse to independent ethical review of individual cases.

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

Do you agree?

No

Please give reasons for your views:

We agree with this proposal because it is impossible for any women to decide conclusively that her family is complete, prior to menopause or irreversible longterm contraception. We also agree that it is essential that any surrogate understands that this process could have implications for her future reproductive capability. However we would advocate for surrogacy being restricted to women who have already been pregnant and given birth. It is impossible for a woman who has never carried a child to fully understand the emotional repercussions of relinquishing a baby who she has nurtured inside her body for the duration of pregnancy. The future adoptive parents as well as the birth mother need to be assured of the greatest possible chance of the surrogate arrangement being successful and we believe that this can only happen if the surrogate mother knows what she is giving up, and this can only happen if she has already carried and birthed a baby.

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

Do you agree?

Yes

Please give reasons for your views:

The child born as a result of surrogacy needs to be given the best possible opportunity to have her/his/their right to knowledge of, and contact with her/his/their birth mother and this provision will help ensure that this right is facilitated.

Question 9: Do you have any other comments about these proposals?

Please give reasons for your views

Reasons:

Your details

What is your name?

Name:

Brenda Hinton

What is your email address?

Email:

mscc@maternity.org.nz

If this feedback is on behalf of an organisation, please name the organisation

Organisation:

Maternity Services Consumer Council

Please provide a brief description of the organisation (if applicable)

Organisation description:

The MSCC is an umbrella organisation made of consumer groups who have an interest in any aspect of reproductive health and reproductive health service provision. Our Steering Group is made up of experienced maternity consumer representatives who provide informed consumer input and information to local and national reproductive health care providers and consumers.

Interest in this topic (eg, user of fertility services, health professional, researcher, member of public)

Interest in topic:

Maternity services consumer representative

Publishing submissions and privacy

Publishing submissions

You may publish this submission

Official Information Act responses

Remove my personal details from responses to Official Information Act requests

Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.:

TD-102
2019-03/002

18 March 2018

Advisory Committee on Assisted Reproductive Technologies
Ministry of Health
Wellington

Tēnā koe

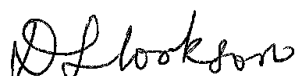
Proposed Donation and Surrogacy Guidelines: Stage 2 consultation

The New Zealand Nurses Organisation *Tōpūtanga Tapuhi Kaitiaki o Aotearoa* (NZNO) welcomes the opportunity to provide feedback on the above consultation. We have consulted widely with members and staff, including all colleges and sections, Nurse Practitioners and Te Runanga o Aotearoa comprising our Māori membership. We have had limited feedback but this has indicated support for replacing four separate guidelines with one set that covers the four procedures for family gamete donation, embryo donation, the use of donated eggs with donated sperm (donated eggs/donated sperm), and clinic-assisted surrogacy. NZNO received no specific objections or recommendations in relation to the guidelines.

NZNO is supportive of ACART's consideration of the importance of Māori needs, beliefs and values (such as whanau, whakapapa and whanungatanga in relation to gamete and embryo donation) when developing the proposals in this document.

We trust the above is useful and would be happy to discuss if necessary.

Nāku noa, nā



Di Cookson
Research and Policy Assistant

New Zealand Nurses Organisation | PO Box 2128 | Wellington 6140
diana.cookson@nzno.org.nz or 04 494 8244

About NZNO

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 52,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements. NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse*.

Second Round of Consultation on the Proposed Donation and Surrogacy Guidelines:

This feedback is on behalf of Repromed Auckland.

Repromed is interested as a provider of fertility services.

Repromed is located at 105 Remuera Rd, Remuera, Auckland

Question 1:

ACART proposes provisions for consent by gamete and embryo donors. Do we agree with proposed consent provisions?

Yes

Question 2:

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

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

Yes

Question 3:

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

Yes

Question 4:

ACART proposes not to amend the Order so that ECART is required to consider all between-family donations. Do we agree?

Yes

Question 5:

ACART proposes the guidelines should include the new requirement, for cases involving donations of family gametes, in place of the provision that was consulted on in 2017. Do we agree?

Yes

Question 6:

ACART proposes that a change to the HART Order is the best way to ensure all clinic-assisted surrogacies be subject to ECART consideration. Do we agree?

Yes

Question 7:

ACART proposes to remove the phrase “the surrogate has competed her family” and replace it with the phrase that asks parties to “consider the risks to the future reproductive capacity of the surrogate”. Do we agree?

Yes

Question 8:

ACART proposes to include a provision that ECART can take into account the participant’s residency status and plans. Do we agree?

Yes

Will ACART provide an example of an arrangement in which the residency status of the parties would not be acceptable?

Other comments:

1) In regards to Embryo donation and use:

Could ECART issue or provide a clear explanation/ guideline that would enable clinics to discuss the intricacies of re-donation with patients/clients as this is a complex area.

Clear processes for family linking

2) In regards to Clinic –assisted surrogacy requirements:

There is the inclusion of the phrase “ECART must be satisfied that

5. in the opinion of the counsellor, the health and wellbeing....”

And

6. all affected parties have considered, and in the opinion of the counsellor, have understood....”

Please provide clarity on how ECART would like the counsellor to state their opinion.

Would ECART want an explicit statement/ statements from the counsellor about their perceived understanding the clients have on these matters? Would this be a particular inclusion/ change to the summary form?

Repromed continues to support:

- A requirement for legal advice in both embryo donation arrangements and surrogacy arrangements.
- A requirement for police vetting of recipients for donated embryos.

Repromed proposes that recipients of donated eggs and donated sperm (in combination) are police vetted.

Repromed proposes a confidential national donor register is established. Such a register would assist clinics in monitoring when the number of families created from a donor reaches the limit of 10 families. This is a concern if donors are donating at more than one clinic. Clinics are currently reliant on donors self-reporting if they are donating at more than one clinic.