

To: Hon Peter Dunne

Cc: Hon Dr Jonathan Coleman

Title: Informed Consent and Assisted Reproductive Technology

A. EXECUTIVE SUMMARY

1. This report provides you with advice from the Advisory Committee on Assisted Reproductive Technology (ACART) about the requirements for informed consent in respect of human assisted reproductive technology (ART). Section 38(d) of the Human Assisted Reproductive Technology Act (HART Act) requires ACART to give such advice to the Minister of Health, following public consultation on the proposed advice (s.39).
2. Informed consent is a decision-making process in which people make choices, based on sufficient information about the nature and the implications of what is being agreed (recognising that in some circumstances people may lack the ability to consent). A well-established body of law and practice concerning informed consent in the context of medical procedures upholds the principle that autonomous individuals have the right to make decisions about procedures carried out on them.
3. Informed consent as it relates to ART is more complicated. The decisions of one person can affect other people (including intending parents, donors, other family members, and any future recipient of donated gametes), and the relationships between those people. Informed consent is not only about a medical procedure such as the retrieval of eggs: it is also about associated processes such as the storage of gametes (sperm and eggs) and embryos, and how gametes or embryos may be used in future. Consents may be given well in advance of the use of gametes or embryos. There is potential for uncertainty or disputes if a person dies or if a relationship ends.
4. Before formulating our proposals, we undertook a small project in 2014 with the goal of understanding how informed consent processes operate within fertility services providers. We were pleased to confirm, from the information we received, that clinics have comprehensive processes for seeking and obtaining informed consent.
5. We undertook public consultation on our proposed advice during August and September 2015, and received submissions from 29 individuals and organisations. Submitters included four fertility services providers, the New Zealand Law Society, the Health and Disability Commissioner, and Fertility New Zealand.
6. The focus of our recommendations is on transparency in regard to the information provided to ensure informed decisions; the avoidance and management of disputes; and recognising the interests of various stakeholders. Some of our recommendations are in line with current provider practice. The recommendations, rationales and impacts are noted in the table on the next page.

7. Our advice does not address informed consent for human reproductive research. Section 37(1)(f) of the HART Act requires ACART to give you such advice, and we plan to address that requirement when we review the guidelines on human reproductive research.
8. We have given a copy of the advice to the Ministry of Health, in case you decide to seek parallel advice. I am available to discuss the advice with you, if you wish. We plan to publish the advice on ACART's website in September 2016.

Table 1: Recommendations

	ACART recommends:	Rationale	Impacts
1	The Ministry of Health should establish a website that provides links to websites with information about assisted reproduction in New Zealand, including to the Human Assisted Reproductive Technology Register website that is hosted by the Department of Internal Affairs.	<ul style="list-style-type: none"> • Need increased ease of access to independent sources of information about ART. 	<ul style="list-style-type: none"> • Enable private access to information before approaching a fertility services provider. • Contribute to improving literacy about ART.
2	Consent, variation of consent and withdrawal of consent to an assisted reproductive process should be recorded in writing where practicable and in accord with best practice.	<ul style="list-style-type: none"> • Contribute to managing uncertainty in case of disputes or lack of specificity about what was agreed. 	<ul style="list-style-type: none"> • Makes explicit established practice.
3	Fertility services providers should obtain consent from donors that their gametes, and embryos created from those gametes, may be used in training.	<ul style="list-style-type: none"> • No formal requirement about consent for use in training – HART Act is silent on the matter. • Donors have a legitimate interest and say in the way their gametes and embryos are used. • Consistent with HDC Code. 	<ul style="list-style-type: none"> • Explicit recognition that training using gametes and embryos is an appropriate activity, provided informed consent is given. • In accord with practice in other jurisdictions.
4	The Ministry of Health should develop a definition of “training”, in consultation with ACART, the sector and the Health and Disability Commissioner.	<ul style="list-style-type: none"> • Donors should know what is included in the term “training” before making a decision. 	<ul style="list-style-type: none"> • Enables informed decisions.
5	Gamete donors should continue to be allowed to place conditions on their donations.	<ul style="list-style-type: none"> • Gamete donation is a gift with potential long term relationships. • Not allowing donors to set conditions might discourage donations. 	<ul style="list-style-type: none"> • Follows established practice. • Clinics are not obligated to accept donations if conditions are unrealistic.

	ACART recommends:	Rationale	Impacts
6	Gamete and embryo donors should be able to make a condition of their consent to donation that the clinic takes reasonable steps to inform them when a child is born as a result of the donation.	<ul style="list-style-type: none"> • Donors should be able to opt-in to receive this information, and not have to take the initiative to enquire. • Opting-in by donors reduces administrative burden on clinics. 	<ul style="list-style-type: none"> • Donors who set the condition must keep contact details up to date.
7	Gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation or insemination.	<ul style="list-style-type: none"> • No explicit requirement in HART Act or elsewhere about “point of no return” for changing a consent. • Withdrawal of gamete donor consent after fertilisation would result in substantial harm to wellbeing on intending parent(s). 	<ul style="list-style-type: none"> • Makes explicit current understandings in the sector. • Transparency. • Any conditions set by donor endure beyond point at which donor can withdraw or vary consent.
8	The consent of a partner, or family/whānau, should not be required for gamete donation.	<ul style="list-style-type: none"> • In accord with HDC Code – individuals make autonomous decisions about their bodies. • Encouraging involvement of partners/whānau recognises impact of donation on other people. 	<ul style="list-style-type: none"> • The Standard will need to be amended to remove requirement for partner consent. • Family/whānau involvement follows established practice and requirements in Standard.
9	A “cooling off” period, of up to 12 months, should be introduced for situations where a couple disputes the use or storage of an embryo that was created for their use.	<ul style="list-style-type: none"> • Need a process for addressing disputes. 	<ul style="list-style-type: none"> • A recognised process is in place where a couple is in dispute about the future of embryos created for their use.
10	The “cooling off” period should begin on a date when the clinic receives written notice that there is a dispute. If the clinic receives such a notice, the clinic should be required to take reasonable steps to notify the other party that consent to the use of the embryo(s) has been withdrawn.	<ul style="list-style-type: none"> • Need a specified start date for “cooling off” period. 	<ul style="list-style-type: none"> • Start date begins when clinic is notified of dispute.
11	When a dispute arises, the clinic should be required to provide information to the parties about mediation services.	<ul style="list-style-type: none"> • Mediation provides the best opportunity to resolve disputes 	<ul style="list-style-type: none"> • Couple can make informed choice about mediation

	ACART recommends:	Rationale	Impacts
12	Where couples cannot agree after 12 months, embryos should remain in storage until the end of a lawful storage period, unless the parties reach a mutual decision about the fate of the embryos before the end of the lawful storage period.	<ul style="list-style-type: none"> At the end of 12 months couple still have an opportunity to reach a shared decision while the embryos are lawfully stored, but ensures embryos are not stored indefinitely. 	<ul style="list-style-type: none"> The HART Act requires that gametes and embryos must be disposed of when they reach the end of a lawful storage period (either 10 years or extended period approved by ECART). Clinics are required to store embryos during lawful storage period, subject to payment of storage fees by consumers.
13	Any amended and new requirements for informed consent in the context of human assisted reproductive technology should be included in the Fertility Services Standard.	<ul style="list-style-type: none"> Need for transparent and accessible requirements. Light touch appropriate for New Zealand: no need for further regulation under HART Act. The Standard is a form of regulation under the Health and Disability Services (Safety) Act 2001. The language used in the Standard is understandable to a lay audience, and Standard is now publicly available. 	<ul style="list-style-type: none"> Clinics will make changes to their practices and information in accord with the Standard's requirements.

B. RECOMMENDATIONS

9. We recommend that you agree to the following recommendations.
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| 1 | The Ministry of Health should establish a website that provides links to websites with information about assisted reproduction in New Zealand, including to the Human Assisted Reproductive Technology Register website that is hosted by the Department of Internal Affairs | Yes / No |
| 2 | Consent, variation of consent and withdrawal of consent to an assisted reproductive process should be recorded in writing, where practicable and in accord with best practice | Yes / No |
| 3 | Fertility services providers should obtain consent from donors that their gametes, and embryos created from those gametes, may be used in training | Yes / No |

4	The Ministry of Health should develop a definition of “training”, in consultation with ACART, the sector and the Health and Disability Commissioner	Yes / No
5	Gamete donors should continue to be allowed to place conditions on their donations	Yes / No
6	Gamete and embryo donors should be able to make a condition of their consent to donation that the clinic takes reasonable steps to inform them when a child is born as a result of the donation	Yes / No
7	Gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation or insemination	Yes / No
8	The consent of a partner, or family/whānau, should not be required for gamete donation	Yes / No
9	A “cooling off” period, of up to 12 months, should be introduced for situations where a couple disputes the use or storage of an embryo that was created for their own use	Yes / No
10	The “cooling off” period should begin on a date when the clinic receives written notice that there is a dispute. If the clinic receives such a notice, the clinic should be required to take reasonable steps to notify the other party that consent to use of the embryo(s) has been withdrawn	Yes / No
11	When a dispute arises, the clinic should be required to provide information to the parties about mediation services	Yes / No
12	Where couples cannot agree after 12 months, embryos should remain in storage until the end of a lawful storage period, unless the parties reach a mutual decision about the fate of the embryos before the end of the lawful storage period	Yes / No
13	Any amended and new requirements for informed consent in the context of human assisted reproductive technology should be included in the Fertility Services Standard	Yes / No

Alison Douglass



Chair

Advisory Committee on Assisted Reproductive Technology

Minister’s signature

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C. PURPOSE OF THIS REPORT

10. This report provides you with advice about the requirements for informed consent in respect of human assisted reproductive technology (ART). Section 38(d) of the Human Assisted Reproductive Technology Act (HART Act) requires the Advisory Committee on Assisted Reproductive Technology (ACART) to give such advice to the Minister of Health, following public consultation on the proposed advice.
11. In developing our advice we have taken into account:
 - the principles of the HART Act, including the health and wellbeing of women and children; the right of donor offspring to access information about their genetic origins; and the needs, values and beliefs of Māori
 - other common ethical principles, including autonomy, wellbeing of families, and transparency
 - wider public policy considerations, including the Code of Health and Disability Services Consumers' Rights (the Code)
 - feedback from public consultation in 2015
 - evidence and information from local and international sources.

D. STRUCTURE OF THIS REPORT

12. Our report discusses:
 - E: Informed consent in the context of human assisted reproductive technology
 - F: Current requirements for informed consent
 - G: Our consultation process
 - H: The scope and focus of our advice
 - I: Our recommendations
 - J: Next steps

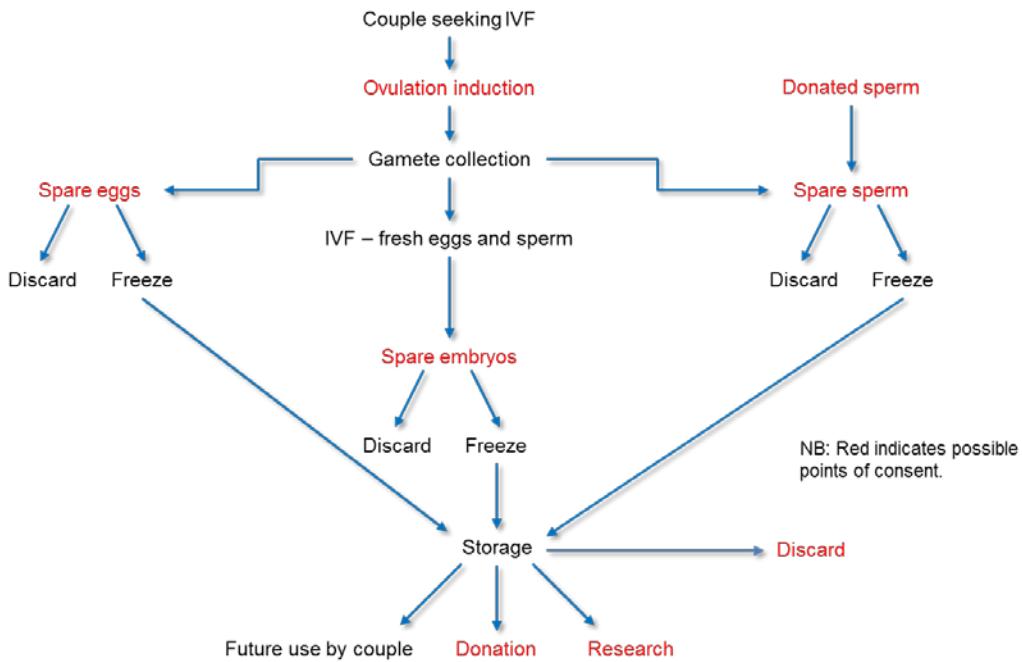
Appendices: list of submitters and the summary of submissions.

E. INFORMED CONSENT IN THE CONTEXT OF HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY

13. Informed consent is a decision-making process in which people make choices, based on sufficient information about the nature and the implications of what is being agreed (recognising that in some circumstances people may lack the ability to consent).
 - The information is provided in a way that can be understood by each individual.
 - The consent is voluntary, with participation that is free from manipulation, coercion, inducement or any other undue influence.
 - The process includes the right to refuse consent, and also the right to change one's mind by withdrawing or varying consent.
14. A well-established body of law and practice concerning informed consent in the context of medical procedures upholds the principle that autonomous individuals have the right to make decisions about procedures carried out on them.
15. Informed consent as it relates to ART is more complicated. As noted below, the decisions of one person can affect other people (including intending parents, donors, other family members, and any future recipient of donated gametes).

Specific factors related to informed consent in the context of assisted reproduction

16. We have considered various factors related to informed consent in the context of ART.
 - A decision by one person to vary or withdraw consent may have a significant impact on another person and the relationships between the various parties. The interests of donors may not be the same as the interests of intending parents, for instance where a donor changes his or her mind.
 - Informed consent is not only about a medical procedure — it is also about processes such as the storage of gametes (sperm and eggs) and embryos, decisions about the future use or storage of gametes or embryos, and decisions to be part of embryo donation and surrogacy.
 - Consents may be given well in advance of the use of gametes or embryos.
 - There is potential for uncertainty or disputes if a relationship ends or a person dies.
17. Informed consent is required at various points throughout assisted reproduction processes. For example, the in vitro fertilisation (IVF) process includes various decision points, as outlined below, whether or not donated gametes are used. Consent may be about the use of embryos for reproduction, or for use in training.
18. The diagram on the next page illustrates an example of decision pathways for a heterosexual couple using their own gametes.



19. The process of making an informed decision will be shaped by cultural factors. In New Zealand we recognise the perspectives of Māori as tangata whenua with a consequent need to consider how these perspectives can be incorporated into the structures and processes of informed consent. An example might be recognising the importance of the concept of takoha which contains the idea that donors are not just gifting biological materials but also gifting the responsibility for their proper care and respect, in keeping with the values underlying tikanga Māori.
20. Principle 4(f) of the HART Act requires that the needs, values and beliefs of Māori should be considered and treated with respect. This does not mean that we support the idea that a pan-Māori perspective exists. There is seldom one single viewpoint representative of Māori concerns any more than there is a likelihood of finding a single viewpoint on matters in any other socio-cultural context.
21. Principle 4(g) of the HART Act recognises the diversity of New Zealand's population, requiring that the different ethical, spiritual and cultural perspectives in society should be treated with respect. For example, the 2013 Census recorded that 7.4 percent of New Zealand's population identified with at least one Pasifika ethnic group such as Samoa, Tonga, Cook Islands, Fiji, Niue, Tokelau and Tuvalu.¹ For Pasifika, as with Māori, decisions about assisted reproduction, including donation, are likely to be in the context of relationships which are understood to involve obligations and responsibilities.

¹ Ministry of Health. Tagata Pasifika in New Zealand. <http://www.health.govt.nz/our-work/populations/pacific-health/tagata-pasifika-new-zealand>.

22. The Human Rights Act 1993 is also relevant, prohibiting discrimination against individuals on the basis of disability. The United Nations Convention on the Rights of Persons with Disabilities, to which New Zealand is a party, requires that people with disabilities should have access to information on the same basis as other members of society.² Failure to provide information in accessible formats to persons with disabilities may therefore be seen as a form of discrimination.³

F. CURRENT REQUIREMENTS FOR INFORMED CONSENT

23. New Zealand requirements relating to informed consent for ART are set out in:
- the HART Act
 - the Code of Health and Disability Services Consumers' Rights
 - guidelines issued by ACART to the Ethics Committee on Assisted Reproductive Technology (ECART)
 - the Fertility Services Standard.

The HART Act

24. The HART Act is the principal law regulating human assisted reproductive technology and human reproductive research in New Zealand. Informed consent is addressed in s.4(d) of the HART Act (Principles), which provides:
- . . . 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.*
25. The HART Act requires ACART to provide the Minister of Health with advice on the requirements for informed consent. This advice must not be inconsistent with the Code. The HART Act also enables regulations to be made for the purpose of prescribing requirements for informed consent.⁴ No such regulations have been made to date.

The Code of Health and Disability Services Consumers' Rights (the Code)

26. The Code extends to any person or organisation providing or receiving health and disability services in New Zealand. Rights 5, 6 and 7 of the Code give every consumer the right to effective communication, to be fully informed, to make an informed choice and to give informed consent. 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.
27. The Health and Disability Commissioner (the HDC) has indicated that the removal, retention, use or return of gametes is covered by the Code. Accordingly, gamete donors are entitled to receive information and make an informed decision as to how the gametes are to be used or stored, and what will happen to them (including whether or not they are to be exported).

² Article 9. <http://www.odi.govt.nz/documents/convention/index.html#English1>

³ The Code states that every consumer has the right to effective communication in a form, language and manner that enable the consumer to understand the information provided. This requirement is incorporated into the Standard (provision 1.1.2).

⁴ HART Act s.76(1)(a)(i).

28. While the Code does not address all matters of informed consent for ART, any regulations or guidelines must be consistent with the Code.⁵

Guidelines issued by ACART

29. All the current guidelines issued by ACART refer to the principle of informed choice and informed consent in s.4(d) of the HART Act. Additional requirements are included where ACART has decided that more detail is needed about how the principle should be applied to a particular procedure.

The Fertility Services Standard (the Standard)

30. 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 is administered by the Ministry of Health.
31. Informed consent is addressed by the Standard in a number of places. Providers must ensure that consumers⁶ 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.

G. OUR CONSULTATION PROCESS

32. Before formulating our proposals, we undertook a small project in 2014 with the goal of understanding how informed consent processes operate within fertility services providers. Based on the information we received, we were pleased to confirm that clinics have comprehensive processes for seeking and obtaining informed consent. We are grateful to the three providers involved for their generosity in sharing information about how the informed consent process operates in each organisation. Staff members interviewed, including representatives of the professional groups working in clinics, gave valuable perspectives.
33. In 2015 we advised you about our forthcoming public consultation on our proposed advice to you on requirements for informed consent in the context of ART. We gave you a copy of the finalised document after it was published in August 2015.
34. We undertook the consultation during August and September 2015, and received submissions from 29 individuals and organisations. Submitters included four fertility services providers, the New Zealand Law Society, the HDC, and Fertility New Zealand.

⁵ HART Act s.76(1)(a)(i).

⁶ In this document we use the word “consumer” in relation to ART in accord with the definition 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.”

35. In addition to receiving written submissions, we held a small number of meetings. We met staff members from the three Auckland fertility services providers, the Otago Bioethics Centre, the HDC, and a former member of ACART. The former ACART member, Adjunct Professor Ken Daniels, came to our December 2015 meeting to present views he had gathered, on our behalf, from a small group of sperm donors. Professor Daniels has access to a confidential network of donors whose views we would otherwise not be able to obtain.
36. Meeting notes and submissions were published on our website except where submitters requested submissions not be published for confidentiality reasons.

Key themes in submissions

37. Key themes in submissions were as follows.
 - Information about ART needs to be given in an appropriate format and in a way that individuals can read and understand. Supplying information does not necessarily constitute effective communication. Providing too much information could deter people from donating. Many submitters suggested ACART should take responsibility for summarising, in plain language, key documents such as the Standard, the HART Act, the Human Assisted Reproductive Technology Order 2005, and the Code.
 - Standardised consent forms could be helpful for consistency across the sector.
 - Many submitters considered that gamete donors should “opt in” to receive later information about the use and outcome of their donations. “Opting in” would not place an unnecessary administration burden on clinics.
 - Most submitters opposed further regulation and did not think it would result in more informed consumers of fertility services. Informed consent was seen as a two way street with both rights and responsibilities. Instead of regulation, what is needed is for consumers to have the information and understanding to exercise informed choice and consent.

H. THE SCOPE AND FOCUS OF OUR ADVICE

38. Our recommendations concern informed consent in the context of ART: in other words, our recommendations are concerned with processes that should be used in clinics to ensure consent by consumers (including donors) is informed. Some of our recommendations are in line with current provider practice. We also include recommendations about consent in the context of training.
39. The focus of our recommendations is on:
 - transparency about the information provided to ensure informed decisions
 - the avoidance and management of disputes (for instance, when a relationship ends or when a person dies)
 - recognising the interests of various stakeholders (including donors, surrogates and potential children).

40. Our advice does not address informed consent for human reproductive research. The HART Act requires ACART to give you such advice (s.37(1)(f)), and we plan to address that requirement when we review the guidelines on human reproductive research.

I. OUR RECOMMENDATIONS

41. Our recommendations are in three categories:

- the initial consent process
- the rights and interests of gamete donors, partners, family and whanau
- the form of requirements for informed consent.

THE INITIAL CONSENT PROCESS

Recommendation 1 - access to information

ACART recommends:

The Ministry of Health should establish a website that provides links to websites with information about assisted reproduction in New Zealand, including to the Human Assisted Reproductive Technology Register website that is hosted by the Department of Internal Affairs.

Issue

42. As noted above, many submissions were concerned with access to information. We noted in the discussion document that the Standard included requirements for providers about consumer rights, including information that must be given to donors and recipients. Some of this information is not available elsewhere. Moreover, until April 2016 the Standard was not freely available: it had to be purchased, or sighted at a fertility service provider's premises.⁷ This was a matter of concern to us, and our proposed advice included a recommendation that the Standard should be freely accessible.
43. We are pleased to note that the Standard is now publicly available on the Ministry of Health website, free of charge. All consumers should have easy access to information about what is required of providers, including requirements related to informed consent.

Ethical and policy arguments

44. The Standard is an important part of the ART regulatory framework, but until very recently, was not freely available, unlike the HART Act and the Code. The principle of transparency suggests that anyone should be able to freely access the Standard's requirements, particularly those concerned with information that must be provided to donors and intending parents.

⁷ ACART does not have any responsibilities to audit providers against the Standard.

Submitter perspectives

45. Most submitters supported our proposal that information about requirements should be more accessible. Some clinics and Fertility New Zealand supported making the Standard freely available.
46. There were varying views about the extent to which more information should be provided. Some submitters wanted more information on specific matters. Others said that while enough information must be provided so that participants are fully informed, it is important not to overwhelm consumers.
47. The HDC reiterated that the Code requires that persons undergoing ART processes have the right to effective communication and full information to make informed choices and give informed consent.
48. Some submitters linked the issue of needing access to full information with the process for obtaining consent. We discuss this issue in the next recommendation.

ACART's view

49. While we were preparing this advice, the Ministry entered a contract with Standards New Zealand to make the Standard available to the public on the Ministry's website <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/services-standards#fertility>.
50. The Standard was written for fertility clinics and auditors, and access to Standard will not meet all the information needs of consumers. Clinics provide comprehensive information about specific procedures. However, some of the information in the Standard may be helpful for understanding the regulated expectations of clinics in regard to information and informed consent.
51. We do not support additional regulation in regard to the provision of information. What is important is increased ease of access to information and a central independent source. To that end, we recommend establishment of a website by the Ministry of Health, with links to other websites with information about fertility services in New Zealand, for instance eligibility criteria for public funding, and the HART Register website that is hosted by the Department of Internal Affairs. The HART Register explains the information that is held about donors and offspring on the two Registers⁸, how the information is collected, and the requirements for accessing the information.
52. While ACART's website contains comprehensive material of interest to consumers, ACART does not have a responsibility for educating and informing the public about all aspects of ART. A Ministry of Health ART website would contribute to improving health literacy, as set out in the People Powered theme in the New Zealand Health Strategy.⁹

⁸ The Registers, established by the HART Act, comprise a voluntary Register relating to donor offspring born before 22 August 2005, and a compulsory Register relating to donor offspring born from donations made on or after 22 August 2005.

⁹ <http://www.health.govt.nz/new-zealand-health-system/new-zealand-health-strategy-future-direction/five-strategic-themes/people-powered>

Recommendation 2 — written consent

ACART recommends:

Consent, variation of consent and withdrawal of consent to an assisted reproductive process should be recorded in writing where practicable and in accord with best practice.

Issue

53. There is no specific requirement that consent to assisted reproductive processes¹⁰ must be in writing. The HART Act is silent on whether consent should be in writing. We note that the Code requires written consent in certain situations, including where a consumer will be under general anaesthetic or there is a significant risk of adverse effects on the consumer (Right 7(6)).
54. In our consultation document we proposed that consent to all assisted reproductive processes, where consent is required, must be in writing (with provision for those unable to sign). Our position was that written consent would contribute to certainty about what was agreed, particularly in the case of disputes.

Ethical and policy arguments

55. The Standard requires consent to be obtained in line with the requirements of the Code and the principles of the HART Act.¹¹ Right 7 of the Code requires informed consent to a health care procedure to be in writing in certain situations.
56. Having noted these policies, we also note that the right to informed consent is subject to the common law¹² and there may be instances where it is accepted that written consent is not necessary. For example, verbal withdrawal of consent is legally valid and a failure to obtain a written record of the withdrawal of consent does not negate that withdrawal.¹³
57. The Standard requires service providers to have consent forms appropriate to the procedures performed by the service.¹⁴ The requirement to have consent forms may be seen as implying that consent should be in writing.
58. Written consent avoids uncertainty in the event of a dispute about what was consented, for example between partners or after a person's death, or between a clinic and consumers. A written record may also provide assurance to donors that the conditions placed on their consent will be implemented by the service provider.

Other jurisdictions

59. Canada requires written donor consent for the use of human reproductive material for the purpose of creating an embryo.

¹⁰ We use the phrase “assisted reproductive processes” in this advice to cover both clinical procedures (eg, IVF, transfer of embryos to a woman’s uterus) and associated processes (eg, decisions relating to donation).

¹¹ Section 1.7 of the Standard.

¹² Right 7(1) of the Code.

¹³ Noted in the submission of the New Zealand Law Society.

¹⁴ Section 1.7.1 of the Standard.

60. The United Kingdom (UK) requires consent to be in writing, and signed by the person giving it.¹⁵ The UK provides for cases where a person is unable to sign. If the person giving consent, or varying or withdrawing consent, has the mental capacity to do so but cannot sign because of illness, injury or physical disability (for example, quadriplegia), they can direct someone to sign on their behalf, provided the person giving consent, or varying or withdrawing consent is present at the time, and the signature is also witnessed, and attested to by at least one other person.¹⁶

Submitter perspectives

61. Many organisations and clinics agreed that consent should be in writing, arguing that an explicit requirement for written consent would help to protect parties involved in ART. Some submitters said that such a requirement would formalise current clinic practice.
62. Other arguments made in support for written consent for all ART processes included reference to the Cartwright Inquiry finding that the use of all forms of human material must have written informed consent. Written consent for ART processes would be consistent with other areas of health care.
63. Submitters who did not agree with ACART's proposal argued that in practice it is not always possible to get consent in writing. These submitters suggested that oral consent should be permitted where someone wished to withdraw consent at short notice. The Law Society noted that where consent or withdrawal of consent is given orally, it is legally valid. A failure to obtain a written record of withdrawal of consent does not negate that withdrawal.
64. Some submitters said that the requirement for written consent can be challenged. If such challenges are made, a considerable effort by all involved in obtaining the consent would be wasted. This would especially be the case if the challenges were successful.
65. From a Māori point of view, an absolute requirement for written consent by the individual might not always work in practice. Many Māori value the ability to take collective responsibility for decisions. For example, whānau might consent to processes when the person undergoing the procedure is unable to consent.

ACART's view

66. While we consider that it is important that there is some flexibility, ideally written consent should be given for all ART processes, whether for medical procedures or non-medical procedures such as storage. We continue to be of the view that requiring written consent would contribute to managing uncertainty, particularly in the case of lack of specificity or disputes about what was agreed.
67. However, we recognise that there may be instances where written consent is not practicable and that oral consent is sufficient. From that position, we consider that, in accord with best practice, consent to and withdrawal of consent from an assisted reproductive process should be in writing where practicable.

¹⁵ Human Fertilisation and Embryology Act 1990.

¹⁶ Human Fertilisation and Embryology Authority guidance 5C, in 5. *Consent to treatment, storage, donation, training and disclosure of information*

Recommendations 3 and 4 — consent for use of gametes and embryos in training

ACART recommends:

3. Fertility services providers should obtain consent from donors that their gametes, and embryos created from those gametes, may be used in training; and
4. The Ministry of Health should develop a definition of “training”, in consultation with ACART, the sector and the Health and Disability Commissioner.

Issue

68. At times clinicians and embryologists use surplus gametes and embryos for training purposes. For example, embryologists need to learn how to manipulate gametes and embryos.
69. However, there is no formal requirement that donors¹⁷ should consent to the use of their gametes, or embryos created from their gametes, in the training of embryologists and clinicians. The HART Act does not include any reference to the use of gametes or embryos for training purposes: the legislation (in Principle (d) of the HART Act) only addresses informed consent in regard to assisted human reproduction and human reproductive research.

Ethical and policy arguments

70. Donor consent falls under Rights 6 and 7 of the Code (Rights to information disclosure and informed consent) and Right 9 of the Code (Rights in respect of teaching or research). The HDC has noted that donors have a right to know all the ways in which their gametes or embryos created from their gametes may be used.¹⁸ Our view is that full information should include the possibility that gametes and embryos may be used for training purposes, and that specific consent to this use should be given.
71. While the HART Act does not specifically provide for the use of gametes and embryos in training, a purpose of the HART Act is to secure the benefits of assisted human reproduction and human reproductive research. From that perspective, training is an appropriate activity. We note that some providers already offer consumers the choice of giving or withholding consent to the potential use of their gametes and embryos for training.

Other jurisdictions

72. The UK requires donors to consent to the use of embryos, created from their gametes, for training. Victoria (Australia) requires that donor consent must specify the kinds of treatment procedures for which eggs, sperm or embryo may be used.¹⁹ Canada’s Informed Consent Regulations (under the Assisted Human Reproduction Act 2004) require donor consent to be obtained if embryos created from donated gametes will be used in training.

¹⁷ We use the word “donors” in this context, although the surplus gametes or embryos concerned may not have been intended for donation to another person/couple for reproductive purposes. However, where gametes and embryos are used for training, in effect they are donated to the clinic in which the training occurs.

¹⁸ HDC. 2013. Submission to ACART Discussion Paper: Import and Export of Gametes and Embryos.

¹⁹ Assisted Reproductive Act 2008 s.17(1)(c), Victoria, Australia.

Submitter perspectives

73. Many submitters agreed that consent should be obtained if gametes and embryos will be used in training. Some submitters noted that donor consent for embryos to be used in formal training for embryologists is covered by Right 6 of the Code, and failure to obtain fully informed consent would be in conflict with this right.

ACART's view

74. We consider that the use of gametes and embryos in training should be based on explicit consent by donors. Donors have a legitimate interest in what happens to their gametes or embryos created from their gametes. Consent to the use of gametes and embryos in training is consistent with Rights 6 and 7 of the Code (right to be fully informed, right to make an informed choice and give informed consent).
75. Our consultation document did not include a definition of training. If people are asked to consent to their gametes and/or embryos being used for training purposes, they will need to know what is encompassed by training, in order to make an informed decision. We suggest the Ministry of Health work with ACART, the sector and the HDC to consider this description of training:

Donated gametes, or embryos created from these gametes, may occasionally be used for training or technique validation purposes in the laboratory. Training is the action of teaching a person a particular skill that is needed for a profession or job. With respect to the embryology laboratory, embryologists need to be trained in the handling and manipulation of gametes and embryos. Occasionally consent will also be needed to use gametes or embryos to validate certain embryological techniques. For example, preimplantation genetic diagnosis is a laboratory technique that involves the biopsy²⁰ of the preimplantation stage embryo in order to test the biopsy specimen for genetic abnormalities. Clinics offering these techniques need to provide biopsied samples for validation every few months in order to remain accredited to perform the technique. Consent is therefore required to use embryos for this process.

THE RIGHTS AND INTERESTS OF GAMETE DONORS, PARTNERS, FAMILY AND WHĀNAU

Recommendation 5 — conditions on donations

ACART recommends:

Gamete donors should continue to be allowed to place conditions on their donations.

Issue

76. In New Zealand it is standard practice to allow gamete donors to set conditions on the use of their gametes, for instance who may use the gametes. We considered this matter because internationally there are a range of views about whether donors should be able to set conditions.
77. Personal donors (family member or friend of the person/couple using the donated gametes) typically donate only to the person known to them. Donors to a clinic and who do not direct the donation to a particular individual may choose to restrict the use of their gametes to particular groups (eg, couples) and specifically exclude other groups (eg, single people).

²⁰ A biopsy is a procedure to remove a sample of cells.

78. In the case of clinic donors, arguments are sometimes made that setting conditions is discriminatory and can have the effect of limiting access to donated gametes for some groups.

Ethical and policy arguments

79. The HART Act makes no reference to whether conditions can be placed on donations. The Standard, however, requires providers to inform donors that they can set conditions on the use of their gametes.²¹
80. We note that the Human Tissue Act 2008 (which does not apply to gametes and embryo) allows people while living to qualify their consent to the use of their human tissue after their death (for example, by limiting consent to transplantation into a specific recipient).²²
81. Comparisons can also be made with adoption and embryo donation policies. Under the Adoption Act 1955, birth mothers can set a very few conditions about who can adopt their child. Over the last 60 years adoption practice has shifted towards open adoptions: a birth mother now has a much greater say about who adopts her child. ACART's embryo donation guidelines are based on potential donors deciding, on the basis of recipient profiles and joint discussion, whom they wish to donate to.
82. One ethical perspective is that donated gametes are a gift, and that gifts should be unconditional. However, we are of the view that people should be able to choose the recipient(s) of gifts. Gamete donors have a stake in the use of their gametes because donations have long-term consequences and create biological and potentially social relationships between a donor and offspring, plus their families.
83. As noted, gamete donors can donate to a specific individual or couple if wished. It could therefore be argued that people donating gametes to a clinic for future use by unknown individuals have the same right to make choices about who will use their gametes. Moreover, people might donate gametes only if they can set conditions.

Other jurisdictions

84. The UK allows gamete donors to place conditions on the number of families using the donation, stipulate that a named individual may use the gametes, and place other restrictions on use of their gametes.
85. In Victoria (Australia) donors must specify the number of women who may use the donor's gametes or embryos, and also the kinds of procedures in which the gametes (or embryos) may be used.

Submitter perspectives

86. Most submitters agreed with our position that donors should continue to be able to place conditions on their consent. Some submitters noted the special nature of a gift that may result in the birth of a child.

²¹ Section 1.11.1 of the Standard.

²² Human Tissue Act 2008 (ss. 9, 19, and 31).

87. A submitter noted that for Māori, an altruistic spirit is often present but it is not always unconditional. The concept of takoha is important: it can be thought of as a gift with responsibility or even as the gifting of the responsibility itself. Takoha creates a lasting biological and personal history, so donors, surrogates and intending parents need to have the opportunity to place conditions on consent.
88. Some submitters observed that placing conditions could be considered discriminatory under the Human Rights Act 1993. There was a concern by some submitters that at the time recipients wished to use donated gametes or embryos, donors might place additional or new conditions that the recipients were not able to meet. These submitters thought donors should not be able to change their conditions after donating (discussed in recommendation 7).

ACART's view

89. We have not changed our original position: donors should be allowed to continue to place conditions on the use of their gametes including the use of embryos created from their gametes. Such conditions are not discriminatory under the Human Rights Act because gamete donation is a gift by an individual, not a service.
90. While general social practice is that the giver does not have any say in how the gift is used, we believe that this position is outweighed by the potential long term relationships that may result.
91. Not allowing donors to set conditions might discourage donation. Donated gametes, particularly eggs, are scarce in New Zealand, and it is preferable that people be able to access donated gametes in New Zealand rather than access gametes overseas (either by importing gametes or travelling overseas for assisted reproduction).
92. There is no need to place a limit on the conditions donors can set. Clinics can refuse to accept donations if conditions are such that the gametes could not be realistically used.

Recommendation 6 — information for donors about the outcomes of their donations

ACART recommends:

Gamete and embryo donors should be able to make a condition of their consent to donation that the clinic takes reasonable steps to inform them when a child is born as a result of the donation.

Issue

93. The HART Act gives donors certain rights to information about donor offspring. If a donor asks, a clinic must tell the donor whether the donor offspring has asked for any information about the donor (s.49(b)). Clinics and the Registrar-General²³ each have obligations to provide information to donors, including whether there have been any children born from the donation, and if so, their sex (ss.60 and 61).

²³ The Registrar-General is responsible for the HART Register.

94. While donors have rights to information about any child born from the donation (if the clinic knows about a birth), donors must take the initiative to obtain this information. In addition, there are no requirements about informing donors about the use of their gametes, for example when the gametes are used in IVF or when all donated gametes have been used.
95. Clinics have told us that they do not inform gamete donors when the gametes are to be used to create embryos or when embryos created from the donated gametes are transferred to patients.

Ethical and policy arguments

96. The HDC²⁴ considers that, consistent with the Code, gamete donors should have the option of making informed decisions about multiple points of the process, as set out in the example diagram in the text of paragraph 18. That is, donors should be advised how their gametes will be used and stored, and what will happen to any surplus gametes. Discussion about and consent to the storage, preservation and use of embryos should also occur.
97. The issue under discussion here is whether, once informed consent is given, gamete donors should be contacted before stages in the process eg, use of donated gametes in IVF or insemination, birth of a child.
98. This would give donors the option of changing their minds (at least up until the time an embryo is created — see recommendation 7). However, it can be argued that constant updates might encourage donors to change their minds about the use of the gametes and conditions of use, and hence limit the availability of donated gametes.

Submitter perspectives

99. Some submitters agreed with our reasoning that it is important to comply with Right 6 of the Code, which requires the consumer to be provided with ongoing information, or at least notification that this information is not going to be provided.
100. Clinics argued that it would be an administrative burden if they were required to contact a gamete donor every time his/her gametes are about to be used. Further, clinics were concerned that donors would be able to ask for more information about the recipient(s) and set new or different conditions to those they had originally set, preventing gametes being used by the designated recipients.
101. From a Māori perspective, submitters thought that donors ought to know who received their gametes especially if a child is born. For Māori, whakapapa is essential for identifying with whānau/hapū/iwi. As New Zealand is a small country, there could be a potential risk of future close relationships between people if they are unaware of their whakapapa.
102. Many submitters suggested that receiving information about the outcome of a donation be an “opt-in” option for donors rather than a requirement for fertility providers to contact all donors. An opt-in system would place the onus on donors to keep their contact details up to date.

²⁴HDC Submission to ACART September 2015.

ACART's view

103. We have concluded that gamete and embryo donors should be able to set a condition that the clinic should inform them, if practicable, if a child is born from the donation. Our view is that it would not be fair to require that clinics inform all donors of a child's birth, particularly where donors might not be interested or regard contact as intrusive.
104. Donors would need to "opt-in" to receive this information, if known by the clinic, and would need to keep the clinic updated about contact details. Donors would also need to be informed that a clinic is reliant on parents informing them of the birth of donor offspring. Clinics must keep track of donor offspring births (s.52 of the HART Act) and are generally informed.
105. However, the HART Act recognises the collection of relevant information may be out of the control of the clinic: s.53 requires a clinic, where it learns of the birth of a donor offspring, to "take all practicable steps" to obtain and forward to the Registrar-General information about the child's birth date, sex and name (as well as information already collected about the donor).
106. It would not be practical to require that clinics inform gamete donors every time their gametes are about to be used, for example in IVF. The administrative burden would be considerable. With embryo donation, the donors and recipients will have discussed and agreed how the process is to be managed, and will generally remain in touch before and after a birth.
107. We note that all donors are free to contact a clinic to enquire whether their donated gametes or embryos have been used.

Recommendation 7 — point at which gamete donors should be able to change their minds

ACART recommends:

Gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation or insemination.

Issue

108. Gamete donors might wish to change or revoke their consent in response to changing circumstances or changing views over time. The question arises: what is the final point where a gamete donor can withdraw or vary consent?
109. At present, it is generally accepted in the sector that gamete donors cannot change their mind once the gametes are being used to create an embryo, or transferred to a women's body. The rationale is that once gametes are used to create an embryo, the gametes no longer exist.

110. However, there is no explicit requirement in the HART Act or elsewhere about the matter. The Standard²⁵ requires fertility service providers to inform potential donors of their right to "... withdraw or vary the terms of their consent and specify limits (subject to any relevant legislation) at any time until the gametes or embryos are used". But the "use" of gametes can be interpreted in more than one way: to create an embryo? Or to transfer the created embryo to a woman's uterus?
111. The "point of no return" for the use of donated embryos has been settled in the *Guidelines on Embryo Donation for Reproductive Purposes*. The guidelines say that donors of embryos can withdraw consent until an embryo has been placed in the recipient woman's uterus.

Ethical and policy arguments

112. A key ethical question in regard to this issue is: whose autonomy should prevail at the various points in the process of donation and use? It is accepted in public policy that women have autonomy over their own bodies, including when a woman is pregnant. But who should have the final say before and after donated gametes are used to create an embryo, and before the embryo is transferred to the woman's uterus?
113. Right 7(9) of the Code says every consumer has a right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure. Right 7(10) of the Code provides that no body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved or used otherwise than with the informed consent of the consumer. There are exceptions to the requirement for consent, including for the purposes of research. Gametes are bodily substances, and therefore a donor should have control over his/her gametes, including withdrawing or varying consent, until the gametes are used to create an embryo. The donor's wishes prevail over the wishes of anyone else, including anyone who hopes to use the gametes.
114. Once an embryo is created, the donated gametes become part of a new entity: an embryo which is intended for a particular patient to use. The potential harm to the patient needs to be taken into account, if the donor withdrew consent at this stage.

Submitter perspectives

115. Clinics were strongly of the view that the "point of no return" for gamete donors is at the point of fertilisation ie, the addition of sperm to eggs. Clinics considered that the matter should be discussed with donors as part of the informed consent process.
116. Some submitters suggested various points that could be deemed the "point of no return" including at the point of donation, noting that a similar change of status does not occur in any other part of procedures or research governed by the Code, or elsewhere in blood or human tissue regulation. Another suggestion was that donors should be able to withdraw consent if they had serious changes in circumstances, such as learning they had a genetic disease.
117. One submitter said that donors could learn something, after donating, about the intending parent(s) and wish to withdraw consent, even if the gametes had already been used to create embryos. The submitter said such a policy would be comparable

²⁵ Section 1.11.1(k).

with embryo donors being allowed to choose who receives their embryos.

ACART's view

118. We support the view that is held by clinics and many submitters: gamete donors should have the right to vary or withdraw consent to the use of their gametes until the point that the gametes are used in fertilisation or insemination.
119. When an embryo is created, it is with the intention of assisting a specific person or a couple to have a child. The intending parents invest in the embryo(s) their hope of creating a family, and take on responsibility for decisions about the embryo, including payment of storage fees and the timing of the use of the embryos.
120. Withdrawal of consent by the donor at this stage would result in substantial harm to the intending parents' health and wellbeing. Moreover, in the case of donated sperm, the potential mother might have to undergo further retrieval of her eggs, with the associated physical risks. She might not be able to readily access further donated sperm.
121. As noted above, the Standard already refers to the capacity of donors to withdraw consent. In order to remove any doubt, we recommend that the Standard be amended, to specify the point at which gamete donors can no longer vary or withdraw consent.
122. It should be noted that any conditions set by the donor in giving consent will prevail after an embryo is created. For instance, if a gamete donor wants his or her gametes to be used by no more than three families, a clinic must not create and use embryos for four or more families.

Recommendations 8 — consent of partners or family/whānau

ACART recommends:

The consent of a partner, or family/whānau, should not be required for gamete donation.

Issue

123. The Code is based on a principle of autonomous individuals making informed decisions about their own medical care. However, the Standard requires that consent for gamete donation shall be obtained from a donor's partner.
124. The Standard does not require consent from family or whānau members, though clinics must ensure that Māori are able to have whānau, hapū and iwi involvement in their care.

Ethical and policy arguments

125. It can be argued that it is important to obtain partner consent as reproductive decisions are ideally made within families. Gamete donation potentially leads to relationships, in the short or long term, between a donor, recipients, donors' current or future children, and any children born from the donation.
126. Valuing a person's autonomy does not necessarily equate to unqualified individualism. While an individual's right to autonomous decision-making should be highly valued, decisions may at times need to be considered against the potential for harm to other individuals or society at large. An individual's autonomy is embedded within the

context of the relationships they have with others. These relationships are important for decisions about ART.

127. However, situations could arise in which a partner could have more influence over the donor's gametes than the donor. For example, partners might give consent to the donation but then withdraw it so the process cannot go ahead. The Code takes the position that autonomous individuals have the right to make their own decisions about the services they receive. Because individuals have autonomy over the use and disposal of their gametes, a partner's consent should not be required.

Other jurisdictions

128. There is no international consensus on whether a gamete donor's partner should be required to consent. In the UK, partner consent is not required if the donor is married, in a civil partnership or in a long-term relationship, but the involvement of partners is encouraged.²⁶

Submitter perspectives

129. Many submitters recognised the value of partner consent, but agreed that the individual's right to autonomous decision-making was paramount. Individual autonomy underpins consent: requiring consent by partners, family or whānau would undermine that principle.
130. The consensus among submitters was that a partner's consent should be encouraged but not required.
131. Some submitters said that the importance of whakapapa should be outlined as part of the consent process, as many Māori value a collective view when making decisions.
132. One submitter noted that the family's knowledge should be required, rather than their consent. Family secrets, such as about adoption, can cause harm, and there should be an effort to avoid secrets where possible.

ACART's view

133. We have concluded that individuals should be encouraged to consult with their partners, and where appropriate family/whānau, when deciding whether to donate gametes. Counselling should address the desirability of including partners in the donation decision, recognising that if children are born from a donation, they may end up having an ongoing relationship with the donor and the donor's family.
134. However, we consider that donors should not be required to obtain the consent of a partner.²⁷ The Standard should be amended accordingly to remove the requirement in Section 1.10.3 that the consent of gamete donors' partners be obtained, but with a stated preference that gamete donors are encouraged to consult and gain consent from their partners. The consent form could therefore record whether consent from the partner has been obtained, with making such consent mandatory.
135. We support the approach of the Standard to the involvement of family or whānau members: clinics should facilitate family and whānau participation in decisions if

²⁶ Human Fertilisation and Embryology Authority Code of Practice, section 5.20.

²⁷ For *embryo* donation, the written consent of both partners donating embryos is required, in accord with the *Guidelines on Embryo Donation for Reproductive Purposes*.

requested by a consumer. The Standard, however, does not require consent from family or whānau members, though clinics must ensure that Māori are able to have whānau, hapū and iwi involvement in their care.

Recommendations 9, 10, 11, and 12 — managing disputes about embryos

ACART recommends:

9. A “cooling off period”, of up to 12 months, should be introduced for situations where a couple disputes the use or storage of an embryo that was created for their use;
10. The “cooling off” period should begin on a date where the clinic receives written notice that there is a dispute. If the clinic receives such a notice, the clinic should be required to take reasonable steps to notify the other party that consent to use of the embryo(s) has been withdrawn;
11. Where a dispute arises the clinic should be required to provide information about mediation services; and
12. Where couples cannot agree after 12 months, embryos should remain in storage until the end of a lawful storage period, unless the parties reach a mutual decision about the fate of the embryos before the end of the lawful storage period.

Issue

136. If a relationship breaks down, there may be a dispute about the future of embryos which a couple has created for their own use. The question is what should happen where one party withdraws consent at a point in the IVF process after the embryo has been created, but before it has been transferred to the uterus of the woman who will gestate it (the intending mother or a surrogate).
137. Does one partner have the right to use the embryo they both consented to create, if one of them has changed his/her mind or the relationship has broken down? Or should the person who does not want to use the embryos prevail? To the best of our knowledge, such disputes are rare in New Zealand, but when they arise, the stakes are high for the people involved, particularly where embryos represent a person’s last chance to have a biologically related child.
138. A UK case highlights the tensions that can arise. Natallie Evans and Howard Johnston had created and stored embryos in 2001, before Evans underwent treatment for ovarian cancer including removal of her ovaries. The relationship ended and Johnston asked the clinic to dispose of the embryos. The clinic advised Evans that it must dispose of the embryos because both parties were required to consent to their use.
139. Evans challenged the clinic’s decision in the UK courts. A series of court and appeal court hearings in the UK and Europe ensued. Ultimately, the European Court of Human Rights delivered a majority ruling that her right to a family life could not overrule Johnston’s withdrawal of consent.
140. Even though Evans’ eggs were used to create the embryo, the Court (including on appeal) ruled against overriding Johnston’s right to withdraw consent. The Court concluded that both parties would be the legal parents of a child resulting from the embryo created for their use, regardless of the source of the gametes. The Court also rejected the claim that the embryo’s right to life was being threatened, taking the view that it is the prerogative of a state to decide when the right to life begins.

141. At present, there is no recognised process in New Zealand for addressing such disputes about the future use and storage of embryos, including what should happen if agreement cannot be reached.

Ethical and policy arguments

142. It is preferable for disputing parties to reach agreement about the future of embryos, whether the embryos are to be disposed of or used by one of the parties.
143. A mandatory “cooling off” period is a practical and fair way to manage cases, by allowing parties to explore options (through, for example, mediation or with support from clinic counsellors), with the goal of reaching a shared view.

Submitter perspectives

144. Most submitters agreed with our proposal to introduce a “cooling off” period. They noted that a 12 month period would be consistent with other areas of dispute resolution such as employment and consumer law. Submitters noted that the start and end points of such a “cooling off” period need to be defined.
145. Some submitters thought that a “cooling off” period could lead to an outcome that is more willingly accepted than one that is decided in the heat of the moment. However, some submitters noted that a “cooling off” period alone might be insufficient to avoid the potential harms from disputes over the future use of embryos. Accordingly, ECART suggested that any “cooling off” period should be combined with the requirement for the couple to attend mediation or counselling to attempt to reach a mutually agreeable resolution.
146. Some submitters were concerned that a 12 month delay might prevent a woman being eligible for public funding due to her age (ie, once the 12 months had elapsed she may have passed the upper age limit at which public funding for fertility treatment is available).
147. Other submitters commented that 12 months might be insufficient time to resolve a dispute. Another concern was that by requiring people to attend mediation or other form of dispute resolution, some participants could experience increased stress.
148. We originally proposed that if agreement could not be reached after 12 months, embryos should be disposed of. Submitters who disagreed were primarily concerned that the mandatory disposal of embryos could deprive an individual of an opportunity to have a biological child, and effectively give an automatic veto to the individual who was not in favour of using the embryos.
149. Submitters also argued that where embryos had been created from donated gametes, disposal of the embryos could mean that new embryos were created using the same gametes (donated gametes plus gametes of the former partner). In such cases, disposal of the embryos would waste a potential human life, waste participant and clinic time, and cause stress for those parties with an interest in using the embryos.
150. Another group of submitters supported disposal of embryos where one partner withdrew consent to use them. Reasons given by these submitters were that no person should be forced to become a parent against his or her will, and it is not in the best interests of a child to be born if one of their parents do not want this to happen.

The continued storage of disputed embryos would exacerbate the tension between the disputing parties.

ACART's view

"Cooling off" period

151. We continue to be of the view that a maximum 12 month "cooling off" period would be a practical and fair way to deal with disputes. We agree with submitters that the starting point of the "cooling off" period needs to be defined. We consider that the "cooling off" period should begin on a date when the clinic receives written notice that there is a dispute. If a clinic receives such a notice, the clinic should be required to take reasonable steps to notify the other party that consent to the use of the embryo(s) has been withdrawn.
152. The HART Act provides for regulations to be made providing for the use or destruction of in vitro gametes or embryos where one party from whom such a gamete has been obtained or formed withdraws his or her consent to any course of action. We do not think separate regulations are necessary. As discussed in the next section, we are of the view that the Standard should be amended to include new and amended requirements about informed consent.

Mediation

153. Mediation would provide the best chance that disputes can be resolved quickly. We recommend that when a dispute arises, the clinic should provide the couple with information about mediation services.

Lack of resolution after 12 months

154. Even with mediation, some disputes might not be resolved. What should happen to the embryos?
155. As noted above, we originally proposed that embryos should be disposed of in such situations. This would follow the UK legislation which requires embryos to be destroyed after 12 months of notification of the dispute, or sooner if all intended recipients consent to the disposal. The rationale for such a process is that the birth of a child should be welcomed by both parents. Disposal of the embryos avoids extending the dispute, and enables the parties to move on.
156. However, we are now of the view that where couples cannot agree after 12 months, embryos should remain in storage until the end of a lawful storage period, unless the parties reach a mutual decision about the fate of the embryos before the end of the lawful storage period. Our recommendation is similar to a requirement in Australian national ethical guidelines for ART which say that if a dispute arises between a couple for whom an embryo is stored, and either person requests the embryo should be kept in storage, the embryo should be kept in storage either until a dispute is resolved or until the maximum storage period has expired.²⁸

²⁸ Ethical Guidelines for the Use of Assisted Reproductive Technology in clinical practice and research (2007). <https://www.nhmrc.gov.au/guidelines-publications/e78>

157. This provides a chance that the couple will reach a shared decision while the embryos are still lawfully stored, but ensures embryos are not stored indefinitely. The HART Act requires that gametes and embryos must be disposed of when they reach the end of a lawful storage period.
158. Counselling and consent forms would need to address the requirement as part of providing full information. Any ongoing storage will need to be paid for by one of the parties: storage is a business arrangement between consumers and clinics, which are not obliged to store embryos.
159. ECART is responsible for deciding applications for extending the storage of gametes and embryos beyond the initial 10 year storage period or an approved extended storage period, using ACART's *Guidelines on Extending the Storage Period of Gametes and Embryos*. ECART designs its own application forms. We plan to discuss with ECART the possibility of including an additional question on the extended storage application form about whether the use or storage of embryos is in dispute, with a requirement that both people in a couple sign the consent to extended storage.
160. We did consider whether ECART should be given the function of deciding what should happen to disputed embryos, using guidelines issued by ACART. This approach would enable consideration of particular circumstances. However, we decided not to recommend this option. All disputes are likely to be very emotive, with each partner claiming special circumstances for their desired course of action. Developing and issuing guidelines would take time, with required public and ministerial consultation, and would be a disproportionate response given the rarity of disputes.
161. We also considered whether to recommend that the Family Court should decide cases where the fate of embryos was in dispute, to give finality and authority. However, embryos are neither children nor property, and therefore do not fall under either the Care of Children Act 2004 or the Property (Relationships) Act 1976.

FORM OF REQUIREMENTS FOR INFORMED CONSENT

Recommendation 13 — form of requirements for informed consent

ACART recommends:

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

Issue

162. Although informed choice and informed consent are included in the principles of the HART Act, the Act does not contain detailed requirements for informed consent. The HART Act provides for regulations to be made on a number of matters about which the Act itself lacks detail, including informed consent.²⁹
163. The Code is a regulation under the Health and Disability Commissioner Act 1994 and is based on a model of autonomous individuals making informed choices. It therefore does not specifically address informed consent in the context of circumstances where

²⁹ Section 76(1)(a)(i).

more than one party must give informed consent, giving rise to a situation where the parties may have different interests.

Ethical and policy arguments

164. The key ethical issues are transparency and accessibility. Clinics and consumers (including donors) should have a shared understanding of the requirements for informed consent, and what should happen when parties are in dispute. The requirements should be understandable and accessible.

Submitter perspectives

165. Many submitters argued that regulations should be made, for consistency with other areas of health and disability research, services and procedures. Past sperm donors supported regulations.
166. Some submitters supported regulations on the basis that regulations would ensure consistency and transparency. Regulations would make it easier to standardise processes by providing guidance and explaining good practice, and would be a safeguard in the event of disputes.
167. Other submitters considered that regulation would introduce unnecessary red tape and create inflexibility. They argued that the existing requirements are sufficient, and that the sector could address any improvements needed to the accessibility and scope of information.
168. Submitters opposed to further regulation said that in general, consumers did not fully understand what was involved in ART in advance of talking to a clinic. From this perspective, providing more information before treatment would not necessarily make the process of assisted reproduction easier to understand. Instead, it was likely that improvements in obtaining truly informed consent would largely come from finding better ways of educating consumers, not from regulations. Regulations cannot anticipate all cases.
169. ECART noted regulations would need to be associated with the establishment of a complaint and enforcement regime. Such a regime would be potentially costly and an administrative burden. Costs would be passed on to consumers.
170. Some submitters said it would be more appropriate to have the requirements for informed consent set out in formal guidelines, because guidelines could be modified as new technologies are developed.
171. Fertility clinics and the HDC supported a more flexible approach than creating regulations, suggesting that current processes appear to be working well. The idea of specific regulations for informed consent for ART was challenged: was there a genuine need for such regulations? Guidance from the HART Act, the Code and Standard was sufficient, and their content could be adjusted if necessary.

ACART's view

172. We have concluded that new regulations for informed consent under the HART Act are unnecessary. The need for transparent and accessible requirements can be met by including new and amended requirements for informed consent in the Standard, which is an existing form of regulation under the Health and Disability Services (Safety) Act

2001. From a policy perspective, it is sensible to have one central source of regulation about informed consent requirements.

173. The language used in the Standard is understandable to a lay audience, and the Standard is now available on-line. Clinics will make any necessary changes to their own practices and information in accord with the Standard's requirements.
174. While some submitters wanted guidelines to be issued about informed consent, we do not think guidelines are appropriate. Procedures regulated through guidelines include provisions about informed consent. ACART does not have jurisdiction to issue guidelines about the conduct of established procedures (procedures which do not require ECART approval but also involve informed consent).
175. We have noted the approach used in some other jurisdictions. In the UK, the Human Fertilisation and Embryology Authority issues guidance and interpretation about informed consent requirements set out in the primary legislation, and also provides standard consent forms.
176. In Victoria (Australia), the Assisted Reproductive Treatment Act 2008 includes requirements for obtaining informed consent. The Assisted Reproductive Procedures Regulations 2009 include counselling requirements for procedures, donation, surrogacy and posthumous use. In New South Wales, the Assisted Reproductive Technology Act 2007 includes provisions about giving, modifying and revoking consent.
177. We think our recommended approach is appropriate for New Zealand's ART regulatory framework. Importantly, we note that informed consent processes within clinics appear to be working well, and therefore a light approach is proportionate.
178. Some submitters advocated for standardised consent forms for all New Zealand clinics, as in the UK. At present clinics develop their own consent forms. We do not think there is a need to follow the UK model. The costs associated with developing new forms would be significant, and we have seen no evidence that New Zealand consumers would be better protected by standardised forms.

ADDITIONAL MATTERS THAT AROSE IN CONSULTATION

179. As is usual in ACART's public consultations, some submitters noted views about matters that were outside the scope of the consultation.
180. Several submitters were not comfortable with references in the HART Act to "disposing of" embryos, and want the term changed. They commented that the word "disposal" is used for rubbish, unwanted objects and suchlike, and considered that the wording does not reflect respect for the embryos.
181. Some submitters wanted the option of donating their surplus embryos for use in research.

J: NEXT STEPS

182. We have given a copy of the advice to the Ministry of Health in case you decide to seek parallel advice.
183. I am available to discuss the advice with you, if you wish.

184. We plan to publish the advice on ACART's website in September 2016.

APPENDIX 1**SUBMITTERS AND INTERVIEWEES**

Organisation/Person	
1	Bioethics Centre, Otago University
	Bioethics Centre, Otago University — minutes of meeting/seminar with ACART members
2	Daniels, Ken (contractor to ACART)
3	Ethics Committee on Assisted Reproductive Technology
4	Else, Anne
5	Fertility Associates
	Fertility Associates — minutes of meeting with ACART members
6	Fertility New Zealand
7	Fertility Plus, ADHB — minutes of meeting with ACART members
8	Forman, John
	Forman, John — minutes of meeting with ACART members
9	France, John
10	Genea
11	Hassall, Ian
12	Health and Disability Commissioner
	Health and Disability Commissioner — minutes of meeting with ACART members
13	Hudson, Maui
14	Jahnke, Huia
15	Ministry of Health
16	Nathaniel Centre
17	National Council of Women of New Zealand
18	New Zealand Family Planning
19	New Zealand Law Society
20	New Zealand Nurses' Organisation
21	Office of Ethnic Communities
22	Quin, Brian
23	Repromed — minutes of meeting with ACART members
24	Right to Life
25	Service, Integration and Development Unit. Wairarapa, Hutt Valley and Capital & Coast DHBs

Organisation/Person	
26	van Rooyen, Amanda
27	Name withheld by request
28	Wilson, Debra
29	Women's Health Action Trust

Introduction

- The Advisory Committee on Assisted Reproductive Technology (ACART) consulted the public in 2015 on its proposed advice to the Minister of Health on requirements for informed consent.
- The Human Assisted Reproductive Technology Act 2004 (HART Act) requires ACART to advise the Minister of Health on requirements for informed consent relating to human assisted reproductive technology (ART). Before giving the advice, ACART must give interested members of the public an opportunity to make submissions about the Committee's proposed advice.
- A discussion document including the draft advice was sent to a range of health professionals and other stakeholders identified as having an interest in this work. The discussion document was also put on ACART's website. This report summarises the feedback ACART received.
- ACART is very grateful to everyone who provided feedback. The information provided was extremely helpful for finalising ACART's advice to the Minister of Health.

Condensed main themes emerging from submissions

- Information about assisted reproductive processes needs to be given in an appropriate format and in a way that individuals can read and understand. The general consensus was that effective communication and supplying information are two different things. For example, too much information about possible outcomes and risks could put people off donating altogether. Many submitters suggested that ACART could summarise documents such as the Fertility Services Standard (the Standard), the HART Act 2004, the HART Order 2005, the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulation 1996, and other relevant documents in a plain language format.
- Creation of standardised consent forms (such as in Belgium) could be helpful to create consistency across the sector.
- There are many current clinic practices that submitters are not aware of that are already requirements under the Standard or the Code.
- Many submitters suggested donors should 'opt in' to receive information about the use of their gametes and outcomes. This would not place an unnecessary administration work on clinics.
- Most submitters opposed creating further regulation and did not think this would result in a more informed consumer population. What was needed instead of regulation is for consumers to have the information and understanding to exercise informed consent.
- Some submitters wanted the opportunity to have the option to donate their surplus embryos for research.

Feedback on proposals in the discussion document

This section summarises the feedback under the ten questions that were asked in the discussion document.

Question 1: Access to information that must be disclosed to patients and donors prior to consent

(a) Do you agree there is a need for better access to the information that must be disclosed to patients and donors prior to consent?

Yes:

- Most submitters agreed that there is a need for better access to information, because making an informed choice depends on full understanding of this information. Submitters were clear about what information is currently available.
- The communication of the information to patients and donors is also important. Many submissions talked about Right 5 of the Code and how it should apply in ART. Submitters talked about accessing and communicating information in plain language to ensure that patients and donors understand the information provided to them.
- Submitters suggested that a plain language information sheet could consist of relevant excerpts from the Standard, the HART Act 2004, the HART Order 2005, and the Code.
- Some submitters suggested amending the copyright for the Standard so it could be accessible online. Other submitters thought that because the Standard is aimed at a professional, rather than lay audience, a plain language version might be more useful.

No:

- A few submitters agreed with ACART's opinion that existing arrangements for providing information to consumers appear to work well. There does not appear to be a genuine need for regulations for better access to information, and regulations would provide unnecessary red tape.
- One submitter questioned whether clinics have an obligation to inform their clients to a specific standard and to assess their clients' understanding of that information, or if clients are obliged to ensure they fully understand and do so by seeking independent legal advice.

(b) Is there other information that should be given to patients and donors as part of the informed consent process?

- Submitters were divided on this issue. Some suggested information that could be given to patients and donors. Some said there is a need to balance the amount of information provided, so that participants can make informed choices and give informed consent without the risk of overwhelming patients with information.
- Suggested additional information included:
 - Simple, plain language legal information.
 - Encouraging donors to seek legal advice in relation to resulting pregnancies, and any rules around traceability.
 - Information about patient and donor rights to withdraw and vary consent.

- Access to appropriate translation services and qualified interpreters to mitigate the risk of compromised accuracy.
- Storage, preservation and use of any embryos.
- Advising donors to make a full disclosure of their circumstances prior to donation: for example, stating that they are adopted, and therefore there will be limited information about their background. Donors should also be made aware that they need to inform the clinic if their details or situation changes.
- Counselling information for donors: submitters who were previous donors are supportive of the idea that counselling for prospective donors should be regulated.
- Information and research on the importance of biological connections for the wellbeing of any potential offspring.

Other comments:

- The requirement to provide information is already covered by section 46 of the HART Act 2004.
- Informed consent is dynamic by nature, and therefore the process is limited by what people can sensibly consent to in advance, as most situations are not comprehensible until they are right in front of you. Therefore, more information at the point of counselling will not necessarily make it easier for consumers to make decisions.
- If regulations are developed, there should be consultation with people who have used ART to create their families and with people born from the use of ART.
- Full information should be presented in writing as patients are often stressed and might not remember everything that they are told.
- There should be a change to the process for obtaining informed consent. For example, rather than a discussion over a period of time resulting in a signature on a piece of paper, informed consent should be more of a series of questions (possibly in the form of a scenario based interview and questionnaire) with 'I' statements to show that there is understanding for informed consent.

Question 2: Form of consent

- (a) Do you agree that consent to all assisted reproductive processes, where consent is required, must be in writing?**
- There was overwhelming support, especially by institutions and clinics, for written consent to be required. Most submitters agreed with the reasoning in ACART's consultation document.
 - Consent in writing is already obtained, and is considered best practice amongst clinics. However, it would help to protect everyone involved in ART for this to be an explicit requirement.
 - Fertility Associates also requires written consent for non-ART reproductive treatments that have a reasonable risk of side effects, such as ovulation induction using gonadotrophins.

Support for consent in writing:

- Fully informed consent is essential to all forms of medical treatment. The Cartwright Inquiry established that the use of all forms of human materials must have written informed consent.
- It provides accountability and enables audit, protecting both patients and fertility services providers.
- This formalises what clinics already do in practice, and aligns regulation with practice.
- Written consent provides patients with an opportunity to reflect on their decisions before consenting, prompting them to give more thought to what they are consenting to than they otherwise might have.

Other comments:

- Some clinics made the argument that in practice it is not always possible to get consent in writing. If written consent were to be an explicit requirement for all procedures, this would have the potential to delay patient treatment, for example where the clinic cannot contact the donor.
- From a Māori point of view, an absolute requirement for written consent by the individual may not always work in practice. Many Māori value the ability to take collective responsibility for decisions that need to be made. An example is the ability for whānau to consent to processes when the person about to undergo some procedure is unable to consent (for example, if they are comatose or if they have passed away).
- The consensus was that obtaining consent orally or in writing should not be the most important point of focus. What is more important is that this consent be fully informed.
- Concerns held by, or matters of interest for, submitters included the following:
 - A signature has not been considered to amount to informed consent in the past where drivers' licences have indicated the wish to donate organs, and also in some cases of advanced directives. That is, consent, even in writing, has been successfully challenged
 - We need to be careful not to overstate the benefits of informed consent. Further regulation will not necessarily provide assurance to donors that the conditions they have placed on their consent will be implemented by the service provider.
 - An industry agreed standard for informed consent would keep more flexibility for developing new technologies in ART.

(b) Do you have any other comments?

- There was support for standardised consent forms by some clinics and lay submitters.
- Supporting information in written form should be available for patients and donors to take home and discuss independently.
- Informed consent processes for ART should align with other areas of health care services and research in New Zealand.

- Oral consent should be permitted where someone wishes to withdraw consent at short notice. For example, withdrawal of consent by donors is reported to be a common occurrence. The Law Society notes that oral consent is legally valid and a failure to obtain a written record of withdrawal of consent does not negate that withdrawal.
- Clinics have taken on the responsibility of going back to donors when there has been a change in circumstances in relation to their donation for example, when a recipient woman wishes to take donor sperm overseas.

Question 3: Donor consent to use gametes or embryos for training purposes

- (a) **Do you agree that the consent of gamete and embryo donors should be obtained if their gametes, or embryos created from their gametes, may be used for training purposes?**
- Most submitters supported obtaining the consent of gamete and embryo donors if their gametes, or embryos created from their gametes, may be used for training purposes, with clinics stating that this is already current practice for research on non-viable embryos. The rationale was that fully informed consent in writing is essential to protect the welfare of donors, as well as to protect clinics.
 - Submitters noted that donor consent for embryos to be used in formal training for embryologists is covered by Right 6 of the Code. Failing to obtain fully informed consent would conflict with this Right.
 - Submitters who did not agree that consent should be obtained were predominately recruited through Professor Ken Daniels. This cohort appeared to believe that appropriate consent is already given at the time of donation for all relevant purposes. This position is consistent with Fertility New Zealand's view that it is inconsistent to require gamete donors to give consent for embryos (created using their gametes) to be used in training. At present, a donor does not consent to the use of an embryo for ART or to discard an embryo, and this should be the same for an embryo to be used for training. Further, there are situations where donor consent is not sought, for example, when a training doctor is learning ICSI.
 - One submitter said that training using donated gametes is not in the spirit of the donation.

(b) **Do you have any other comments?**

- Submitters noted that the consultation document did not explain what training involves, and it would be useful for ACART to clarify the circumstances in which gametes or embryos would be used for training purposes. Consent would not be possible without this understanding. ECART noted that it would also be useful to define 'training purposes' to ensure that this term is distinguishable from "research purposes".
- If regulations are formed, ACART will need to balance the ethical and practical challenges of conveying information about training and research on gametes and embryos to donors, with the value of public understanding of the science, ethical considerations and constraints that govern training and research. Any regulations will also need to balance the flexibility required for experts to be able to keep up with new developments, with the public need for transparency.
- One submitter noted that because of the difference between gametes and embryos, there should be a different consent process.

- ECART suggests that in progressing this work, ACART may wish to consult with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists about what is considered current best practice.

Question 4: Placing conditions on donor consent

(a) Do you agree that donors should continue to be able to place conditions on their consent?

- Most submitters agreed that donors should continue to be able to place conditions on their consent.

(b) If so, should there be any limits on the conditions placed?

- Submitters were divided on this question. Many grappled with the ethical issues associated with this question. However, most agreed with ACART's conclusion and ethical and policy arguments that donors should continue to exercise their autonomy to make choices about how their donated gametes are used and who can use them. Submitters all came to the general conclusion that any conditions placed should be limited, reasonable, and non-discriminatory.
- Setting conditions could potentially be considered grounds for discrimination under the Human Rights Act 1990. Donors should be able to place conditions up to a point without the conditions being discriminatory. For example, conditions should be reasonable and practical, and able to be refused by the clinic if they do not meet the criteria.
- If a donor sets conditions that are difficult to interpret or subjective (eg, if a man specifies that his sperm can only be used for couples who are 'well mannered'), then Fertility Associates would ask the person to be a personal donor instead and chose his or her recipient.
- One submitter considered donation of gametes is a gift, and therefore follows normal social practice that the giver does not have any say in how the gift is used.
- Submitters noted that there is something special and complex about the nature of gamete donation and argue that gamete and embryo donations are different from blood and organ donation, so the current limits on setting conditions should remain. Further, there is a shortage of donors and allowing donors to place conditions could potentially increase the pool of available gametes.
- From a Māori point of view, an altruistic spirit is often present in the Māori community but it is not always unconditional. Takoha has emerged as a key concept in projects around Māori views on biobanking, as the use of genetic material is closely connected to whakapapa. Takoha can be thought of as a gift with responsibility or even as the gifting of the responsibility itself. Takoha creates a lasting biological and personal history, so donors and intending surrogates and recipients need to be able to place conditions on consent.
- In Victoria, Australia, there is a limit to the conditions that donors may place, including the number of women who may use the donor's gametes or embryos and the kinds of procedures they can be used for.
- ACART may wish to consider further the legal status of any conditions imposed on donation, including who is responsible for compliance with the conditions imposed; how

compliance is monitored; and how any breaches are dealt with. External oversight of the conditions set, may help provide assurance that the conditions are not discriminatory.

(c) Do you have any other comments?

- Clinics noted that conditions on gamete and embryo donations are uncommon and that most donors are altruistic and want to help.
- Submitters generally thought that donors should not be able to change conditions after donating. Many gave the example that if donors could change the conditions they had set, the recipients might find that they do not meet the new conditions when the time comes to create biological siblings for any existing children.

Question 5: Ongoing information for donors on the use of their gametes

(a) Do you agree that gamete donors should be given the option of receiving ongoing information on the use of their gametes for the following situations

(i) if the gamete is about to be used?

- Submitters were divided on this issue.

Yes:

- Right 6 of the Code requires the consumer to be provided with ongoing information (or at least notification that this information is not going to be provided).
- The position of gamete donors can be distinguished from organ donors. The biological connection that donors have to any resulting children is important and information should be provided to respect this.

No:

- Clinics noted that it would be impractical to contact gamete donors every time their gametes are about to be used. This would create an enormous administrative burden. Further, there is no real outcome to inform a donor about at this stage.
- Many submitters noted the potential for donors to discriminate that would arise from this being a requirement. Donors would be able to ask for more information about the recipient(s) and set new or different conditions to those they had originally set. This would add another element of stress to an already difficult situation for the recipients.
- There are possible privacy issues for the recipient if the donor is informed that their gamete is about to be used and then it does not result in a pregnancy. This would be very common situation in ART and is not considered appropriate. One clinic had at least one formal complaint in this area which led to defining what information would be shared between donors and recipients, and what would not be shared in donor egg treatment. This particular clinic now will ask a person to become a personal donor if they want this level of information, and get the information directly from the recipient.

(ii) on the outcome(s) of the donation?

- Most submitters said that the information on the outcome of the donation should be available to the donor if they request it.
- From a Māori perspective, it was thought that donors ought to know who received their gametes especially if a child is born. For Māori, whakapapa is essential for claims as a

member of whānau/hapū/iwi. As New Zealand is a small country, there could be a potential risk of future close relationships between people if they are unaware of their whakapapa.

- However there was the recurring suggestion that receiving information about the outcome of a donation should be an “opt-in” option for donors rather than a requirement for fertility providers to contact donors. An opt-in system places the onus on the donor to update their information as required under the HART Act if there is new medical or family information available, or if contact details change. This would benefit any future children born from their donation.
- Submitters concluded that donors should not be informed that their gamete is about to be used, but should be informed through an opt-in system if a child is born from the use of the donated gametes.

(b) Is there any other information that you think should be offered to gamete donors after consent has been given?

- Submitters suggested: donors being made aware that they have a right to information after donation, even if the right to exercise this is not chosen; donors should know the number of children born and their gender; and if children born or tested through preimplantation genetic diagnosis have inherited genetic conditions.

Question 6: Withdrawal or variation of consent by donors

(a) Do you agree that gamete donors should be able to withdraw or vary consent to the use of their gametes up to the point of fertilisation?

- The general consensus was that ACART’s argument represents a balancing of interests. Submitters believe that being able to withdraw consent is appropriate, but variation of consent after initial consent is not appropriate as this has the potential to become personal to recipients who are considered extremely vulnerable. Not allowing variation of consent should be the norm: the donor should not be able to request personal information about recipients in order to determine whether he/she wishes to vary the conditions of consent.
- Submitters thought that any variation to conditions or consent should be donor triggered, and not as a consequence of the clinic informing the donor of an intended use. Clinics made clear in their submissions that donors are made aware of how their donation will be used and are free to withdraw anytime.

(b) If not, when do you consider the ‘point of no return’ should be?

Status quo position:

- Clinics are strongly of the view that the “point of no return” is at the point of fertilisation for gamete donors (ie, the addition of sperm to eggs) or the transfer of embryos to the uterus for an embryo donor.
- ECART considered that this widely accepted “point of no return” provision works well.

Other views on the “point of no return”:

- The “point of no return” occurs:
 - When the donor is informed that gametes are about to be used. At this stage, recipient/s are involved and respect must be given to them. The point of fertilisation is too late in the process.

- Upon donation. A similar change of status does not occur in any other part of Code-governed procedures or research, or elsewhere in blood or human tissue regulation.
 - Before the treatment cycle begins.
 - Any time that serious circumstantial changes occur with the donor, such as learning that he/she has a genetic disease.
 - Depending on those who bear the responsibility to protect the rights and wellbeing of the child.
- The New Zealand Nurses' Organisation considers a withdrawal of consent at any time is inappropriate. The New Zealand Nurses' Organisation recognises the importance of preparation before a procedure.
- An exception to withdrawal of consent could be made if the embryo/embryos in dispute already have an existing sibling, on that basis that the new genetic whānau is already established so the effect of the birth on the donor is less significant.
- It is important that the “point of no return” is defined clearly to donors at the time of donation. The definition should be discussed and explained to all donors as part of the informed consent process.

Question 7: Consent of a partner, family or whānau to donation or use of donor gametes

- (a) **Do you agree that the consent of partners to the donation or use of a donor's gametes should not be required?**
- The question of what constitutes a partner is a personal one, as is the choice to donate. Donors are more certain and less likely to change their mind about a procedure if they have support from their family and partner. If partners and family are not comfortable with a donor's decision, it does not make the situation better by excluding them. If a partner refuses to give consent, the clinic should undertake a risk analysis to decide whether to accept the person as a donor. There are practical risks associated with a partner not agreeing to donation or refusing to receive information, including a higher chance of the donor withdrawing later on and disharmony in the donor's relationship that can affect the recipient and the clinic.
 - If a woman becomes pregnant through donor sperm, her non-donor partner is not a parent unless they had given consent (this is consistent with the Status of Children Act). If the partner has no rights in relation to the child, it may reasonably follow that the partner's consent is not necessary.
 - Where existing children are involved, the partner should be encouraged to be consulted, as any resulting children will be genetically related.
 - The wellbeing of the offspring is paramount, and if one of the intending parents did not want to have a child, that child's wellbeing could be compromised.
 - In the interests of trust and relationship stability partners and family/whānau are encouraged to receive counselling.

(b) Do you agree that the consent of family or whānau to the donation or use of a donor's gametes should not be required?

- Submitters thought that consent of family and whānau to the donation or use of donor gametes should not be required.
- The importance of whakapapa should be outlined as part of the consent process, as Māori value a collective view regarding decisions.
- One submitter noted that the family's knowledge should be required rather than their consent. Family secrets, such as about adoption, can cause harm, and there should be an effort to avoid this where possible.

Question 8: Couple disputes about the future use of embryos

(a) Do you agree that where one party in a couple disputes the future use of embryos that have been created for them, there should be a “cooling-off” period of 12 months – and if not, why not?

- The majority of submitters agree with ACART's proposal that where one party withdraws consent to the use of embryos created for a couple's use, this should be possible up to the accepted “point of no return” ie, where the embryo is transferred into the uterus.
- Submitters considered that a 12 month “cooling-off” period would be consistent with other areas of dispute like employment and consumer law. Submitters were interested to know when the “cooling off” period might be reasonably expected to commence during an IVF process. Submitters recommended that the start and end of such a “cooling-off” period needs defining.
- Submitters noted that a “cooling-off” period alone may be insufficient to avoid the potential harms from disputes over the future use of embryos. Accordingly, ECART suggested that any “cooling-off” period should be combined with the requirement for the couple to attend mediation or counselling to attempt to reach a mutually agreeable resolution.

(b) Do you agree that, if the couple cannot agree about the use of the embryos within that period, the embryos should be disposed of – and if not, why not?

- This is a complex situation.
- A “cooling-off” period may lead to an outcome that is more considered than one decided in the heat of the moment. It may be inevitable that one member of the couple does not get his/her preference met, and this would be a very difficult outcome to accept.
- Submitters raised various scenarios, highlighting the reasons for and against the destruction of embryos when one party withdraws their consent:

Disagree with destruction of the embryos at the end of the cooling off period:

- It may deprive an individual of an opportunity to have a biological child. However, this must be balanced against the harm of forcing one partner to become a parent against their will.
- A 12 month period may not be sufficient to reconcile disputes.
- Destroying embryos if an agreement cannot be reached within the time limit gives an automatic veto to the individual who is not in favour of using the embryos. From an ethical and legal perspective there is no clear logic to this approach as rights of both parties should carry equal weight.

Agree to destruction of embryos at the end of the cooling off period:

- A 12 month period with a skilled mediator seems appropriate. The mediator should also act as the advocate for the embryos.
- ECART and clinics agreed that if the couple cannot agree about the use of the embryos within a lawful period, the embryos should be disposed of
- Continuing storage can increase tension between parties.
- It is not in best interests of a child if they are born, or embryos donated, against one of their parent's wishes

Other comments:

- A 12 month delay might prevent a woman being eligible for public funding due to age.
- Precedence should be given to the female partner if there is a dispute over an embryo created for a couple.
- Clinics noted an exception. If a couple creates an embryo using donor sperm, then the woman should be able to use that embryo even if her partner disagrees. The reasoning follows that if the general principle of disposing of embryos applies in all cases, then this embryo would be discarded. The woman could then have a new cycle of IVF treatment using the same sperm donor to create an embryo with the same genetic composition as the embryo which was discarded. It is illogical, expensive, and wasteful of a potential human life to require an embryo to be discarded only to create a replacement embryo from the same gametes

Question 9: Form of requirements for informed consent

(a) Do you agree that requirements for informed consent should be set out in regulations?

- Many submitters argued that there should be regulations for ART to align with those that exist for all other areas of health and disability research, services and procedures.
- Donors who had previously donated material and the Ministry of Health were in favour of regulation. Fertility clinics and the Health and Disability Commissioner supported a more flexible approach than regulation.

Yes:

- Regulations would ensure consistency and transparency.
- Regulations would align current best practice and general principles of informed consent for ART. It would be easier to standardise processes if regulations are available to provide guidance setting out good practice.
- Regulation would be a safeguard in the event of disputes.

No:

- The Standard and the Code (Rights 5, 6 and 7 together) already provide appropriate regulation but could benefit from general strengthening. Right 5 of the HDC Code sets out the right of health and disability services consumers to effective communication from providers.

- Right 6 of the Code relates to the provision of information. Specifically, Right 6(1) of the Code provides that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. A reasonable consumer undergoing ART, where that procedure is to remove gametes for future use, would expect to know what will happen to the gametes, including about embryos made from them.
- Right 7 of the Code provides that services may only be provided if a consumer makes an informed choice and gives informed consent to those services.
- As medical professionals, those working in ART already have high standards of ensuring informed consent.
- The idea of ART exceptionalism questions whether ACART's proposal to create regulations for informed consent processes comes from a place of genuine need, when processes seem to be currently working well. Guidance from the HART Act, the Code and the Standard are sufficient, and their content could be adjusted if necessary. One submitter suggested clarifying the application of these to informed consent requirements in relation to ART.
- ECART noted that a complaint and enforcement regime would need to be established, but is potentially costly and may create a burdensome regulatory environment.
- Regulation can help clinics and participants manage unexpected situations but will not necessarily provide guidance for every scenario. A potential downside of regulation is that it can increase costs and create work. Costs would ultimately be passed on to consumers.
- The Standard is just as legally binding as the HART Act but easier to amend. Fertility Associates does not think that further regulation of informed consent is needed because existing regulations provide sufficient scope and can be amended.
- It would be more appropriate to have the requirements for informed consent set out in formal guidelines, which can be more easily modified as new technologies are developed.

(b) Do you have any other comments?

- Any regulations or guidelines must be compassionate to the circumstances of those using ART.
- We need to be careful about using informed consent as the only way to protect the interests of people, their whānau, and the clinicians. Informed consent has a number of limitations partly because a number of the consent decisions are distant from the point of application.
- One of the key principles of the HART Act 2004 (s.4(a)) is that the well-being of children born as a result of ART should be an important consideration in all decisions about that procedure. However, there is little mention of this principle in the consultation document.

Question 10: Comments or suggestions

- If ACART develops regulations or guidelines, the Committee should consult Child, Youth and Family, the Children's Commissioner, and the Ministry of Social Development. These agencies will have a particular insight into the impact of ARTs, including the expanding definitions of family.

- Informed consent is based on a patient's knowledge and understanding. It is likely that improvements in effective consent will largely come from finding better ways of educating patients, not from regulations about consent forms or the consenting process itself. The current level of regulation is suitable, for the reason that regulations can restrict unusual cases, and cannot anticipate all cases.
- The Code does not specifically address when consent by donors should take place. Full disclosure about how gametes will be used, stored, what will happen to them after treatment is complete, and storage, preservation and use of any embryos created, and related consent should occur at the initial donation of gametes. However, consent is a process over time, and as noted in the consultation document includes any right to refuse consent, and also the right to change one's mind by withdrawing or varying consent. This principle therefore supports the conclusion that gamete donors should be given the opportunity to be consulted again when their gametes are to be used in the future as noted in the discussion document. For this reason, the next step could be to develop guidelines or standards that outline how the Code specifically relates to ART. Any standards set by ACART in relation to informed consent and ART would effectively be imported into the Code which is itself a regulation.

Issue noted that is separate from the specific consultation:

- Many submitters noted their discomfort with terminology in the HART Act referring to "disposal" of embryos. Submitters asked that this terminology be changed, because the language is associated with disposal of rubbish, unwanted objects and suchlike. The wording does not reflect respect for living human beings.