Advisory Committee on
Assisted Reproductive Technology

ACART Advice and Guidelines for Gamete and Embryo Donation and Surrogacy

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To: Hon Jenny Salesa

cc: Hon Dr David Clark; Hon Julie Anne Genter; Hon Carmel Sepuloni

Title: ACART is about to publish guidelines for gamete and embryo donation and surrogacy

Contents

A Executive summary

1. The Advisory Committee for Assisted Reproductive Technology (ACART) is about to issue amended guidelines for the donation of eggs, sperm and embryos and for surrogacy. The new guidelines combine four previous guidelines; Table 1 summarises the changes, the reasons for them and their effects.

2. ACART recommends that you ask Cabinet to change the Human Assisted Reproductive Technology Order 2005 (the HART Order) so that it requires all clinic assisted surrogacies to be subject to guidelines and explicitly states that all embryo donations (with one exception) are subject to guidelines. Once the Order has been changed, ACART will issue a final set of guidelines that state that all clinic assisted surrogacies are subject to guidelines.

3. The guidelines have been amended to remove the mandatory biological link between at least one intending parent and offspring. By removing this requirement, ACART has removed a potential source of discrimination and enabled gametes and embryos to be donated in a greater range of situations. The new guidelines make clear the circumstances in which embryos can and cannot be donated and who has authority to consent to donations.

4. Other changes include clarification of the issues people must consider if taking part in a surrogacy arrangement and of the requirement for the Ethics Committee on Assisted Reproductive Technology (ECART) to check for intergenerational risks and undue influence.

5. Several factors have prompted ACART to make these changes. In 2011, ACART received a complaint that the surrogacy guidelines discriminated on the basis of sex and sexual orientation. Consequently, ACART issued new surrogacy guidelines in 2013. At the same time, ACART issued new family gamete donation guidelines as it wanted to make them consistent with the new surrogacy guidelines, which no longer required a medical reason to justify a surrogacy.

6. Subsequently, ACART concluded that the mandatory biological link, between at least one intending parent and any offspring, was likely to be an unjustified discrimination. ACART consulted the public on proposed amended guidelines in 2017 and again in 2019 and, taking submissions into account, settled on the guidelines in this advice.

7. In developing this advice, ACART carefully considered the wellbeing of children born from assisted reproductive technology (ART) and mitigated potential risks through, for example, the detailed requirements for counselling, consent and limiting full genetic siblings to a maximum of two families. These provisions are intended to both protect future relationships between children, their parents and other relevant parties and to meet the other statutory principles in the Human Assisted Reproductive Technology Act 2004 (HART Act).

8. Under section 35(1)(a) of the HART Act, ACART is required to review its guidelines regularly.

Table 1: Changes, recommendations, rationale and effects

Change/recommendation		Rationale	Effects
1.	**Removal of the "biological link" and medical requirements** (page 28) *(Note the related changes to embryo donation and consent – see separate sections below)*		
A.	The mandatory biological link has been removed.	The previous policy may have been unjustifiably discriminatory and restricted some activities unnecessarily.	The risk of inadvertent discrimination is removed. More people can use fertility procedures. More people can donate their gametes. Embryos can be donated in a greater range of situations. More 'surplus' embryos can be used (rather than disposed of).
B.	The requirement that a person must have a medical condition to use certain procedures has been replaced with a requirement that a procedure is the best or the only opportunity for the person to have a child.	The previous provision might have inadvertently discriminated against people who had limited options to form a family due to, for example, sexual orientation or sex.	ECART can consider a greater range of personal circumstances. The risk of inadvertent discrimination has been removed.
2.	**Clarifying when embryo donations must be considered by ECART** (page 33)		
A.	ACART **recommends** a change to the HART Order to explicitly state that embryo donations (with the one exception set out in item 2B) are not established procedures.	Not all parties are aware that all embryo donations are subject to ECART consideration. Embryo donation is ethically complex so should, in most cases, be subject to ECART consideration.	ECART will consider all cases of embryo donation (with one exception) thereby managing any risks associated with those cases.
B.	ACART **recommends** a change to the HART Order to define one particular scenario of embryo donation as an established procedure.	Despite the ethical complexity of embryo donation, ECART would not need to consider cases where an embryo created in one relationship is to be used by one of the partners from that relationship with a new partner (with consent from the previous partner).	Certain embryo donations would not need to be seen by ECART, as is currently practised. ECART could assess the proposed procedure for risks if asked to do so by the fertility clinic. ECART would be able to decline, or advise on, risky donations.

	Change/recommendation	Rationale	Effects
3.	**The consent requirements are more detailed and there are now more options for donating embryos** (page 35)		
A.	New consent requirements have been introduced for the new situations that the revised guidelines have made possible. Existing consent requirements have been elaborated on.	The new donation scenarios need to be specified in the guidelines to ensure participants are aware of them and can agree to them. Removing the biological link increases the range of possible donation scenarios, so more complex risks and ethical matters could arise. Therefore, it is important that all parties understand the implications of different scenarios. The expanded provisions clarify when and why consent must be obtained.	All parties will be aware of the implications of the procedures and be able to give informed consent accordingly. All parties will have a clearer understanding of the consent requirements. Retrospective consent from gamete donors will be sought if a new donation scenario is planned that they did not know about when they originally consented to gamete donation.
B.	The authority to donate embryos is explained and a new provision gives the authority to on-donate embryos to the recipients of donated embryos **if certain criteria are met**.	Removing the mandatory biological link opens up the possibility of a scenario in which people who have received donated embryos should have the authority over what happens to the embryos.	The recipients of donated embryos will have authority in one scenario where certain criteria are met. The original donors will not have any say in the use of the embryos (other than through conditions they placed before originally donating).
4.	**Recommendation that all clinic assisted surrogacies be subject to ECART consideration; and remove the requirement that a surrogate must have completed her family** (page 39)		
A.	ACART **recommends** changing the HART Order to exclude all clinic assisted surrogacies from being established procedures (so that all would be required to be considered by ECART).	Traditional surrogacies[1] are not subject to ECART consideration; nor are surrogacies where the egg is donated to the surrogate and she uses her partner's sperm. All clinic assisted surrogacies are ethically complex and should be subject to ECART consideration.	ECART will be able to manage risks consistently across all surrogacies and to focus on ethical considerations.
B.	A new provision requires surrogates to consider their future reproductive capacity.	The previous provision (requiring surrogates to have finished their families) was not enforceable. Nevertheless, gestating and giving birth could compromise a woman's ability to have further children so she needs to consider these risks.	The provision makes it clear surrogates have important matters to consider but does not prohibit a woman from being a surrogate without first finishing her family.

[1] In a traditional surrogacy, the surrogate uses her own egg, with either in vitro fertilisation (IVF) or insemination. In a gestational surrogacy, the surrogate uses an embryo created for the intending parents (usually from their own gametes, but removing the mandatory biological link also makes it possible to be a donated embryo).

Change/recommendation		Rationale	Effects
C.	An amended provision requires all parties to consider how their residency will affect relationships in the future.	The previous provision was less future focused. It is important for parties to be able to communicate and their residency could affect that communication in the future. Overseas surrogacies can affect immigration and citizenship rights of children.	The wellbeing of all parties, particularly children, is better protected. ECART will be able to consider whether the residency plans will provide such protections.
5.	**One guideline replaces four, and the language and format have been standardised** (page 45)		
A.	ACART has combined the three previous sets of donation guidelines and the surrogacy guidelines into one set of guidelines. It has also standardised the language and format.	The previous guidelines had some provisions that were mutually exclusive but these exclusions have now been removed. The previous guidelines were inconsistent in their language and format.	ECART can consider more complex cases. The single set of guidelines is more consistent in its language and clearer in its meaning.
6.	**The two family limit for full genetic siblings is now universal** (page 46)		
A.	The two-family limit for full genetic siblings is now specified for all embryo donations or donations of eggs in conjunction with sperm.	Although the limit applied previously, some of the separate sets of guidelines did not explicitly state it.	All parties will understand that the limit applies regardless of the procedures they are considering.
7.	**Stronger mitigation of risks for donations between family members** (page 48)		
A.	Greater emphasis has been given to managing intergenerational risks.	The previous provisions were not strong enough to fully manage possible intergenerational risks.	The potential effects of intergenerational risks are minimised.
B.	More family gamete donations are prohibited.	The previous list was less comprehensive and might not have sufficiently minimised the risks of consanguinity (blood relationships).	The amendments are consistent with current clinic practice and clear regulation reduces the risk of consanguinity.
8.	**Stronger provisions for managing undue influence** (page 50)		
A.	Greater emphasis has been given to managing undue influence.	The previous provision was not strong enough, especially for family gamete donations and surrogacy.	The new provisions minimise the risks of undue influence.
9.	**The provisions about obtaining legal advice have been rationalised** (page 52)		
A.	The requirement to obtain legal advice is now mandatory in cases involving surrogacy and optional for cases not involving surrogacy.	The previous provision was that parties must have understood legal advice: this requirement was difficult to enforce. Nevertheless, in a surrogacy all affected parties must have received legal advice. In fertility procedures other than surrogacy, the legal implications are simpler but affected parties should still consider seeking legal advice.	In surrogacy cases, the requirement for the parties to receive independent legal reports will continue but counsellors will not have to ascertain whether the parties have understood the advice. In cases not involving surrogacy, ECART must be satisfied that the affected parties have considered seeking legal advice.

	Change/recommendation	Rationale	Effects
10.	**Improved access for donor offspring to information about their genetic origins** (page 53)		
A.	ACART **recommends** to the Department of Internal Affairs that, on its web page about obtaining birth certificates, it should add a statement that information about people's genetic origins might be available on the HART register.	Such a statement would raise awareness about the register and the information it contains. Not all donor offspring are aware of their genetic heritage despite the HART Act requirement that offspring from assisted reproduction can learn their genetic heritage. This option can be achieved without changes to birth certificates.	The suggested change could raise awareness of the HART register among the public, and help donor offspring to learn about their genetic heritage.
B.	ACART **recommends** that the Births, Deaths, Marriages and Registrations Act should be amended so that birth certificates could include a statement that the Births, Deaths and Marriages register might contain other information that the certificate's owner may access.	Not all donor offspring are aware of their genetic heritage despite the HART Act requirement that offspring from assisted reproduction can learn their genetic heritage. Section 67(1) of the Births, Deaths, Marriages and Registrations Act prescribes the information that can and must be on birth certificates.	The suggested change could raise awareness of the HART register among the public, and help donor offspring to learn about their genetic heritage.

B Recommendations

9. We recommend that you:

1	**note** ACART is about to issue the first set of combined, amended guidelines for the donation of eggs, sperm and embryos and for surrogacy	
2	**agree** to recommend to Cabinet a change to the HART Order to state that all embryo donations are assisted reproductive procedures	Yes / No
3	**agree** to recommend to Cabinet a change to the HART Order to state that the use of embryos in one particular scenario is not an assisted reproductive procedure	Yes / No
4	**agree** to recommend to Cabinet a change to the HART Order to state that all clinic assisted surrogacies are assisted reproductive procedures	Yes / No
5	**agree** that the Births, Deaths, Marriages and Registrations Act should be amended so that birth certificates could include a statement that the Births, Deaths and Marriages register might contain other information that the certificate's owner may access	Yes / No
6	**present** a copy of the guidelines to the House of Representatives in accordance with section 36(3) of the HART Act	Yes / No
7	**note** these first combined guidelines will be used before and until the HART Order is changed and will then be updated if and when the HART Order is changed as recommended.	

Dr Kathleen Logan
Chair, Advisory Committee on Assisted Reproductive Technology

Minister's signature **Date**

Dr Kathleen Logan		Martin Kennedy	
Chair, ACART		Senior Policy Analyst, Ministry of Health	
Phone	04 495 7804 (business)	Phone	04 816 4459
Cellphone		Cellphone	N/A

C The new guidelines

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

Preamble
ACART can issue guidelines. The Advisory Committee for Assisted Reproductive Technology (ACART) is appointed by the Minister of Health. 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 Human Assisted Reproductive Technology Act 2004 (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 Human Assisted Reproductive Technology Order 2005 (HART Order).
Principles
When considering an application to carry out any of the following procedures, the Ethics Committee on Assisted Reproductive Technology (ECART) must be guided by the principles of the HART Act. The principles state: All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function: (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure (b) the human health, safety, and dignity of present and future generations should be preserved and promoted (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins (f) the needs, values, and beliefs of Māori should be considered and treated with respect (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.
Scope of the guidelines
In these guidelines, ACART sets out the requirements for assisted reproductive procedures that require a party other than the intended parents (third party assistance) to contribute to family formation and where a fertility services provider is involved.

Provisions that apply to all procedures covered in these guidelines
General requirements
ECART must be satisfied that: 1. all relevant parties have consented to the procedure 2. the parties have not been subjected to any undue influence 3. 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) 4. the procedure is the best or the only opportunity for intending parents to have a child 5. the intending parents are not using the procedures for social or financial convenience or gain 6. the potential genetic, social, cultural and intergenerational aspects of the proposed arrangement safeguard the wellbeing of all parties and especially any resulting children 7. any relationships between the parties safeguard the wellbeing of all parties and especially any resulting children.
Counselling requirements
ECART must be satisfied that counselling: 8. has been received by each party in accordance with the current Fertility Services Standard 9. will be available throughout the donation and/or treatment process 10. is culturally appropriate 11. has provided for whānau or extended family involvement 12. has provided for the inclusion of any existing children of the parties 13. has addressed any matters raised by donation(s) between family members 14. has included implications counselling for all parties, and parties have considered and, in the opinion of the counsellor, have understood: a. the rights of offspring, including their rights to obtain identifying information about the donor 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 that the birth mother (whether she is the intending mother or a surrogate) may terminate the pregnancy g. issues related to the 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

Notes

For the purposes of these guidelines:

- a **donor** is as defined in the HART Act
- a **recipient** is the person or people who receive donated gametes or embryos with the intention of parenting the offspring
- a **patient** is as defined in the HART Order
- an **original intending parent** is the person or people who originally intended to parent the offspring that would be born from the use of the gametes or embryos.

When a person or people donated gametes or embryos before these guidelines were issued, and a procedure is now intended that had not been possible under the previous guidelines, the donors must give new consent.

Consent requirements

ECART must be satisfied that:

15. where a procedure will involve the use of an embryo created from donated eggs and/or sperm, the gamete donor(s) consented to the specific use of their gametes at the time of donation or subsequently
16. implications counselling about the potential use of gametes was provided before the gamete donor consented
17. 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)
18. where a procedure will involve the use of a donated embryo, the original intending parents (ie, the people who originally had the embryo created for themselves) must consent to the specific use of that embryo:
    a. at the time of donation, or
    b. if consent was not obtained at the time of the donation, when a procedure using such a donated embryo is contemplated[2]

[2] 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 all parties have agree to the embryo donation).

Consent requirements (continued)

19. where a procedure will involve the use of a re-donated embryo:
    a. consent to the specific use of the embryo is needed from both the:
        - original intending parents 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
        - recipient(s) of the donated embryos if they have already had offspring that would be a full genetic sibling to a child that would be born from the embryos that are now being donated
    b. that consent must be given:
        - at the time of donation, or
        - if consent was not obtained at the time of the donation, when a procedure using such a donated embryo is contemplated
    c. a re-donation can only be made if either the original intending parent(s) or the recipients have not had offspring that would be a full genetic sibling to a child that would be born from the embryos (ie, the limit of two families that can have full genetic siblings applies)
20. all parties understand that, once an embryo is created, the original intending parents have the authority to vary or withdraw consent up to the time the embryo is transferred to the uterus. The recipients have the authority to consent to the embryo donation if all of the following conditions apply:
    - the original intending parents did not have a child that would be a full genetic sibling to a child born from the donated embryo
    - the original intending parents did not have any gametes in the embryos
    - the recipients who will now donate did have a child that would be so related.

Legal advice requirements

ECART must be satisfied that:

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

Health advice requirements

ECART must be satisfied that:

24. all parties have received independent medical advice
25. 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:

26. the parties to the donation are not subject to undue influence
27. 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
28. affected parties have received joint counselling
29. the relationship between the intending parent(s) and the other family members safeguards the wellbeing of all parties and especially of any resulting offspring.

Notes

Ethical approval is not required for family donations where:

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

If a clinic is unsure about a case, it can request an ethical review from ECART.

The HART Order defines a family member, for the purposes of donation, as any other person who:

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

Embryo donation and use

Notes

(a) Embryo **donation** includes the:
- agreement to donate a stated number of surplus embryos
- transfer of an embryo into the uterus of the gestating woman (intending parent or surrogate).

(b) Embryo **re**-donation is:
- the donation of embryos by the original intending parents to new recipient(s).

(c) Embryo **on**-donation is:
- the donation of embryos by the recipient(s) of donated embryos.

(d) Donated embryos may be **re**-donated by the original intending parents if:
- 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 prior recipient(s) of the donated embryos have had offspring that would be full genetic sibling(s) 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 prior recipient(s) of the donated embryos have not had offspring that would be full genetic sibling(s) to a child that would be born from the embryos, **or**
- neither they nor the prior recipients have had offspring that would be full genetic sibling(s) to a child that would be born from the embryos.

(e) Donated embryos may be **on**-donated by the recipients only if the:
- original intending parents have no gametes in the embryos **and**
- original intending parents did not have offspring using embryos that would be full siblings to those that would be born from the embryos being donated **and**
- recipients have had offspring using embryos that would be full siblings to offspring that would be born from the embryos being donated.

(f) Any donation, re-donation or on-donation requires an application to ECART.

Requirements

ECART must be satisfied that:

30. all affected parties understand that embryo donors can withdraw or vary consent up to the point of placing the embryo in the gestating woman's uterus
31. the embryo donors and recipients have received joint counselling relating to the implications of embryo donation
32. all affected parties have discussed, understood and agreed between themselves on matters relating to the use and storage of embryos and disposal of any unused embryos
33. if the original intending parents are donating the embryos for the first time, those embryos:
    - have been created for the fertility treatment of the donor(s)
    - are surplus to the needs of the donor(s); that is, they have completed their family or no longer intend to have children
34. if embryos are being re-donated, they fit the circumstances specified in Notes 29(d) and (e) above
35. recipients have been vetted by the Police.

Use of embryos created from donated eggs in conjunction with donated sperm

Note

Although donated eggs and donated sperm from the same two people may be used together to produce full genetic siblings in up to two families, neither donor is precluded from separately donating sperm or eggs to another couple or person.

Clinic assisted surrogacy

Notes

For the purpose of these guidelines:

- **surrogacy** describes a procedure facilitated by a New Zealand fertility clinic where a woman gestates an embryo for one or more intending parents
- a **surrogate** is a woman who becomes pregnant, and carries and delivers a child on behalf of one or more other intending parents.

Commercial surrogacy is prohibited under the HART Act.

A surrogacy arrangement is not enforceable by or against any person.

Any surrogacy that involves an assisted reproductive procedure requires an application to ECART.

Where a case involves established procedures, a clinic can still request an ethical review from ECART.

Requirements

ECART must be satisfied that:

36. affected parties have discussed, understood and declared intentions between themselves about the day-to-day care, guardianship and adoption of any resulting child and any ongoing contact
37. the risks associated with a surrogacy for the adult parties and any resulting child are justified in the proposal. These risks include risks to the health and wellbeing of:
    a. the intending surrogate, including risks:
        - associated with pregnancy, childbirth and relinquishment of a resulting child to the intending parent(s)
        - that the intending parent(s) may change their mind about parenting a resulting child
        - to the surrogate's reproductive capacity in the future
    b. the intending parent(s) (and embryo donor if applicable), including risks that the surrogate changes her mind about relinquishing a resulting child
    c. a resulting child, including risks that arise where that child becomes the subject of a dispute if the relationship between the surrogate and intending parents breaks down
38. 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
39. all affected parties have received joint and individual counselling
40. counselling will be made available to all parties before and after pregnancy is achieved
41. in the opinion of the counsellor, the health and wellbeing of the intending surrogate and any resulting offspring are adequately safeguarded
42. 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.

D Purpose of this report

10. This report consults you, under section 41(2) of the HART Act, on proposed guidelines that ACART is about to issue to ECART. The new guidelines amend and combine four previous sets of guidelines for the donation of eggs, sperm and embryos and for surrogacy.

11. ACART recommends that you ask Cabinet to change the HART Order to:

    - require all clinic assisted surrogacies to be considered by ECART (with ACART issuing a final set of guidelines after this change is made)
    - state that ECART must consider all embryo donations (with one exception).

12. ACART's advice explains why it has reviewed and revised the guidelines, how it consulted stakeholders and took their views into account, and what the implications of the changes will be.

E Structure of this report

13. This report discusses:
    - the scope of this advice and of the guidelines
    - how New Zealand regulates assisted reproduction
    - why ACART has amended the guidelines
    - matters ACART has taken into account
    - the consultation process
    - the changes in the revised guidelines and how ACART decided to make those changes
    - next steps.

F The scope of this advice and the guidelines

In scope

14. This advice recommends changes to the HART Order and explains the reasons for those recommendations. It also presents amended guidelines for donations and surrogacy that will be published in the near future. The advice explains the reasons for, and likely implications of, the amended guidelines.

15. The first recommended change to the HART Order is to make all surrogacies that clinics perform subject to ECART consideration. The other significant recommended change is to clarify the regulatory status of the donation of embryos. On the basis of advice it has received, ACART believes that ECART approval is required under current legislation but, to remove any ambiguity, ACART is recommending the change to the HART Order. The recommendations also propose one exception in which an embryo donation should be exempt from ECART consideration by becoming an 'established procedure'.

16. The guidelines have been amended to:
    - remove a potentially discriminatory provision
    - enable gametes and embryos to be donated in a greater range of situations
    - clearly state the circumstances in which embryos can and cannot be donated
    - state who can and must consent to activities now that the mandatory biological link has been removed and new donation options are available
    - clarify the issues parties must consider if they are taking part in a surrogacy arrangement
    - clarify the requirement for ECART to check for intergenerational risks and undue influence
    - rationalise the requirements for obtaining legal advice.

Out of scope

17. Neither the amended guidelines nor this advice address donations relating to human reproductive research. The Human Assisted Reproductive Technology Act 2004 requires ACART to give you advice on this subject (s 37(1)) and ACART plans to address that requirement when it reviews the guidelines on human reproductive research.

G How New Zealand regulates assisted reproduction

18. New Zealand's requirements for assisted reproduction are set out in:
    - the HART Act and the HART Order
    - the Code of Health and Disability Services Consumers' Rights (the Code)
    - guidelines issued by ACART to ECART
    - the Fertility Services Standard.

The HART Act

19. The HART Act is the principal law regulating human assisted reproductive technology and human reproductive research in New Zealand. The HART Act requires ACART to advise the Minister of Health on specific matters related to assisted reproduction. This advice must not be inconsistent with the Code.

The HART Order

20. The HART Order lists the established procedures (that clinics are permitted to do without ECART approval), and the exceptions to those procedures, that require ethical review by ECART in accordance with ACART guidelines.

Guidelines issued by ACART

21. ACART issues guidelines to ECART, as required by section 35 of the HART Act, for assisted reproductive procedures that ECART needs to consider. As part of this advice, ACART is proposing that certain activities would require ECART's ethical approval.

The Code of Health and Disability Services Consumers' Rights

22. 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. Right 7 also gives every consumer the right to make decisions about what happens to their body parts or bodily substances removed or obtained in the course of a health care procedure.

23. While the Code does not address all matters of informed consent for assisted reproductive technology, any regulations, or guidelines issued by ACART, must be consistent with the Code.[3]

The Fertility Services Standard

24. Providers of fertility services in New Zealand must operate in accordance with the Fertility Services Standard 2007 (the Standard), which sets out requirements for the safety and quality of fertility services in New Zealand. The Standard is a form of regulation issued under the Health and Disability Services (Safety) Act 2001. Providers are audited and certified against the Standard, which the Ministry of Health administers.

Informed consent

25. A well-established body of law and practice concerning informed consent for medical procedures upholds the principle that autonomous individuals have the right to make decisions about procedures carried out on them.

26. Section 4 of the HART Act (Principles) addresses informed consent. It provides:

> *(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.*

[3] HART Act s 76(1)(a)(i).

27. When carrying out any medical procedure, providers must ensure that consumers[4] receive information about all important aspects of their procedures. Appropriate consent forms for the procedure are required, and providers must have clear policies and procedures to obtain informed consent from consumers.

Other relevant legislation relating to adoption of children from surrogacy

28. The legal status of children born as a result of assisted reproductive procedures is governed by the Status of Children Act 1969.[5] 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.

29. 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.[6] For the intending parents to assume legal parenthood of a child born from surrogacy, the Family Court must first issue an adoption order under the Adoption Act 1955.[7]

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[4] In this document, an ART 'consumer' has the definition given in the glossary of the Fertility Services Standard: 'A user or participant in the service, including client, patient, gamete or embryo donor. Where appropriate this may include the family/whānau or other representatives.'

[5] Status of Children Act 1969, s 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.)

[6] Peart N. 2015. Alternative means of reproduction. In P Skegg and R Paterson (eds) *Health Law in New Zealand*. Wellington: Thomson Reuters (p 537).

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

H Why ACART has amended the guidelines

Guidelines should not discriminate and should be consistent

30. ACART issued four separate sets of guidelines from 2008 to 2010 to cover family gamete donation, embryo donation, the use of donated eggs with donated sperm and surrogacy. In 2011, it received a complaint through the Human Rights Commission that the surrogacy guidelines discriminated on the basis of sex and sexual orientation. In response, ACART issued new surrogacy guidelines to ECART in 2013, which allowed ECART to approve applications by single men and male couples to use surrogacy to become parents.

31. At the same time, ACART also 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. In doing so, it 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.

32. Under section 35(1)(a) of the HART Act, ACART is required to review its guidelines regularly. Thus, in 2015 ACART decided to review the other two sets of donation guidelines to ensure that they were consistent with the guidelines issued in 2013. ACART also decided to consider the feasibility of having one set of guidelines to cover all four procedures.

33. More specifically, ACART concluded that the mandatory biological link, between at least one intending parent and any offspring, was likely to be an unjustified discrimination against some parties who wished to have a child. Consequently, that requirement needed to be changed. Several other necessary changes were also identified including that ECART should consider all embryo donations and all clinic assisted surrogacies.

34. Other necessary changes identified were to standardise terminology and replace ineffective provisions with more practical provisions.

ACART keeps guidelines current and provides you advice

35. Section 35(1)(b)(ii) of the HART Act requires ACART to advise you following public consultation on proposed advice (s 39). ACART has analysed the guidelines in question and submitters' responses to the consultations as required under section 6 of the HART Act.

36. One of ACART's functions is to issue guidelines and give advice to ECART on any matter relating to any kind of assisted reproductive procedure or human reproductive research and to keep such guidelines and advice under review.

37. ACART may issue guidelines to ECART only after it has:

- on the basis of a discussion paper or an outline of the proposed guidelines, given interested parties and members of the public a reasonable opportunity to make submissions
- taken any such submissions into account
- consulted on the proposed guidelines with the Minister of Health.

ACART's monitoring identified necessary changes

38. ACART's functions include monitoring the application of assisted reproductive procedures and liaising with ECART on general and specific matters relating to assisted reproductive procedures (section 35 of the HART Act). Section 35(1)(b)(ii) directs ACART to assess whether any established procedure should be modified or should cease to be an established procedure.

39. ACART has carried out these functions and observed several matters that need attention. Specifically, the 10 'change' matters discussed in Section K became apparent as ECART has considered cases.

Literature review

40. ACART also monitors the literature on assisted reproduction, as required in section 35 of the HART Act. This review of the literature informed ACART's thinking on each of the changes discussed in Section K.

Comments from the sector and interested parties

41. The sector and stakeholders had commented on some practices that were not allowed, under the HART Act, HART Order and guidelines. For example, the effect of the mandatory biological link in the guidelines was that any people or couples who could not provide their own eggs or sperm were not allowed to have a surrogate gestate a child for them. Also, some people could never donate their embryos because they had been made with donated gametes.

I Matters ACART has taken into account

42. In developing the proposed guidelines and advice, ACART has taken into account:
    - the principles of the HART Act
    - other common ethical principles, including autonomy, families and 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
    - feedback from public consultation on related matters
    - evidence and information from local and international sources
    - ACART's ethical framework.

43. 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.[8]

44. 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.[9]

45. 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 many Māori may share certain views, individuals and whānau will have their own preferences and practices.

46. Nonetheless, the concept of te ao Māori (Māori world view) has 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.

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

9 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).

47. Principle 4(g) of the HART Act recognises the diversity resulting from migration and a pluralistic, multicultural society. It requires the different ethical, spiritual and cultural perspectives to be considered and treated with respect in the context of assisted reproduction.

48. 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.

J ACART's consultation process – two stages

49. To develop these revised guidelines and combine them for the first time, ACART consulted the public twice. The initial consultation, from 5 September to 13 November 2017, was about relinquishing the biological link policy and other policies. Then from 14 February to 25 March 2019 ACART consulted about changes to other policies in light of the first consultation. ACART's summary of all submissions is attached as Appendix 1 and the full submissions are on ACART's website.

50. On 23 August 2017, ACART advised the (then) Associate Minister of Health Hon Peter Dunne about its intention to consult the public on the proposed guidelines and the advice it would provide about the guidelines. ACART provided Mr Dunne a copy of the consultation document.

51. In the first consultation, ACART received written submissions from 14 individuals and organisations including one fertility services provider, Fertility New Zealand (a consumer group), the Bioethics Centre (University of Otago) and a number of women's health advocacy groups. These submitters are those ACART would normally expect to hear from when consulting on fertility matters.

52. In addition to receiving written submissions, ACART held three meetings with stakeholders. One was with staff members from a fertility services provider (Fertility Associates), one with Fertility New Zealand and the third with the Northern Regional Fertility Service. Public meetings were also held in the main centres of New Zealand.

53. ACART published the meeting notes and submissions on its website.

54. Overall, submitters supported the proposal. They raised a number of matters, many of which ACART addressed in the consultation document. ACART's recommendations and advice to you take their comments into account. A list of submitters and interviewees is included in Appendix 1, with the summaries of all submissions.

55. The submissions made compelling arguments that four of ACART's proposed changes needed to be reconsidered. Those changes were that (a) ECART should consider all family gamete donations, (b) three of the surrogacy provisions needed refining, (c) the embryo donation scenarios needed to be explained in more detail and (d) the consent provisions needed to be clarified.

56. ACART prepared a second consultation document and provided it to Hon Dr David Clark, as the Minister of Health, on 4 December 2018. During the second consultation, ACART made a correction to the document to insert a section of the guidelines that had inadvertently been omitted and advised all stakeholders of the amendment.

57. The next section discusses the submissions as part of the assessment of each proposed change.

K The changes to the guidelines

58. This section explains ACART's decisions and/or recommendations with reference to: the problem that each one addresses, the proposed solution and its risks and benefits, and submitters' perspectives. The discussion of benefits notes how the amended guidelines are better placed to deliver the full benefits anticipated in the HART Act and how they more closely follow the principles of the HART Act.

Change 1: Removal of the 'biological link' and medical requirements

59. The 'biological link policy' required that a child born from an assisted reproductive procedure must have at least one biological link (either genetic or gestational) to an intending parent.[10] The surrogacy guidelines explicitly expressed this policy through the requirement that at least one intending parent must be the genetic parent of any resulting child.

ACART's conclusions/decisions

60. By rescinding the requirement that intending parents must have a biological link to the children born from fertility treatment, ACART makes it possible for more people to use fertility treatment and to be donors. Under the previous guidelines, some people (intending parents, donors and surrogates) may have been discriminated against because of the requirement. The removal of the mandatory biological link has implications for the provisions for embryo donation and for consent and surrogacy.

61. The implications for surrogacy are discussed under Change 4 with the other changes to the surrogacy provisions.

62. Removing the biological link requirement is closely related to the removal of the medical condition requirement.[11] That change is discussed in this section because, as well as being related to the matter of the biological link, it involves the matter of 'best or only opportunity' for a person to have a child.

[10] 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.

[11] That requirement was in the guidelines for the use of donated eggs in conjunction with donated sperm.

The problems

63. The biological link policy meant that surrogacy could not take place with either embryo donation or donated eggs in conjunction with donated sperm. Both of those procedures use an embryo that is created from gametes of two people who are not the intending parents.

64. Additionally, the requirement for a biological link was implicit in the previous guidelines for embryo donation and for donated eggs/donated sperm. Those guidelines stated that parties must have had a medical condition in order to use the procedures. Consequently, some people were precluded from using those procedures due to their sexual orientation and the provision was potentially discriminatory.

65. If ACART wished to retain the biological link policy in any or all of the guidelines that involve third-party assistance to have a child, it would need to consider the justification in accordance with the New Zealand Bill of Rights Act 1990 (NZBORA). The NZBORA applies to the government and also to people and bodies that perform lawful public functions, powers or duties (s 3). The NZBORA therefore applies to ACART guidelines.

66. ACART 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. One example of a negative effect is that the policy precludes infertile men (single or male couple) from surrogacy, which may be their only opportunity to have a child and is discriminatory.

67. The intent of the original policy is likely to have been related to the safety and wellbeing of children by ensuring they are genetically related to one or more intending parents. However, while a genetic or gestational link to a child may be a protective factor, it is not necessarily the only consideration that ensures safety and wellbeing of children born using ART. Other considerations are the family dynamics and the desire of the intending parent(s) to have children.

Benefits of the changes

68. By rescinding the mandatory biological link between offspring and at least one intending parent, more people can now take advantage of fertility procedures. This change means that New Zealand will more fully secure the benefits of assisted reproduction which is the first purpose of the HART Act. More specifically, ECART can now consider cases that involve surrogacy and embryo donation or donated eggs in conjunction with donated sperm, provided it is satisfied that the circumstances of the specific case justify using the procedures in question. For example, single people who are infertile, or couples in which both partners are infertile, can now seek fertility treatment using surrogacy if necessary.

69. Similarly, removing the implicit requirement for parties to have a medical condition to be eligible to use donated embryos or donated eggs in conjunction with donated sperm removes the potential discrimination. As a consequence, more people will be able to use these methods of ART to have children.

70. Also, more people who are willing to donate embryos or gametes will be able to do so. This includes couples who had embryos created for them using donated gametes.

71. In addition, rescinding the biological link policy may encourage some people, who are currently excluded from fertility treatment in New Zealand, to remain in this country for their treatment. Treatment in New Zealand, as noted in ACART's 2015 Import/Export Advice, offers the following advantages.

    - The HART Act's provisions protect intending parents and resulting children (particularly in respect of identifiable genetic parentage through the HART register).
    - The intending parents can remain close to family and friend support networks.
    - The intending parents do not incur overseas travel costs.[12]

A procedure must be the best or the only opportunity for a person to have a child

72. The new provision (with no mandatory biological link or medical need requirements) recognises that using a particular procedure is not always based on a medical need. The change brings consistency to the provisions. However, there are ethical matters and risks to manage so a provision is needed. For this reason, ACART has introduced a requirement that a procedure is the 'best or only opportunity' for the person to have a child. ECART must still be satisfied that the use of the procedures is justified, for example, by someone's infertility and/or relationship status.

Risks of the changes

73. Allowing procedures that result in no genetic or gestational link between the intending parents and offspring will increase the ethical complexity and introduce legal complexity, in particular in cases using surrogacy. Such procedures will also increase the number and complexity of relationships for all parties involved and any resulting children.

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

74. People might choose not to donate sperm or eggs if they have reservations about the new possibilities for donation, re-donation or on-donation. However, donors have the right to place restrictions on the subsequent use of embryos created from their gametes.

75. Although the HART Act prohibits valuable consideration (eg, payment) for surrogates and gamete donors, even without valuable consideration there is a risk that children could be seen or treated as commodities to be created from eggs, sperm and a uterus outside the context of an ongoing relationship between parties.[13]

76. A growing number of children are being born through the donation of gametes or embryos, or surrogacy, thus creating families in which the children lack a gestational and/or genetic relationship with one or both parents. Although less is known about non-traditional families formed through reproductive donation than about traditional families, research suggests these new family types may not be at sufficiently greater risk of parenting or child-adjustment problems than the traditional family make-up to justify discrimination.[14,15]

77. For these reasons, ECART must be satisfied that any application that does not include a genetic or gestational link is justified. For a discussion of the issue of justification to use a procedure, see paragraph 72.

Risk acceptability and management

78. ACART's view is that mechanisms are available to mitigate the risks associated with allowing children to be born with no genetic or biological link to an intending parent. These mitigations include the stringent counselling and consenting processes that must be followed (for a detailed discussion of consent provisions, see Change 3). The HART Act requires that no assisted reproductive procedure be performed on an individual unless the individual has made an informed choice and given informed consent – by including clear and strong consent requirements, the guidelines meet that principle.

79. New Zealand law also requires that offspring are able to learn about their genetic origins.

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

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

15 Golombok S, Ilioi E, Blake L, et al. 2017. A longitudinal study of families formed through reproductive donation: parent-adolescent relationships and adolescent adjustment at age 14. *Developmental Psychology* 53(10): 1966–77.

80. Further, ACART notes that several other jurisdictions allow children to be born with no genetic or biological link to an intending parent and that these jurisdictions also believe risks can be managed.

81. Also, fertility treatment generally, and some of the procedures that will be enabled by this change, are becoming gradually accepted as valid methods for people to become parents as the technology has evolved and social norms have changed.

82. Although people generally prefer to have a close biological link to their children, the new guidelines will enable people to have children to whom they have no genetic link. Given that this is the only or the best option for some intending parents, it is likely that ECART will receive more applications. The extent of the increase in applications is difficult to estimate.

Submitters' views and ACART's assessment of them

83. Submitters were evenly divided on the proposal. Those supporting the change stated that more people would be able to use fertility services and that social norms have changed to the extent that many people would consider it acceptable to allow such procedures. These submitters noted that, for the most part, people will still choose to have a biological link if possible.

84. Conversely, those opposing the change were concerned about the welfare of the children in particular, as they could have several 'parents' and be uncertain about their identity. They emphasised that it is essential that children are able to learn their biological origins and that the proposed changes put that at risk.

Principles from ACART's ethical framework

85. ACART's ethical analysis is guided by the principles of the HART Act.[16] Overall, ACART has not identified any ethical issues that could not be managed through the ECART process, in counselling or between the parties to a procedure.

Respect for the needs, values and beliefs of Māori

86. Genetic connectedness within iwi is of importance to many Māori. However, rescinding the mandatory biological link policy does not undermine this importance, as people can choose to maintain biological links and genetic connectedness.

[16] Section 4, HART Act 2004.

Change 2: Clarifying when embryo donations must be considered by ECART

Recommendation: Amend the HART Order to make embryo donation within a relationship an established procedure and to be clear that ECART approval is needed for all other embryo donations.

ACART's conclusions/decisions

87. ACART considers that ECART need not consider embryo donations where those embryos will be used by a person for whom they were created, but with a new partner, if the former partner (whether deceased or still alive) has consented to that use. All other embryo donations have ethical risks significant enough to be subject to ECART consideration and the HART Order should explicitly state this requirement.

88. In cases where embryos will be used by a person for whom they were created but with a new partner (if the former partner has consented), the ethical matters or risks would be insufficient to warrant the procedure being subject to ECART consideration. In these situations, use is appropriately covered by the requirements of informed consent.[17]

The problems – unclear legal status; complexity and ethical considerations

89. Neither the HART Act nor the HART Order is explicit about the status of embryo donation in the regulatory framework. While the HART Act includes a definition of 'donated embryo',[18] the HART Order does not refer to embryo donation at all.

90. ACART has learned there is a degree of uncertainty about the legal status of embryo donation and so recommends a change to the HART Order to state that donation within a relationship is an established procedure (as explained above) and all other embryo donations are assisted reproductive procedures. ACART takes the view that embryo donation is an assisted reproductive procedure and requires ECART approval and, for clarity, this status should be explicit in the HART Order.

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

[18] Section 5, HART Act 2004.

91. When ACART issued the initial guidelines, embryo donation was seen as one of the most ethically complex procedures.[19] Recent research has highlighted the challenges for the parties involved in embryo donation and for resulting and existing children. These challenges include:

- uncertainty about how the relationship between donors and recipients will unfold in the future and how the children involved will see it (embryo donation is a comparatively new procedure, and the New Zealand model is unique)
- for donors, a sense of connection to a resulting child who is a full genetic sibling to their own existing offspring but with whom they have no parental role
- for recipients, the recognition that a resulting child will have links to another family and may want some degree of contact with the donor family.[20]

92. The previous guidelines precluded some people from donating surplus embryos because of the requirement that donated embryos must have been created from the gametes of a donating couple.

93. Now that ACART has rescinded the mandatory biological link policy, it is consistent that the guidelines should also enable the donation of surplus embryos that were created from donated gametes. However, it is essential that ECART takes into account the potential complexity of resulting relationships and that the gamete donors have consented to the donation, either at the time of donating or later (in accord with ACART's new consent provisions applying to all procedures).

Benefits of ECART considering all embryo donations and of the exception

94. Amending the HART Order, to explicitly state that all embryo donations (with one exception) must be considered by ECART will remove any uncertainty about the requirement. Any risks associated with such donations are then likely to be identified and managed accordingly.

95. The benefit of not requiring ECART to consider cases where a person will use embryos created for themselves, but with a new partner, is that the parties will not need to go through the time and cost of the ECART process. Such use is appropriately covered by the requirements of informed consent.[21]

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[19] Goedeke S, Daniels K, Thorpe M. 2016. Embryo donation and counselling for the welfare of donors, recipients, their families and children. *Human Reproduction* 31(2): 412–8.

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

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

Risks of the changes

96. The risks of allowing embryo donations in a greater range of situations are explained in paragraphs 72 to 76 (above) and 125 and 126 (below).

97. Because of these risks, and the possibility that embryo donation might become more common, ECART must be satisfied that any application to use a procedure that does not include a genetic or gestational link is the best or the only opportunity for the applicant to have a child.

Submitters' views and ACART's assessment of them

98. In ACART's 2017 consultation, 13 submitters supported the proposal and three opposed it. Those supporting the proposal stated that because embryo donation is ethically complex, it should be carefully managed.

99. One submitter opposed the proposal because they thought that all embryo donations should go to ECART (ie, that there should be no exemptions). Another submitter who opposed the proposal thought that virtually all cases could be handled by clinics and therefore should not need to go to ECART.

100. ACART concluded the proposal was sound, that none of the submissions outweighed ACART's rationale and the change should go ahead.

Change 3: Consent requirements are more detailed and there are now more options for donating embryos

101. This section covers two closely related changes. Change 3A covers ACART's new, detailed provisions for consent. Change 3B is a specific new provision that allows people to donate on to further recipients embryos that they have received from original intending parents or other recipients **if** certain criteria are met. These donations, referred to as 'on-donations', could have significant implications and ACART has carefully considered stakeholders' submissions. Re-donation (by the original intending parents) is also now permitted, as discussed under Change 3B.

3A New, detailed provisions for consent

ACART's conclusions/decisions

102. ACART decided to include new and more detailed provisions for consent in the amended guidelines, with some changes for clarification.

103. The new provisions carefully set out who must consent to which activities, and when that consent must be given, if a procedure is to go ahead.

104. As is the case now, gamete donors will be able to change or withdraw their consent up to the point the gametes are used to create an embryo. However, because the guidelines introduce new donation scenarios, ACART has also introduced a consent provision to cover potential retrospective effects of the new guidelines. That is, when a person or people had donated gametes or embryos **before these new guidelines were issued** and a procedure is now intended that had not been possible under the previous guidelines, the donors must give new consent. This requirement for a new consent applies even when donated gametes have already been used to create embryos under the previous guidelines because the gamete donors might not have considered or consented to the use of the embryo that is now intended.

105. ACART will provide a supplementary narrative to stakeholders when it publishes the guidelines, to ensure they understand how the consent process works. Some submitters suggested this option and ACART agrees that this is a good idea. A draft of the supplementary narrative is attached for your information and ACART expects to have it finalised by October 2019.

The problem

106. Because ACART has rescinded the mandatory biological link policy, it is now possible for a greater range of donations to be made and for more complex relationships to be created. Consequently, ACART needed to change the consent requirements to ensure they address the new donation scenarios and to ensure that all parties give informed consent and that clinics and ECART understand who can or must consent to an activity.

107. More specifically, allowing procedures in which there is no genetic or gestational link between the intending parents and offspring is likely to increase the complexity of their relationships and of relationships between them and gamete or embryo donors and surrogates. In cases involving surrogacy, the legal complexity will also increase.

108. Additionally, the introduction of new donation and surrogacy options meant that people might wish to use stored gametes or embryos in a way that the donors had not considered when they initially donated the gametes or embryos. Therefore, ACART needed to introduce a new provision for donor consent to cover potential retrospective effects of the new guidelines.

ACART's initial and subsequent proposals

109. ACART's 2017 consultation asked submitters to comment on the proposed provisions for obtaining consent from gamete and embryo donors and any other parties to a fertility procedure. The submissions made it apparent that some people had interpreted the provisions in ways ACART had not anticipated and also that some submitters had not understood some of ACART's intentions.

110. Consequently, ACART further amended the consent requirements and consulted on these in 2019. The consent provisions in the 2019 consultation are more detailed than those in the 2017 consultation and cover all of the types of donation that could arise.

Benefits of the changes

111. The amended provisions will account for all of the new donation scenarios and ensure parties make informed choices about the specific use of their gametes or embryos, taking into account the long-term implications. The provisions make it clear when certain donations are not permitted, giving all parties a clear understanding of their options.

Risks of the changes

112. ACART has not identified any risks associated with the new consent provisions. They exist to mitigate potential risks from the greater variety of donation scenarios possible. Although the consent provisions are detailed, and in some cases refer to one another, they are clear and logical.

Submitters' views and ACART's assessment of them

113. When ACART consulted in 2017, 80 percent (16 of 20) of submitters supported the proposed provisions. The four who were not in favour were not opposed in principle but rather they wanted clarifications. Some submitters asked whether re-consenting would be needed and some submitters appeared not to have fully understood ACART's intentions.

114. Consequently, ACART consulted again in 2019 to clarify its intentions and provide clearer, more detailed consent provisions. Nine submitters supported these revised provisions, two opposed, and three commented on the timing of consent and the need to ensure that the right people could consent at the right time.

115. One opposing submitter was concerned about the increased complexity of relationships and considered that there will be more families with donor-conceived children than ACART anticipates.

116. ACART concluded that the provisions are suitable and any risks will be managed with proper, informed consent, counselling and the ECART process. Based on the responses to the 2019 consultation, ACART made minor changes to improve clarity and believes the provisions are fit for purpose. ACART agrees that it is important that all parties understand the timing of consent and will include commentary on that in its supplementary narrative.

3B Authority regarding use of embryos, on-donation and re-donation

ACART's conclusions/decisions

117. ACART's conclusion is that the provision for consenting to the donation of embryos is fit for purpose. The provision will ensure that when embryos are donated, under the conditions discussed below (such as on-donation and re-donation), the party that agrees to make that donation is the appropriate one to do so.

118. In most cases, the original intending parents (for whom the embryos were created) will have the authority to donate or re-donate embryos. Such donations will be possible if the criteria are met, including the two-families limit for full genetic siblings.

119. While other parties might believe they could or should have a say in the use of the embryo, the counselling process will ensure parties are aware of the potential donation of embryos when they first take part in fertility treatment. Parties will be made aware that an embryo donation might happen that they could have no control over, although they could place conditions on their initial donation to preclude further donations.

120. ACART decided it would also add narrative to the supplementary advice to clinics so that they understand the purpose of the provision and any expectations on ECART and clinics.

The problem

121. Removing the mandatory biological link extends the range of donations that can be made and allows more complex family arrangements to be created. ACART needed to elaborate on the provisions for donating embryos and consenting and make them clearer so that parties could readily understand which donations were permitted, which were not, and whose consent needed to be obtained in the different scenarios.

ACART's proposed changes

122. 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-family limit would not be breached. ACART proposed that the original intending parents would always have the authority to decide on the use of donated embryos.

123. After that initial consultation, ACART further considered the provisions for embryo donation and concluded that the authority over embryos should lie with the **recipients** of donated embryos **if**:

- the original intending parents did not have any gametes in the embryos **and**
- no more than one party had had a child using embryos that would be a full sibling to the child that would be born from the embryos to be donated.

Benefits of the change

124. This provision reflects the stronger interest of the first recipients in the embryos, as a result of the genetic relationship that would be created between their existing children and any child subsequently born from those embryos.

Risks of the change

125. A risk of this change is that the people who originally had the embryos created for themselves might feel they have a special connection to the embryos but will not have any say in how the embryos are used in this scenario. This risk is mitigated by the counselling and informed consent required before they make the donation. In contrast, in cases of **re**-donation the original embryo donors would continue to choose who receives their surplus embryos.

126. Risks of on-donation also include:

- added complexity to resulting relationships
- offspring having concerns about their origins and identity.

Submitters' views and ACART's assessment of them

127. Nine submitters supported this provision, one opposed it and four made additional comments.

128. A common theme from the submitters who were opposed to the provision or had other comments was a concern that people who are unknown to the gamete donors might receive the embryos. ACART is aware of this possibility and will add text to its

supplementary narrative to explain that gamete donors must be made aware, by counsellors, that an embryo might be donated and possibly re-donated or on-donated and that they will have no say in any donation (other than through conditions they might have placed before their gametes are used).

129. Another matter one submitter raised was that on-donations should only be allowed once. After considering this matter, ACART has concluded that ECART should have the discretion to assess each case on its merits and decide whether any additional on-donation should be permitted. ACART believes that on-donations and any subsequent on-donations are likely to be very rare.

130. ACART consulted the Department of Internal Affairs (DIA) on the legal requirements for recording donations and offspring on the HART register when new types of gamete and embryo donations, and re-donation and on-donation, become options. The DIA advised ACART that there are no legal barriers to recording this information.

Change 4: Make all clinic assisted surrogacies subject to ECART consideration and remove the requirement that a surrogate must have completed her family

131. ACART has introduced or amended three provisions for clinic assisted surrogacy. It also recommends one change to the HART Order.

132. ACART's **recommendation** for surrogacy is to:

- amend the HART Order so that ACART can issue guidelines that would require **all** clinic assisted surrogacies to be considered by ECART.

133. The two changes to the guidelines mean that:

- a surrogate is no longer required to complete her family and instead must consider her future reproductive capacity
- all parties must consider how their residency will affect relationships in the future.

4A Recommendation: amend the HART Order so that all clinic assisted surrogacies must be considered by ECART

ACART's conclusion/recommendation

134. ACART concluded the proposal is sound and recommends that the HART Order be amended so that all clinic assisted surrogacies must be considered by ECART.

The problem

135. All surrogacies can be ethically complex and involve both a woman's choices about her body, and the sometimes conflicting interests of the potential child and the intending parents. Despite this, not all clinic assisted surrogacies require ECART approval, because 'traditional surrogacy' (surrogacy where the surrogate uses her own eggs) is not considered to be an 'assisted reproductive procedure' as defined in the HART Act.[22] Similarly, surrogacies in which the surrogate uses a donor egg (that is, the intending mother's egg) and her own partner's sperm are also established procedures and therefore not subject to ECART consideration.[23]

136. Also, if clinic assisted surrogacies were not subject to ECART approval, the responsibility for managing those surrogacies would lie entirely with the clinics.

ACART's proposal

137. ACART's 2017 consultation asked readers if they agreed with the recommendation to amend the HART Order to state that 'all clinic assisted surrogacies should be subject to ECART consideration'. Its 2019 consultation restated the proposal.

Benefits of the change

138. Many submitters stated the counselling required for ECART applications was beneficial to people taking part in a surrogacy and safeguarded the arrangement. Once the HART Order is amended, ACART will be able to amend the guidelines to require all clinic assisted surrogacies to be considered by ECART. ECART's oversight of these cases will be an ideal way of managing the risks associated with surrogacy.

Risks of the change

139. Requiring all surrogacy cases to go to ECART might delay people's treatment and cause them stress. As a result, some people might choose not to go through fertility clinics and instead use 'home insemination'. The change would not make more work for ECART and clinics because, in practice, clinics tend to refer all clinic assisted surrogacies to ECART for review.

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

[23] However, if the eggs as well as the sperm are donated, as is often the case, it is an assisted reproductive procedure and therefore requires ECART approval. An intending parent who contributes sperm or eggs to the gestated embryo is technically donating gametes to the surrogate.

Submitters' views and ACART's assessment of them

140. Of those who submitted to the 2017 consultation, seventeen supported the proposal and three opposed it. Those opposing stated that requiring all surrogacy cases to go to ECART would cause delays and stress, make more work for ECART and clinics, and potentially dissuade people from going to clinics.

141. Of those who submitted to the 2019 consultation, 14 were in favour. None of the 2019 submitters opposed the proposal, but in a survey of the public an academic[24] found some respondents do not support having ECART consider all clinic assisted surrogacies. These people believed that other mechanisms can be used to address risk, such as counselling, discussions between parties if they already know one another, or having clinical experts rather than ECART assess cases. They noted that the ECART process can be daunting. A submitter to the 2017 proposal had made the same points when opposing it.

142. ACART accepts the validity of the opposition but believes the risks of the problem that need to be managed outweigh the arguments against the proposal.

4B Surrogates should consider their future reproductive capacity

ACART's conclusions/decisions

143. ACART has removed the provision that a woman must have finished her family before acting as a surrogate and replaced it with a provision that a woman must consider her future reproductive capacity before acting as a surrogate.

The problem

144. The previous requirement that a woman must have finished her family before acting as a surrogate was not actually enforceable or measurable. A woman might have another child for herself after being a surrogate and might change her mind at any time.

145. Nonetheless, ACART believes that before acting as a surrogate 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 – the woman's autonomy is maintained.

[24] Details are in the summary of submissions (see Appendix 1).

ACART's initial and subsequent proposals

146. In 2017, ACART's consultation proposed retaining the provision that a woman must have finished her family. On further reflection after the consultation, ACART concluded that the provision was not enforceable and that an alternative was needed. Consequently, ACART's 2019 consultation proposed the new provision that surrogates should have considered their future reproductive capacity.

Benefits of the change

147. By requiring women to consider the risks of carrying a child and relinquishing that child to another party, the new provision helps to ensure women will be adequately informed to give consent. The provision will ensure that women are aware of the various risks, particularly to their own fertility, and have considered them adequately.

148. The provision helps all parties to understand the implications of surrogacy in order to give informed consent. The parties other than the surrogate also face risks (eg, providing sperm and/or eggs to a surrogate but then not becoming parents to the child if the surrogate chooses to keep it).

Risks

149. Surrogacies involve several risks,[25] including the risk addressed by this provision that a woman's fertility might be compromised by carrying a child. If a woman acts as a surrogate and the pregnancy compromises her fertility, then she may be unable to have or finish a family of her own.

150. Another risk is that a woman who has never had a baby may be a surrogate, so neither she nor the intending parents will know how her body reacts to pregnancy. This poses greater risks for all parties than using a surrogate who has experienced pregnancy and child birth, as she would know more about what to expect and can make a more informed decision.

[25] Surrogacies can be ethically complex. The wellbeing of offspring depends on the relationship between the surrogate (and any partner she may have) and the intending parents, or whether the intending parents will adopt the child, thereby legalising their status as parents. Also, a surrogate's behaviour and choices can conflict with the interests of the potential child and the intending parents; surrogates could be subject to undue influence, particularly if the surrogacy involves close family members; or the surrogate might not relinquish the child even if it is the genetic child of the intending parents.

Submitters' views and ACART's assessment of them

151. Eleven submitters supported ACART's proposal, while three opposed it.

152. Those agreeing with the proposal stated the new provisions are better as they are workable and less restrictive on women's choices.

153. The submitters opposing the amended surrogacy provisions did not want to remove them; instead, they suggested the existing provisions should be **stronger**. They stated the provision should give greater direction to ECART as women who act as surrogates without having previously given birth face significant risks. One fertility services provider recommended adding to the provision 'consider the risks to the future reproductive capacity of the surrogate' so that it further states 'and consider the physical and mental health of the surrogate in her previous pregnancies'.

154. Two other submitters proposed the provision should state that it is preferable that a surrogate should have experienced childbirth. After discussing the advantages of this suggestion, ACART concluded that associated risks are mitigated through the counselling provisions and ECART being satisfied all the parties are making an informed choice. A woman should be able to choose to be a surrogate if she really wants to do so, but does not wish to be a parent.

4C All parties must consider how their residency will affect relationships in the future

ACART's conclusions/decisions

155. ACART believes this provision will ensure parties to a surrogacy will have plans in place to protect the wellbeing 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.

156. ACART also decided it would add narrative to the supplementary advice so that the purpose of the provision and any expectations on ECART and clinics are understood.

The problem

157. The previous guidelines required ECART to take into account whether the residency of the parties safeguards the wellbeing of all parties and especially any resulting child. ACART considered that requiring people to anticipate their place of residence would be unenforceable and potentially unreliable and would not necessarily help maintain relationships even if the predictions proved accurate.

ACART's initial and subsequent proposals

158. In 2017, ACART's consultation proposed replacing the provision with a requirement that ECART must be satisfied that the affected parties have discussed and understood one another's intentions, including the matter of ongoing contact.

159. Respondents to the 2017 consultation commented on the need to manage the risks involved with parties potentially living overseas and also the risk that a child born to a surrogate overseas might be stateless. Consequently, ACART restored the residency provision but in the following modified form.

160. ACART's final provision about the residency of the parties states that ECART must be satisfied that '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'.

Benefits of the change

161. This provision will enable ECART to identify whether residency plans are in place and whether they will protect the parties, especially the citizenship of the child.

Risks of the change

162. ACART has not identified any risks associated with this change.

Submitters' views and ACART's assessment of them

163. Nine submitters supported the proposal and one of these believed the proposal should be strengthened to state that ECART 'should' take residency into account.

164. Two submitters opposed the change. One stated that it would be impossible to track all participants and keep the details in the HART register current.

165. One submitter provided an 'other' response, stating that it is not clear what role ECART would have in deciding surrogacies where the surrogate will give birth overseas or where the intending parents will live overseas.

166. ACART acknowledges that in surrogacy arrangements involving other countries, it could be more difficult to safeguard the wellbeing of all the parties. Consequently, it is important that ECART elicits as much information as needed to create residency plans that are sufficient to ensure the child will not be stateless, and the parties can maintain contact with one another.

Change 5: One guideline replaces four, and the language and format have been standardised

ACART's conclusions/decisions

167. ACART's revised guidelines for donations and surrogacy bring four procedures under one set of guidelines. These procedures are: family gamete donation; embryo donation; the use of donated eggs with donated sperm; and clinic assisted surrogacy. The language and format have also been standardised.

The problem

168. The previous separate sets of guidelines were designed for use when it was mandatory for a child to have a biological link to at least one intending parent. Now that ACART has agreed to rescind the mandatory link, there is no need for separate donation and surrogacy guidelines as the procedures are no longer mutually exclusive.

169. Also, ECART is likely to receive some applications that involve more complex procedures and resulting relationships. For instance, it could receive an application that involves surrogacy, donated eggs or donated sperm and family gamete donation.

170. Additionally, the previous guidelines contained some inconsistent language. In some cases, the separate guidelines used different words to describe similar processes and ethical issues.

Benefits of the change

171. Using one set of guidelines will simplify the ethical review process and help clinics prepare applications to ECART. Cases that involve more than one procedure will be easier to manage as clinics will no longer need to cross-reference separate guidelines.

172. Standardising the language will remove any sources of potential ambiguity.

Risks of the change – operational implications for ECART and clinics

173. ECART publishes application forms on its website and, as with any new guidelines, will need to design a new application form for clinics to use.

174. The clinics will need to understand the new range of possible treatment scenarios, although this range arises from the changes to the permitted donations rather than from having a single set of guidelines as such.

Submitters' views and ACART's assessment of them

175. Eighteen submitters supported the proposal and one submitter was opposed.

176. Those in favour cited the benefits of simplifying the guidelines, removing overlap and standardising language. The submitter who was opposed to the single set of guidelines was actually opposed to the various changes, including the removal of the biological link, rather than to having the single set of guidelines and new format.

177. ACART believes the change should be made on the basis of the benefits discussed and that risk mitigation is integral to the guidelines.

Change 6: The two family limit for full genetic siblings is now universal

ACART's conclusions/decisions

178. ACART has introduced a general provision that full genetic siblings can exist in no more than two families. This provision applies regardless of other factors involved in the case. Applications to ECART, where relevant, will need to include information about any existing children who would be full genetic siblings of any children born from a procedure.

The problem

179. The changes of rescinding the biological link policy and also allowing ECART to consider the donation of embryos created where both gametes have been donated introduce the potential for the resulting relationships to be more complex.

180. ACART's previous guidelines for embryo donation limited full genetic siblings to a maximum of two families. The purpose of this limit was to manage the number and complexity of relationships between parties and to minimise the risk of consanguinity (blood relationships).

181. With the changes to the four sets of guidelines, including merging them into one, it was important to ensure that the limit remained in place and that it would be understood by all parties that it applies to, regardless of the fertility procedure being used.

Benefits of the change

182. All parties to fertility treatment will understand that full genetic siblings will only be allowed in two families. This provision minimises the risk of relationships becoming overly complicated and of children in particular being unsure of how they are related to other parties.

183. The risk of consanguinity (blood relationships) will be minimised despite the greater range of donations that are now available.

Risks of the change

184. ACART has not identified any risks associated with this proposal.

Submitters' views and ACART's assessment of them

185. Nineteen submitters supported the proposal and none opposed it, although one stated ECART should be able to consider exceptional cases. ACART concluded it would proceed with the proposal.

186. ACART also considers that this policy supports the wellbeing of donor-conceived offspring, based on research evidence relating to children's desire to know about, and be in touch with, their full and half siblings. ACART considers that children can navigate having full siblings in up to one other family, but no more.

Change 7: Stronger mitigation of risks for donations between family members

ACART's conclusions/decisions

187. ACART has made three substantive changes to the provisions for the donation of gametes between family members. It has:

    a) added a provision that requires ECART to check for intergenerational risks

    b) added a provision that requires ECART to check for undue influence (this provision is discussed under Change 8)

    c) extended the list of family gamete donations that are prohibited.

The problem

188. The donation of gametes between family members can raise ethical matters and the previous guidelines did not adequately take into account the way that donations between family members could result in intergenerational risks (eg, resulting confusion about relationships) and/or one party's undue influence on another. The guidelines also left open a small risk of consanguinity where a child could be formed from the gametes of two people who are closely genetically related.

ACART's initial and subsequent proposals

189. In 2017, ACART's first round of consultation proposed that all donations of family gametes should be subject to ECART consideration. ACART made this proposal because it believed the risks associated with such donations would most appropriately be managed by ECART and the existing guidelines did not require all such donations to be considered by ECART.

190. ACART removed that proposal in its second (2019) consultation, as it agreed with submitters' views that such a requirement was unnecessary and would cause practical problems. ACART's 2019 consultation extended the list of prohibited family gamete donations (between family members who are closely genetically related) and strengthened the provisions for undue influence and intergenerational effects.

Benefits of the changes

191. The strengthened provision for intergenerational effects reduces risks such as confusion about relationships. Change 8 elaborates on the new provision that is specifically about undue influence.

192. The extended list of prohibited donations minimises the risk of consanguinity (blood relationships).

Risks of the changes

193. ACART did not identify any risks associated with extending the list of prohibited donations, and submitters did not raise any.

Submitters' views and ACART's assessment of them

194. In 2017, when responding to ACART's original proposal to make **all** family gamete donations subject to ECART approval, 10 of the 21 submitters stated that the requirement was unnecessary and would cause practical problems. Those problems were that ECART's workload would increase considerably and create time and financial impediments for the people seeking treatment, for a proposal that would simply address what submitters thought was a low-risk activity. Submitters stated that, in many cases, families would be able to manage risks while in other cases the clinics could manage them. Eleven of the 21 supported the proposal.

195. Having taken all the submissions into account and having identified alternative ways of addressing the matters raised, ACART changed the proposal.

196. Of the submitters to ACART's 2019 consultation, 12 commented on the revised proposals for family gamete donations, and all 12 supported them. They noted that undue influence (some submitters referred to 'coercion') can be difficult to identify and they supported attempts to identify and address it. One submitter stated that coercion is more likely to occur in intergenerational settings; ACART has taken this into account in its final provisions for family gamete donations.

197. ACART concluded it could proceed with the proposal and also decided to add narrative to the supplementary information it is going to provide for ECART and clinics. The narrative will state that clinics can seek an ethical review from ECART if they have a case for an established procedure where they believe additional expert consideration would be beneficial.

198. Other ethical matters of importance to the donation of gametes between family members include potential confusion about relationships. ACART believes the counselling process adequately manages that risk.

No change needed to the HART Order

199. In its 2019 consultation document, ACART stated that, to extend the list of prohibited donations, the HART Order would need to be amended. However, on receiving further legal advice ACART understands that the policy can be implemented through its guidelines without a change to the HART Order.

Change 8: Stronger provisions for managing undue influence

ACART's conclusions/decisions

200. ACART has strengthened the provisions for managing undue influence by requiring that ECART must be satisfied that nobody has been subject to such influence. ACART has added two provisions: one to the general provisions and one in the provisions for family gamete donations, clearly directing ECART to check for undue influence.

The problem

201. Undue influence could occur in any donation or surrogacy case and could have detrimental effects on some or all of the parties – in particular, parties might make a choice that is not authentically theirs. In some cases, the influence could be strong enough to be considered 'coercion'. By its nature, **consent** must be free of undue influence (or coercion) to be truly informed and willingly given.

202. In the previous guidelines for embryo donation, the provisions for undue influence (which refer to it as 'coercion') may not have been strong enough for ECART to check for coercion or undue influence. The guidelines for family gamete donations mentioned coercion but did not explicitly require ECART to check for it. The other relevant guidelines (donated eggs with donated sperm, and surrogacy) did not mention undue influence or coercion despite the possibility of it arising.

203. Additionally, now that a surrogate can gestate a child to whom neither she nor the intending parents have any genetic link, the need to carefully manage the risk of undue influence or coercion in surrogacy cases is even greater.

ACART's proposal

204. ACART's 2017 consultation proposed strengthening the guidelines by explicitly requiring ECART to take account of any factors in a relationship that might lead to coercion or unduly influence a party to consent to a procedure. This provision is included in the general requirements for all procedures and is also discussed in the 2019 consultation. In the 2019 consultation, the section on family gamete donations included a provision that the parties must not be subject to undue influence, as the risks of undue influence between family members could be exacerbated because of their longstanding relationships, expectations and inability to escape the relationship. In addition, some relationships may involve dependency.

Risks of the change

205. A risk of now more clearly requiring ECART to check for undue influence (or coercion) is that ECART might interpret a situation that is acceptable to all parties as involving undue influence or coercion. For example, some parties might have social, cultural or family norms that mean they do not view some behaviours or expectations as undue influence (or coercion) whereas ECART could take the opposite view.

Benefits of the change

206. The new provisions for undue influence more clearly emphasise the need for ECART to check for it, making it more likely that any potential undue influence will be identified and addressed accordingly. These stronger provisions will increase protection for all parties.

Submitters' views and ACART's assessment of them

207. Almost all of the submitters who commented on this proposal supported it.[26] They noted that undue influence or coercion can be difficult to identify and supported steps to identify and address it. One submitter stated that coercion is more likely to occur in intergenerational settings. ACART has taken this concern into account in the provisions for family gamete donations by specifically directing ECART to check that parties to a donation are not subject to undue influence.

Māori interests, and consent matters

208. Māori often consider the use of whāngai arrangements to be acceptable. It will be important for counsellors and ECART to be aware that this could be a factor when family members are making certain arrangements for fertility treatment. That is, such arrangements should be assessed on a case-by-case basis to ensure that all parties are willingly taking part in them.

209. ACART believes the risk of ECART wrongly concluding that undue influence (or coercion) has been involved is very small. Further, counselling will identify any social, cultural or family norms that ECART should consider.

[26] In the first consultation, 18 submitters supported the proposal and none opposed it. In the second consultation, 13 supported and none opposed it.

Change 9: The provisions about obtaining legal advice have been rationalised

ACART's conclusions/decisions

210. ACART has amended guidelines to state that:
    a) it is mandatory for all the parties to a surrogacy to obtain legal advice
    b) where an application does not include a surrogacy arrangement, each party has considered seeking independent legal advice
    c) any legal reports show that parties understand the legal implications of the procedure(s).

The problem

211. In the previous guidelines for surrogacy and embryo donation, provisions required all parties involved to obtain, and have understood, legal advice. This requirement was difficult to enforce as counsellors could never be completely certain that a person had fully understood any legal advice.

ACART's initial proposal

212. ACART's 2017 consultation proposed that, in cases involving surrogacy, the affected parties must have obtained legal advice. In cases not involving surrogacy, it proposed ECART must be satisfied that the affected parties have considered seeking legal advice.

Risks of the change

213. In cases involving surrogacy, the risks of requiring parties to obtain legal advice are that the parties may experience stress, delays in treatment, and financial costs. In cases other than surrogacy (including embryo donation), the risks of making legal advice optional are that parties might not obtain legal advice and then encounter legal implications that they have not anticipated. The legal implications are likely to be simpler in cases that do not involve surrogacy than in surrogacy cases.

Benefits of the change

214. When a child is born from a surrogacy, the surrogate is the legal mother and legal parenthood is transferred to the intending parents by an adoption order issued by the Family Court. It is therefore critical that all affected parties understand the legal implications of surrogacy and adoption, given the interface with the Adoption Act 1955 and the Adult Adoption Information Act 1985.

215. Where a surrogacy arrangement is not part of a case, the legal parenthood issues are more straightforward because the intending mother gives birth to the child and is the legal mother. As such, parties may have less need to obtain legal advice and so could save time and money by not seeking it. Despite this, each affected party should have **considered** the merits of receiving independent legal advice. In particular circumstances, a party may wish to consider any legal issues associated with a procedure, for example, implications for estate planning, and the rights (or absence of rights) of embryo donors to offspring living in other families.

Submitters' views and ACART's assessment of them

216. Most submitters (17 of the 19 who responded to ACART's 2017 proposal) supported the proposal. One recommended that, when legal advice is required, parties should obtain it before counselling so that the counsellor can ascertain if, or to what extent, the parties understand the legal implications.

217. One submitter opposing the proposal of optional legal advice in cases involving embryo donation suggested that, if the proposal proceeds, a mechanism must be in place to ensure that the parties involved understand they have no legal rights over the resulting children.

218. ACART agrees with the submitters' suggestions and has changed the provisions in the guidelines accordingly. It will also add text to its supplementary advice (which will be issued when the guidelines are published) recommending that clinics and counsellors advise embryo donors that they will have no legal rights over the resulting children, and advise them that any offspring will have a legal right to find out about their genetic parentage through the HART register.

219. ACART considers that the provisions, in combination with counselling, will manage any risks appropriately, and deliver the benefits envisaged in the proposal.

Change 10: Improved access for donor offspring to information about their genetic origins

ACART'S conclusions

220. ACART has two recommendations for extending the information that donor offspring can obtain about their genetic origins. It developed the second recommendation after the two rounds of consultation; it has not consulted on this recommendation but it is simply an operational issue with officials at the Department of Internal Affairs.

221. First, ACART recommends adopting the Law Commission's 2005 recommendation to amend all birth certificates to include a statement that the Births, Deaths and Marriages register might contain other information that the certificate's owner may access.

222. Second, ACART proposes that the website hosted by the Department of Internal Affairs, for people to request birth certificates, could be amended to include a statement that the DIA might hold information (on the HART register) about people born from donated sperm, eggs or embryos. Interested parties might respond to this statement by asking DIA for any information about their status as being donor conceived. Although the effects of this change would probably be limited, it could help some individuals learn about their genetic origins. More importantly, the change could help to raise public awareness of the HART register.

The problem

223. Many people's sense of identity is, at least in part, based on knowing their genetic lineage. Offspring may want to know their genetic heritage for many other reasons, such as to find out about their medical history.[27] ACART is aware that in some instances the offspring of assisted reproduction are not made aware of their genetic origins. Another potential problem is that, through medical tests or genealogy involving DNA sequencing, people could accidentally discover that they are not genetically related to their parents. Further, the changes ACART has made to the donation and surrogacy guidelines might add complexity to some relationships: for example, more people could be born who have no genetic link to either of their parents. People should be able to obtain accurate information identifying their genetic parents.

[27] Ravelingien A, Provoost V, Pennings G. 2013. Donor-conceived children looking for their sperm donor: what do they want to know? *Facts, Views and Vision: Issues in Obstetrics, Gynaecology and Reproductive Health* 5(4): 257–64. URL: www.ncbi.nlm.nih.gov/pmc/articles/PMC3987373 (accessed 11 August 2019).

ACART's initial proposal

224. In 2017, ACART asked submitters about potential strategies to strengthen the access donor offspring have to information about their origins. It explained it would consider whether to provide advice to the Minister of Health on the matter.

225. The consultation explained earlier work on this topic, including the New Zealand Law Commission's 2005 report, *New Issues in Legal Parenthood*.[28] As noted above, that report recommended amending all birth certificates to include a statement indicating that the Births, Deaths and Marriages register contains other information that the certificate's owner may access. In addition, it recommended that Births, Deaths and Marriages should consider allowing parents to choose to have an annotation stating that the certificate's owner was born by 'donor'.

Benefits of improved access to information

226. A principle of the HART Act is that donor offspring should have access to information about their origins. By increasing awareness of the HART register and making it easier for people to obtain information about their genetic origins, ACART would ensure that the guideline are addressing the principles of the HART Act.

Risks of the change

227. If a person discovered that he or she was donor conceived and that person's parents had not told him or her of this fact, tension in their relationship with their parents could arise. The potential for such tensions needs careful consideration when enforcing the principle that donor offspring should have access to information about their origins. However, ACART notes that such a discovery could happen accidentally in other ways as well, such as through medical tests, science experiments using DNA, or genealogy services.

228. Further, it is not possible to enforce the principle (in the HART Act) without unduly intruding on the rights of parents to make decisions about what they tell their children. Currently, counsellors encourage parents to disclose to their offspring at an early age that they are donor conceived and often give them resources such as books to help them do so.

[28] New Zealand Law Commission. 2005. *New Issues in Legal Parenthood*. NZLC R88. Wellington: New Zealand Law Commission.

Submitters' views

229. Twenty-one submitters supported the proposal to allow donor offspring to learn about their genetic origins and 17 made suggestions. Four submitters suggested that birth certificates should be annotated, as the New Zealand Law Commission recommended in 2005, to state that a person had been born from donor conception. Four others stated work should be done to find a suitable way for offspring to learn of their heritage. Seven submitters stated that privacy matters should be taken into account.

230. No submitters suggested other changes that could be effectively implemented.

L Next steps

231. ACART has given a copy of this advice to the Ministry of Health in case you decide to seek parallel advice from the Ministry. In particular, you might seek parallel advice from the Ministry about ACART's recommendations to change the HART Order.

232. If you agree to recommendations 2, 3 and 4 to amend the HART Order, ACART would make a further change to the guidelines to make all clinic assisted surrogacies subject to ECART consideration.

233. The Chair of ACART is available to discuss the advice with you, if you wish.

234. ACART plans to publish this advice on its website in October 2019.