



**Advisory Committee on
Assisted Reproductive Technology**

**Informed Consent and Assisted
Reproductive Technology**

Proposed advice
to the Minister of Health

Consultation Document

Citation: Advisory Committee on Assisted Reproductive Technology. 2015. *Informed Consent and Assisted Reproductive Technology: Proposed advice to the Minister of Health*. Wellington: Advisory Committee on Assisted Reproductive Technology.

Published in July 2015 by the Advisory Committee on Assisted Reproductive Technology,
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-478-44833-7 (online)

ISBN 978-0-478-44844-3 (print)

HP 6209

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





Foreword

The Advisory Committee on Assisted Reproductive Technology (ACART) has prepared this consultation document to present the Committee's proposed advice to the Minister of Health on requirements for informed consent for human assisted reproductive technology.

One of the principles of the Human Assisted Reproductive Technology Act 2004 is that individuals should make informed choices and give informed consent. In the context of assisted reproductive technology (ART), informed consent and decision-making can be complex. ART procedures always require informed consent by at least two parties, even where donated gametes are not used. Often procedures involve consent by multiple parties – for instance, embryo donation may involve two donors and two recipients. The interests of children who may be born from the use of gametes and embryos must also be taken into consideration. Questions arise as to who may consent, who may withdraw or vary consent to ART procedures, how to balance those interests and what should be the timeframe within which parties to the procedure have a say.

As part of ACART's work to develop proposed advice, we undertook a small project aimed at understanding the policies and processes used by fertility services providers in respect of informed consent. Providers were generous in sharing information and perspectives, and we are grateful for their contribution to the project.

There is a well-established body of law and practice concerning informed consent. Most of ACART's proposed recommendations in this document are concerned with confirming current practice rather than proposing substantial change in the ART regulatory framework. We welcome feedback on our proposed advice. Thank you in advance for contributing to this important area.



Alison Douglass

Chair, Advisory Committee on Assisted Reproductive Technology



How to have your say

Please take this opportunity to have your say. A feedback form is at the back of this document.

You may give feedback on your own behalf or as a member of an organisation. You can contribute your views either by:

- emailing a completed feedback form or your comments to acart@moh.govt.nz, or
- posting a completed feedback form or your comments to:
Secretariat
Advisory Committee on Assisted Reproductive Technology
PO Box 5013
Wellington.

We will place all feedback on ACART's website as it is received, and therefore prefer that feedback is submitted electronically if possible. However, we will accept and consider all feedback regardless of how we receive it.

Where you give feedback on your own behalf, we will remove your contact details before placing the feedback on ACART's website. Alternatively, you may request that all or part of your feedback is withheld from publication for reasons of confidentiality.

The closing date for feedback is 4 September 2015.

After receiving and considering feedback, we will finalise our advice to the Minister of Health on the requirement for informed consent. We anticipate forwarding our finalised advice to the Minister in late 2015.

You can obtain additional copies of this paper and feedback form from the ACART website (www.acart.health.govt.nz). If you require a hard copy, please contact the ACART Secretariat (email acart@moh.govt.nz or telephone 04 816 4387).

Sources for additional information relating to assisted reproduction and human reproductive research in New Zealand include:

- www.acart.health.govt.nz (ACART agendas and minutes, guidelines, archives of earlier consultations, annual reports, other publications)
- www.ecart.health.govt.nz (Ethics Committee on Assisted Reproductive Technology agendas and minutes)
- www.legislation.govt.nz (New Zealand Acts and Regulations)



Contents

Foreword	iii
How to have your say	v
Executive summary	ix
1 Introduction	1
1.1 Purpose.....	1
1.2 Scope of ACART’s proposed advice on informed consent.....	1
1.3 Process followed by ACART in preparing this advice	2
1.4 Outcomes of consultation on informed consent	3
2 Background	4
2.1 What is informed consent?	4
2.2 What are the current requirements for informed consent?	7
3 ACART’S proposed advice	9
3.1 Summary.....	9
Glossary	29
Appendices	
Appendix 1: Members of ACART	30
Appendix 2: Section 46 of the Human Assisted Reproductive Technology Act 2004	31
Appendix 3: The Code of Health and Disability Services Consumers’ Rights.....	32
Appendix 4: Extracts from the Fertility Services Standard and the Fertility Services Audit Workbook.....	39
Feedback form	41
Questions for response	43

Executive summary

The Human Assisted Reproductive Technology Act 2004 (the HART Act) requires the Advisory Committee on Assisted Reproductive Technology (ACART) to advise the Minister of Health about the requirements for informed consent relating to human assisted reproductive technology.

This consultation document invites public comment on ACART's proposed advice to the Minister of Health on the requirements for informed consent in the context of assisted reproductive technology.

Informed consent is a decision-making process in which people make choices based on sufficient information about what is being agreed and on the implications of the decision. The information also needs to be provided in a form that can be understood by the person giving consent.

In a medical context, individuals generally make autonomous decisions about procedures carried out on them. By contrast, informed consent in the context of assisted reproductive technology may involve a number of parties, and questions arise about the relative weight to be given to individual views.

The proposals in this consultation document form a package intended to clarify informed consent requirements in relation to assisted reproductive procedures at the point of initial consent and at later stages of the donation process.

Our proposals are not based on a concern that there are significant operational problems in relation to informed consent, but rather on a concern that the requirements should be clear and transparent. Some aspects of informed consent are not currently addressed in the regulatory framework or lack specificity. ACART considers that clear requirements will provide transparency for all parties and minimise the risk of misunderstandings.

We recognise that some of our proposals reflect current practice. We have sought information from providers about their processes for giving information and obtaining consent, and found these to be working well. However, we conclude that there may be a need for an explicit set of requirements around informed consent to be codified in regulations.

While the HART Act does not provide detailed requirements for informed consent, it provides for regulations to be made. Our proposed advice is intended to help clarify policy and provide a legislative platform to support practice guidelines and processes around informed consent.

In summary, ACART makes the following proposals for advice to the Minister of Health.

Initial consent process

- (a) There should be better access to the information that must be disclosed to patients and donors prior to consent.
- (b) Consent to all assisted reproductive processes, where consent is required, must be in writing.
- (c) The consent of donors should be obtained if their gametes, or embryos created from their gametes, may be used for training purposes.¹

Ongoing involvement of gamete donor

- (a) Gamete donors should continue to be able to place conditions on their consent.
- (b) Gamete donors should be given the option of receiving ongoing information on the use of their gametes.
- (c) Gamete donors should be able to withdraw or vary consent to the use of their gametes up to the point of fertilisation.

Partner, family and whānau rights and interests

- (a) The consent of a partner, family or whānau to the donation or use of a donor's gametes should not be required.
- (b) Where one party of a couple disputes the future use of embryos that have been created for them, there should be a 'cooling-off' period of 12 months.

Regulations

- (a) Requirements for informed consent should be set out in regulations, where appropriate.

The closing date for responses to the consultation document is 4 September 2015. ACART will then finalise its advice to the Minister for submission in late 2015.

¹ While training is outside the scope of the HART Act, we consider that it should be addressed in the context of informed consent.



1 Introduction

1.1 Purpose

1. This consultation document invites public comment on the proposed advice from the Advisory Committee on Assisted Reproductive Technology (ACART) to the Minister of Health (the Minister) on the requirements for informed consent relating to human assisted reproductive technology.

1.2 Scope of ACART's proposed advice on informed consent

1.2.1 *In scope*

2. Section 38(d) of the Human Assisted Reproductive Technology Act 2004 (HART Act) requires ACART to provide the Minister with information, advice and, if it thinks fit, recommendations about the requirements for informed consent in respect of **human assisted reproductive technology**.
3. ACART's proposals focus on informed consent in respect of human assisted reproductive technology.

1.2.2 *Out of scope*

4. Section 37(1)(f) of the HART Act also requires ACART to provide specific advice to the Minister on the requirements for informed consent in respect of **human reproductive research**.
5. ACART has decided not to include advice on informed consent requirements in respect of human reproductive research. We consider that this should be undertaken as part of any future work to revise the current guidelines on human reproductive research.
6. The proposals do not address informed consent requirements relating to the use of gametes or embryos posthumously; the collection, storage and use of gametes from a deceased person; or the collection, storage and use of gametes from a comatose person. ACART plans to address these matters separately.

1.3 Process followed by ACART in preparing this advice

7. In 2013 ACART decided that it would be useful to gain a picture of how informed consent processes currently operate within clinics. A small project was subsequently undertaken in 2014 to describe the policies and processes used by fertility services providers in respect of informed consent. A report on the findings is published on ACART's website.²
8. We are extremely grateful to the three Auckland providers for the time taken to provide information on how the informed consent process operates within each organisation and for the valuable perspectives of staff members (including representatives of the various professional groups within the clinics).
9. In the course of ACART's earlier work and the 2014 project, the following general questions emerged to frame consideration of consent issues.
 - What information should be given to consumers and donors to inform their decisions?
 - Who should be asked to give consent, or be involved in the decision in some way?
 - When can a person amend or withdraw consent to using their gametes or embryos created from their gametes?
 - What should happen when one person in a couple changes their mind about using an embryo?
 - How should requirements for informed consent be set out?
10. When considering these matters, we consulted ACART's **Ethical Framework**, which incorporates the principles of the HART Act and generally accepted ethical principles. The Framework considers the welfare of those affected by the procedure and the autonomy of those involved; as well as altruism, social trust and responsibility, the special status of the embryo, justice and equality.³
11. We also took account of relevant public policy and the **Code of Health and Disability Services Consumers' Rights** ('the Code'). Further, we compared the approach to informed consent in this country with requirements in the United Kingdom and some Australian states, as jurisdictions based on similar principles to those that apply in New Zealand.

² ACART. 2014. *Informed consent sub-project: Clinic policies, rules and processes*.

³ For a copy of ACART's *Ethical Framework*, go to the ACART website: www.acart.health.govt.nz

1.4 Outcomes of consultation on informed consent

12. Following the current consultation, ACART will finalise its proposals concerning informed consent in respect of human assisted reproductive technology, and submit its advice to the Minister.
13. The Minister will decide whether to accept any or all of ACART's advice. If his decision is that regulations should be made (as provided by s 76 (1)(ii) of the HART Act), the Ministry of Health will develop the regulations. ACART guidelines would be amended if required, so they are consistent with any decisions made.



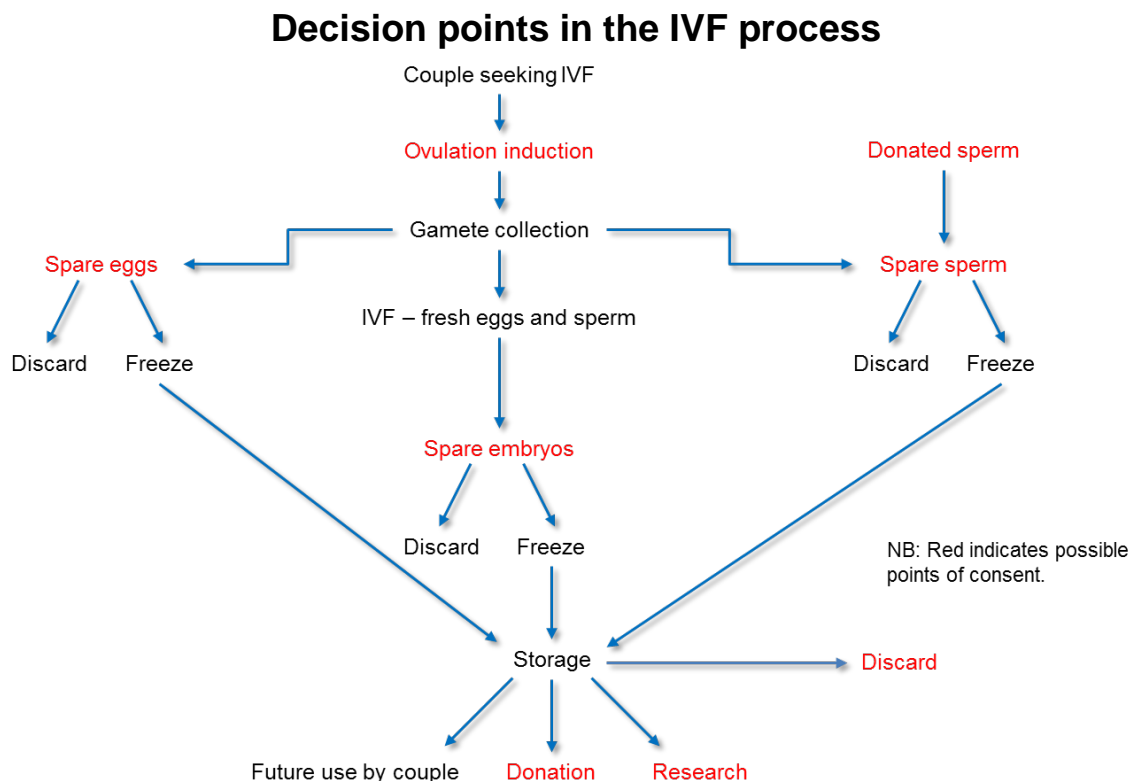
2 Background

2.1 What is informed consent?

14. 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 in nature, 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.
15. 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.
16. Informed consent as it relates to assisted reproduction is more complicated, as the decisions of one person can affect other people (including intending parents, donors, other family members, and any future recipient of donated gametes).
17. Assisted reproduction gives rise to the situation where an individual may be a biological parent, but not a legal parent with the responsibilities of parenthood. Gamete donors give their gametes to assist another person or couple to have a child, in the knowledge that donors do not have any parental rights or responsibilities.
18. A key issue is the weight that should be given to the interests of donors, versus the interests of intending parents, in situations where an embryo has been created from donated gametes and one of the parties changes their mind. This is distinguished from a surrogacy situation, where the surrogate is the legal parent of the resulting child at birth, even though she intends to relinquish the child to the intending parents. At the same time, we maintain that all interests need to be recognised and protected.

2.1.1 Challenges related to informed consent in the context of assisted reproduction

19. The following are some of the factors that need to be considered in developing policy on informed consent in the context of assisted reproduction.
- A decision by one person to vary or withdraw consent may have a significant impact on another person.
 - Informed consent does not just relate to a one-off medical procedure – it is also about processes such as the storage of gametes (sperm and eggs), the storage of 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.
 - People from whom consent is required may be difficult to find.
 - There is potential for uncertainty or disputes if a person dies or if a relationship ends.
20. Informed consent is ongoing throughout the *in vitro* fertilisation (IVF) process, which contains a continuum of decision points, as outlined below.



2.1.2 *Cultural dimension*

21. Views on what is involved in making informed decisions have a cultural dimension. In New Zealand, we need to recognise the perspectives of Māori as tangata whenua and consider how their perspectives can be incorporated into the structures and processes relating to informed consent.
22. 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 ACART supports the idea that a pan-Māori perspective exists. There is rarely one single viewpoint representative of Māori concerns, any more than there is a single religious viewpoint.
23. ACART supports the approach taken in Principle 4(g) of the HART Act to different ethical, spiritual and cultural perspectives in society generally. This principle requires that these perspectives should also be considered and treated with respect in the context of assisted reproduction.

2.1.3 *Disability perspective*

24. The informed consent process can present unique challenges for people with disabilities.
25. ACART acknowledges the efforts made by fertility services providers to provide information in an accessible form appropriate to the needs of disabled consumers.
26. 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 Fertility Services Standard (1.1.2).
27. The Human Rights Act 1993 prohibits discrimination against individuals on the basis of disability. In addition, the United Nations Convention on the Rights of People with Disabilities (Article 9), 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. Failure to provide information in accessible formats to people with disabilities may therefore be seen as a form of discrimination.

2.2 What are the current requirements for informed consent?

28. New Zealand requirements relating to informed consent for human assisted reproductive technology are set out in:
- the HART Act
 - the Code of Health and Disability Services Consumers' Rights
 - Guidelines issued by ACART
 - the Fertility Services Standard.

2.2.1 *Human Assisted Reproductive Technology Act 2004*

29. The HART Act is the key law that regulates human assisted reproductive technology and human reproductive research in New Zealand.
30. Informed consent is addressed in section 4(d) of the HART Act, as one of the principles of the Act:
- All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function ... 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.
31. 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 of Health and Disability Services Consumers' Rights. 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 at this stage.

2.2.2 *Code of Health and Disability Services Consumers' Rights*

32. The Code of Health and Disability Services Consumers' Rights (the Code) is wide-ranging, extending 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.

⁴ HART Act s 76(1)(a)(i).

33. The Health and Disability Commissioner 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).
34. While the Code does not address all matters of informed consent in relation to assisted reproduction, any regulations or guidelines must be consistent with the Code. (A copy of the Code is attached as Appendix 3.)

2.2.3 Guidelines issued by ACART

35. All the current Guidelines issued by ACART make reference to the principle of informed choice and informed consent, which is set out in section 4(d) of the HART Act. Additional requirements may be included where ACART has decided that more detail is needed about how the principle should be applied to a particular procedure.

2.2.4 New Zealand Fertility Services Standard

36. Providers of fertility services in New Zealand must operate in accordance with the New Zealand Fertility Services Standard, which sets out requirements for the safety and quality of fertility services in New Zealand. Providers are audited and certified against the Standard.
37. Informed consent is addressed by the Fertility Services Standard in a number of places (see Appendix 4). Providers must ensure that consumers 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.

3 ACART'S proposed advice

3.1 Summary

38. Our proposed advice addresses informed consent requirements in the context of assisted reproduction.
39. The following discussion concerns issues around the information to be provided to donors and patients; and giving, varying and withdrawing consent. Key themes throughout the proposals are:
- the transparency of informed consent requirements
 - the accessibility of information provided to donors and patients.
40. The proposals we are seeking feedback on are summarised below.

Initial consent process

- (a) There should be better access to the information that must be disclosed to patients and donors prior to consent.
- (b) Consent to all assisted reproductive processes, where consent is required, must be in writing.
- (c) The consent of donors should be obtained if their gametes, or embryos created from their gametes, may be used for training purposes.⁵

Ongoing involvement of gamete donor

- (d) Gamete donors should continue to be able to place conditions on their consent.
- (e) Gamete donors should be given the option of receiving ongoing information on the use of their gametes.
- (f) Gamete donors should be able to withdraw or vary consent to the use of their gametes up to the point of fertilisation.

Partner, family and whānau rights and interests

- (g) The consent of a partner, family or whānau to the donation or use of a donor's gametes should not be required.
- (h) Where one party of a couple disputes the future use of embryos that have been created for them, there should be a 'cooling-off' period of 12 months.

⁵ While training is outside the scope of the HART Act, we consider that it should be addressed in the context of informed consent.

Regulations

- (i) Requirements for informed consent should be set out in regulations, where appropriate.

41. In the following sections we discuss each proposal in turn, noting:

- the issue
- ethical and policy arguments
- ACART's conclusion and reasoning.

(a) *There should be better access to the information that must be disclosed to patients and donors prior to consent*

Issue

42. Access to information is a prerequisite for informed consent. Unless sufficient information is disclosed to the donor or recipient of an assisted reproductive procedure, the consent will not be 'informed'.
43. The Fertility Services Standard ('the Standard') sets out detailed requirements on the information to be disclosed to patients and donors. Service providers are audited against the requirements in the Standard and the associated audit handbook.
44. The Standard is not freely available, however: it must be purchased or sighted at a fertility service provider's premises. This creates an obstacle for donors, patients and anyone with an interest in the information who may wish to access it.

Public policy

45. The disclosure of information prior to consent is addressed in legislation by the HART Act 2004 and by the Code of Health and Disability Services Consumers' Rights Regulation 1996 (see Appendix 3).⁶ These requirements are reflected in the Fertility Services Standard.
46. Section 46 of the HART Act sets out the information that must be provided to prospective donors and prospective parents using donated gametes before they can give consent for any service involving a donated embryo or donated gamete (see Appendix 2).
47. The rights of consumers of health and disability services are set out in the Code. Of particular relevance to this document are the right to effective communication, the right to be fully informed, and the right to make an informed choice and give informed consent (Rights 5, 6 and 7).

⁶ The Code is a regulation under the Health and Disability Commissioner Act 1996.

Ethical and policy arguments

48. Our investigations suggest that existing arrangements for providing information to consumers prior to consent to an assisted reproductive procedure are working well.⁷
49. The principle of transparency would appear to demand that anyone should be able to readily access, or receive on request, the information set out in the Standard.

ACART's conclusion and reasoning

50. We consider that, while it is not a provider compliance issue, access to the information that must be disclosed to patients and donors is a transparency issue and a legal right.
51. ACART's view is that there needs to be easier access to the information that is required to be provided to donors and patients. Consultation may be required with Standards New Zealand about how the Fertility Services Standard could be made more accessible to consumers.

Question 1

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

- (b) *Consent to all assisted reproductive processes, where consent is required, must be in writing*

Issue

52. There is no clear requirement for consent to assisted reproductive processes to be in writing.

Public policy

53. The Fertility Services Standard requires that consumer consent be obtained in line with the requirements of the Code and the principles of the HART Act.⁸
54. Right 6 of the Code requires informed consent to a health care procedure to be in writing in certain situations; for example, where there is a significant risk of adverse effects on the consumer. Reproductive procedures could be considered to fall into

⁷ ACART. 2014. *Informed consent sub-project: Clinic policies, rules and processes*.

⁸ Section 1.7 of the Standard.

this category. However, the right to informed consent is subject to the common law⁹ and there may be instances where it is accepted that written consent is not necessary.

55. The HART Act is silent on whether consent should be in writing.

Ethical and policy arguments

56. The Fertility Services Standard requires service providers to have consent forms appropriate to the procedures performed by the service.¹⁰ The requirement to have consent forms may be seen as implying that consent should be in writing.
57. Clinic practice is to obtain consent in writing. This is a good practice standard.
58. While it is not necessarily a legal requirement, written (signed) consent avoids uncertainty in the event of a dispute about what was consented to. The keeping of written records is also good business practice.
59. A clear requirement for written consent may give peace of mind to recipients who are feeling anxious about the outcome of an assisted reproductive procedure. 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

60. Other jurisdictions require written consent for various procedures. For example, Canada requires written donor consent for the use of human reproductive material for the purpose of creating an embryo.
61. The United Kingdom requires consent to be in writing, and signed by the person giving it.¹¹ Provision is also made in the event that a person is unable to sign owing to illness, injury or disability.

ACART's conclusion and reasoning

62. ACART affirms the current approach taken by providers to obtain written consent to reproductive procedures.
63. We propose that all decisions involving consent to assisted reproduction procedures (including initial consent, the setting of conditions and variation/withdrawal of consent) should be recorded in writing and signed by the relevant parties.

⁹ Right 7(1) of the Code.

¹⁰ Section 1.7.1 of the Standard.

¹¹ Human Fertilisation and Embryology Act 1990 (as amended).

64. ACART acknowledges that there are legal complexities around the requirement for consent to be provided in writing. The Fertility Services Standard may need to be amended to include a requirement for all relevant parties to provide consent to reproductive procedures in writing (with provision for those unable to sign).

Question 2

- (a) Do you agree that consent to all assisted reproductive processes, where consent is required, must be in writing?
- (b) Do you have any other comments?

- (c) *The consent of donors should be obtained if their gametes, or embryos created from their gametes, may be used for training purposes*

Issue

65. There is no formal requirement for donor consent to be obtained for the use of donor gametes, or embryos created from their gametes, in the training of embryologists and clinicians.
66. The use of gametes or embryos for training purposes is not specifically mentioned in the HART Act.¹²
67. However, IVF consent forms used by clinics offer the donor the option of consent to the use of eggs and embryos for training purposes when they are not suitable for use or freezing; and options for their disposal.

Ethical and policy arguments

Transparency

68. The issue of donor consent to the use of gametes or embryos for training purposes falls under Right 6 of the Code of Health and Disability Services Consumers' Rights (the Right to be Fully Informed).
69. The Health and Disability Commissioner (HDC) has suggested that donors have a right to know all the ways in which their gametes or embryos created from their gametes may be used.¹³ This should include the possibility they may be used for training purposes.

¹² The HART Act contains requirements for the use of gametes and embryos for research purposes. This is outside the scope of the consultation on informed consent and will be addressed separately.

¹³ HDC. 2013. *Submission to ACART Discussion Paper: Import and Export of Gametes and Embryos*.

70. The HART Act does not specifically provide for the use of gametes and embryos in the training of embryologists and clinicians. However, it is an activity that directly relates to a purpose of the HART Act – that is, to secure the benefits of assisted human reproduction and human reproductive research.

Other jurisdictions

71. The United Kingdom has specific requirements regarding donor consent to the use of embryos created with their gametes for training people in embryo biopsy, embryo storage or other embryological techniques.
72. Victoria (Australia) requires that donor consent must specify the kinds of treatment procedures for which eggs, sperm or embryo may be used.¹⁴
73. Canada's Informed Consent Regulations (under the Assisted Human Reproduction Act 2004) require that donor consent be obtained if embryos created from donated gametes are used to provide instruction in assisted reproduction procedures.

ACART's conclusion and reasoning

74. We consider that it is important for consumers and fertility service providers to have a shared understanding about the use for training purposes of a donor's gametes or embryos created from their gametes.
75. Although the use and disposal of the donor's gametes, and embryos created from their gametes, for training purposes is not covered by the HART Act, it is related to a purpose of the Act. It would be appropriate to address the issue in the process of obtaining consent to donation.
76. ACART is of the opinion that, while existing consent forms offer donors the choice of giving or withholding consent to the potential use and options for the disposal of their gametes and embryos for training purposes, it would be desirable for the consent requirement to be regulated.

Question 3

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

¹⁴ Assisted Reproductive Act 2008 s 17(1)(c), Victoria, Australia.

(d) *Gamete donors should continue to be able to place conditions on their consent*

Issue

77. In New Zealand, gamete donors (whether or not they are known to the recipients) may place conditions on the use of their gametes prior to giving consent to donation.
78. In practice, a donor could place conditions on their consent. For example, they might:
- specify who may use their gametes (eg, married couples, single women, same sex couples)
 - set a time limit on the use of their gametes
 - apply a restriction on the number of families who are able to use their gametes.
79. The following discussion raises questions about whether gamete donors should be able to place conditions on their consent and whether there should be any restriction on the type of conditions that they may place.

Public policy

80. The HART Act does not take a position one way or another on this matter.
81. The Fertility Services Standard currently requires providers to inform donors of the option of placing boundaries on the use of their gametes.¹⁵
82. The HART Act¹⁶ does prohibit the performance of any reproductive procedure that aims to influence whether an embryo will be of a particular sex. This provision would exclude sex selection, at least, from being placed as a condition of consent.

Ethical and policy arguments

Altruism

83. We recognise that there are different views about the nature of the gift relationship established by donation or the act of giving. There is an argument that a gift should be unconditional – that is, made without constraining how it may be used. It might equally be argued that a gift does not create an obligation and the donor should be free to place conditions on it.
84. In reality, the donor's consent may be dependent on whether certain conditions will be met. For example, sperm donors may have ethical objections to the creation and potential disposal of *in vitro* embryos, and request that the sperm be used only for donor insemination.

¹⁵ Section 1.11.1 of the Standard.

¹⁶ Section 11(1)(b).

85. There may be a concern that in setting conditions, donors could discriminate against certain groups of people and limit the chances of using donated gametes for people in that group. For example, a number of donors might exclude recipients with a particular characteristic in common, such as gay couples.
86. It can be argued that donors have a valid interest in the outcomes of the donation as gamete donation has long-term consequences, and creates biological relationships.
87. Even so, donors do not have the power to limit the decisions of prospective parents after an embryo created from donated gametes has been fertilised, or after a donated embryo has been transferred to a uterus.

Public policy

88. Private gamete donors are able to make the choice to donate to a specific individual or couple. 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 how their gametes will be used.
89. Embryo donors also have choices about who receives their donated embryos. ACART's *Guidelines on Embryo Donation for Reproductive Purposes* require that the profiles of potential recipients offered to the embryo donor include any police vetting information, and donors and recipients must meet in joint counselling before an application is made to the Ethics Committee on Assisted Reproductive Technology (ECART).
90. Under the Adoption Act 1955, birth mothers are able to set limited conditions about who can adopt their child. Over the last 60 years, adoption practice has shifted towards open adoptions, in which a birth mother has a much greater say about who adopts her child than is set out in the legislation.
91. People are able to choose who receives one of their organs (eg, a kidney or part of a liver) in a live organ donation. In contrast, people are unable to set conditions as to who may use their donated organs if they die.

Other jurisdictions

92. The United Kingdom allows gamete donors to place conditions on their consent. The consent forms allow for conditions to be placed on the number of families using the donation, for the donor to stipulate that a named individual may use the gametes, and for the opportunity for the donor to place other restrictions on use of their gametes.
93. The options for donors in Victoria (Australia) are more limited. 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.

ACART's conclusion and reasoning

94. Our view is that donors should continue to exercise their autonomy to make choices about how their donated gametes are used and who can use them.
95. Gamete and embryo donations are different from blood or organ donations, in that they create relationships and are likely to have long-term consequences. Accordingly, donors may have a strong interest in ensuring the best possible outcome for any resulting children.
96. We do not propose that there should be any specified limits on the types of conditions a gamete donor may place on their consent, except that any conditions should be within what is currently permitted by law or current guidelines. For example, a donor could not require that their gametes may be used by more families than is allowed in the guidelines and advice issued to ECART.

Question 4

- (a) Do you agree that donors should continue to be able to set conditions on their consent?
- (b) If so, should there be any limits on the conditions placed?
- (c) Do you have any other comments?

- (e) *Gamete donors should be given the option of receiving ongoing information on the use of their gametes*

(Note: The information that must be provided to prospective donors **prior** to consent is addressed in Proposal a.)

Issue

97. This proposal raises a question as to whether donors should have the right to receive information at various points of the donation process **after** consent has been given (eg, when donated gametes or embryos are offered to intending parents; when a gamete is used for *in vitro* fertilisation or for donor insemination; when fertilisation has taken place; when an embryo is transferred to a patient's uterus; or when a child is born) (see the diagram under paragraph 20).
98. Currently there is no provision in the HART Act, the Standard or ACART Guidelines that allows for information on the use of donors' gametes, or embryos created from their gametes, to be passed on to donors after consent.
99. Clinics have told ACART that they do not inform gamete donors when the gametes are to be used, either to create embryos or to transfer embryos to patients.

Ethical and policy arguments

100. Providing information to donors about the progress of their gametes could increase the chances of donors changing their mind about use of their gametes. It could also provide an opportunity for donors to vary any conditions. (Note: This proposal is about the donor's right to receive information. The 'point of no return' for donors to change their mind is discussed under Proposal f.)
101. Since donors are advised that they may withdraw or vary the terms of their consent at any time up to the point of use, it could be argued that they should be notified at key points of the process before their gametes are used so they have an opportunity to do so.
102. We acknowledge that as it is not current practice (with exceptions) to provide ongoing information to a gamete donor, introducing this requirement may place an administrative burden on clinics.
103. Donors might be difficult to track down if their contact details become out of date, especially if the gametes are in storage for a long period. However, donors who have indicated that they wish to receive ongoing information could be required to take responsibility for informing the clinic if there is a change in their contact details.
104. The Health and Disability Commissioner¹⁷ has expressed the opinion that, consistent with the Code, gamete donors should have the option of making an informed decisions at multiple points of the process (ie, how their gametes will be used and stored, what will happen to them after treatment is completed – including in relation to the export of gametes – and any future use of the gametes).

ACART's conclusion and reasoning

105. ACART appreciates that introducing a new requirement for clinics to provide information to donors may create some additional work, but suggests this would be minimised if donors were made responsible for updating their contact details. In reality, few donors withdraw consent, and we would expect that only those with a particular interest in receiving ongoing information would choose to be kept informed.
106. On balance, ACART considers that the principles of transparency and fairness require donors to be offered the choice of receiving some information after consent about the use of their gametes.
107. Accordingly, we propose that a condition be attached to the consent process to allow gamete donors to choose to receive (or opt out of) the ongoing disclosure of information (i) if the gamete is about to be used or (ii) on the outcome/s of the donation.

¹⁷ HDC. 2013. Submission to *ACART Discussion Paper: Import and Export of Gametes and Embryos*.

Question 5

- (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?
 - (ii) on the outcome(s) of the donation?
- (b) Is there any other information that you think should be offered to gamete donors after consent has been given?

(f) *Gamete donors should be able to withdraw or vary consent to the use of their gametes up to the point of fertilisation*

Issue

108. The question here is: at what point should a gamete donor no longer be able to withdraw or vary consent?
109. Consent may extend over many years while gametes or embryos are stored, and donors may wish to revoke it in response to changing circumstances or changing views over time.
110. The Fertility Services Standard¹⁸ 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’.
111. However, gametes and embryos may be used at different stages of an assisted reproductive procedure. Also, the point at which consent may be withdrawn or varied is different for embryo donors and gamete donors. It is generally accepted that the ‘point of no return’ for gamete donor consent is fertilisation – that is, when sperm meets egg (or insemination as part of an assisted reproduction procedure).¹⁹
112. The underlying principle is that the donor cannot withdraw consent once an embryo exists. Once an embryo has been created, a gamete (or embryo) donor can still withdraw consent to the use of any gametes (or embryos) that remain in storage.
113. The HART Act does not address issues around the variation or withdrawal of consent.

¹⁸ Section 1.11.1(k).

¹⁹ For embryo donors, the point is when an embryo is transferred into a uterus.

Ethical and policy arguments

114. At the heart of the issue are the donor's autonomy and the question of whose interests should prevail – the interests of the donor or a known or unknown recipient.
115. While a gamete is being stored for future use, and up until the time a new entity has been created, the donor's autonomy and right to withdraw consent are stronger than any potential harm done by not proceeding with the donation, or by varying the conditions.
116. The 'point of no return' (where consent can no longer be withdrawn or varied) is a well-established concept in donation.²⁰ It is also a tool for managing relationships and expectations between donors and recipients.

ACART's conclusion and reasoning

117. Our view is that gamete donors should be able to withdraw or vary consent up to the point that an embryo is created from a donor's gametes (that is, fertilisation) or at the point of insemination as part of an assisted reproductive procedure.
118. Any conditions on the use of the donor's gametes that have not been withdrawn, should continue to be honoured. The donor should continue to be unable to impose conditions on the intended parents of the embryo created from the donor's gametes.
119. ACART proposes that provision for the withdrawal and variation of consent, and a definition of the 'point of no return' are needed to provide certainty and consistency in decision-making. We note that amendments to the Standard would be required.

Question 6

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

²⁰ As noted in ACART's sub-project on informed consent.

(g) The consent of a partner, family or whānau to the donation or use of a donor's gametes should not be required

(Note: Partner consent to the use of an embryo created for a couple's own use is considered in Proposal h.)

Issue

120. This proposal raises a question about the involvement of a gamete donor's partner, family or whānau in the donation process. Should a donor be required to obtain the consent of their partner, family or whānau if they wish to donate their own gametes?

Public policy

121. The Fertility Services Standard requires that consent for donation be obtained from the donor's partner if they are married, in a civil union or in a de facto relationship.²¹ This is standard practice in fertility clinics.

122. There is no requirement in the HART Act for a gamete donor to obtain consent to the donation of their gametes from their partner, family or whānau.

123. It is a principle of the HART Act that the needs, values and beliefs of Māori are to be considered and treated with respect.²² These principles are reflected in practice guidelines. For example, ECART must take into account whether the donor's family or whānau have been involved in counselling when it assesses applications for assisted reproductive procedures.

124. The Standard requires that consumers receive services in a manner that recognises their cultural and individual values and beliefs.²³ Consequently, organisations are required to ensure that service providers identify and respond sensitively to the belief and value systems of consumers during service delivery.

125. More broadly, the HART Act requires the different ethical, spiritual and cultural perspectives in society to be considered and treated with respect.²⁴ This principle acknowledges the considerable diversity of opinion that exists in relation to assisted reproduction. In a diverse society like New Zealand, moral pluralism needs to be acknowledged.

²¹ Section 1.10.3 of the Standard.

²² Section 4(l).

²³ Section 1.3.1 of the Standard.

²⁴ Section 4(m).

Ethical and policy arguments

Family relationships

126. It can be argued that it is important to obtain partner consent as reproductive decisions are made in the context of family relationships. This is because any current, ongoing or future relationships between a donor, recipients and any resulting children may affect the donor's partner and any existing or future children of their relationship.

Autonomy

127. However, situations may arise in which a partner could have more influence over the use of a donor's gametes than the donor themselves. For example, if the consent of partners is required, a partner may give consent to the donation but then withdraw their consent so the process cannot go ahead.

128. 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

129. There is no international consensus on whether a gamete donor's partner should be required to consent. In the United Kingdom, although partner consent is not required if the donor is married, in a civil partnership or in a long-term relationship, the involvement of partners is encouraged.²⁵

ACART's conclusion and reasoning

130. ACART concludes that the consent of a partner, family or whānau should not be a requirement for gamete donation.

131. While it will always be good practice to involve a partner in decision-making, we consider that individuals should have autonomy over their own gametes. Our position on this matter is that fertility service providers should recommend to donors that their partners be involved in the counselling process, but the involvement should not be mandatory.

132. Valuing a person's autonomy does not necessarily equate to unqualified individualism. This is particularly relevant in light of the differing emphases given to individualism versus communitarian values, especially for Māori.

²⁵ Human Fertilisation and Embryology Authority Code of Practice, section 5.20.

133. ACART is of the view that, while an individual's right to autonomous decision-making should be highly valued, it may at times need to be balanced against the potential for harm to other individuals or society at large.

Question 7

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

- (h) *Where one party of a couple disputes the future use of embryos that have been created for them, there should be a 'cooling-off' period of 12 months*

(Note: The requirement for partner consent to **gamete** donation is discussed in Proposal g.)

Issue

134. As noted previously, consent to the use of embryos for assisted reproductive purposes can remain valid over a period of years. If a relationship breaks down, there may be a dispute about the future of embryos a couple have created for their own use. One party may wish to use the embryos while the other may prefer to dispose of them.
135. The question is whether one party should be able to withdraw consent at a point in the IVF process after the embryo has been created, but before it has been transferred to the recipient. Does one partner have the right to use the embryo they both consented to create, if one of them has changed their mind or the relationship has broken down?
136. This issue was traversed in a court case in the United Kingdom. Natalie Evans and Howard Johnston had created and stored embryos in 2001, before Evans underwent surgery to remove her ovaries as part of her cancer treatment. The relationship ended six months later 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.
137. Evans challenged the clinic's decision in the United Kingdom courts. She was joined by another woman, Lorraine Hadley, who was divorced from her husband but wished to use two of their stored embryos to become pregnant. The High Court ruled against the women, stating that the embryos must be destroyed when the appeal process had concluded.

138. Evans then proceeded to appeal the decision. When her application was dismissed, she appealed to the European Court of Human Rights, which delivered a majority ruling that her right to a family life could not overrule Johnston's withdrawal of consent. 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. The Grand Chamber of the European Court of Appeals also ruled against Evans' appeal under three articles of the European Convention of Human Rights.

Ethical and policy arguments

Interests of one party in becoming a parent

139. Weighing the ethical positions and the factors involved in a dispute over an embryo a couple have created for their own use is a complex exercise. Consider whose interests should prevail where an embryo has been created. Should it be the interests of a person who has changed their mind about becoming a biological parent? Or should it be the interests of a recipient woman (who may have a new partner), who will become the legal parent of a resulting child, and assume all the legal and moral responsibilities of a parent?
140. It could be argued that if it were the woman's last opportunity to become a parent, and she was prepared to accept all legal responsibility for the child, her interests should override the interests of the man who has changed his mind. This argument might apply especially if the man has other opportunities to become a parent (such as with another partner).
141. It is a public policy principle that women have control over their own bodies. Ethically it would be unthinkable for the man to override the woman's interests by having an embryo created for the couple's use transferred into her uterus without her consent. It would also be outside the law, as under the HART Act no assisted reproductive procedure can be performed on an individual without their informed consent.
142. Similarly it would be ethically unacceptable for a man to override the interests of the woman with whom the embryo was created, and have it transferred into the uterus of another woman. This practice would be unacceptable even if it was the last opportunity for him to become a parent.
143. Would it make a difference if one party changed their mind but the couple were still living together? The reality is that both parties of the couple would be the legal parents of the child resulting from an embryo created for their use, and both would be required to assume the responsibilities of parenthood, whether the relationship continued or ended.

Source of the gametes

144. It could be argued that the source of the gametes – that is, which party’s genetic material was involved in creating the embryo – influences the ethical position.
145. Possible scenarios are:
- (a) the embryo is created from the woman’s egg and donated sperm
 - (b) the embryo is created from her partner’s sperm and a donated egg
 - (c) the embryo is created from donated sperm and a donated egg
 - (d) the embryo is created from the woman’s egg and her partner’s sperm.
146. Notably in the Evans case, even though she had a genetic connection with the embryo, the United Kingdom and European courts and courts of appeal ruled resoundingly against overriding Johnston’s right to withdraw consent.
147. 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.

ACART’s conclusion and reasoning

148. We maintain that in the situation where a couple intend to use embryos created for their use, one of the parties should be able to vary or withdraw consent to use of the embryo. Consistent with the accepted ‘point of no return’, this should only be possible up to the point that the embryo is transferred into the uterus of the female of the couple (or a surrogate).
149. A person should not be required to become a parent against their wishes if the embryo has not yet been transferred to a uterus.
150. At the same time, the withdrawal of consent needs to be balanced against the potential harms to the various parties caused by its withdrawal. It would not be in the interests of the parties (including siblings and potential offspring) for an irrevocable decision to be made without time for reflection.
151. In our view, the United Kingdom example of a ‘cooling-off’ period is a practical and fair way to manage cases where one party withdraws consent to ongoing storage and subsequent use. The cooling-off period would allow parties to explore options (through, for example, mediation or with support from clinic counsellors), with the goal of reaching a shared view. We propose that the cooling-off period should be for a maximum of 12 months. If at the end of the period the parties have not agreed, the embryos should be disposed of.
152. We note that section 76(a)(ii) of the HART Act makes provision for regulations to be made for the purpose of providing for the use or disposal of *in vitro* gametes or *in vitro* embryos. In particular, it makes this provision in cases where one party from whom the embryo has been formed withdraws their consent.

Question 8

- (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?
- (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?

- (i) *Requirements for informed consent should be set out in regulations, where appropriate*

Issue

- 153. 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.
- 154. ACART guidelines and advice issued to ECART include provisions relating to information and consent. However, the lack of a detailed regulatory framework for informed consent in regard to assisted human reproduction means that ACART has to consider specific informed consent provisions each time new guidelines are created.
- 155. The Code provides guidance on informed consent, but is based on a model of autonomous individuals making informed choices. It does not specifically address assisted reproduction, which is more complex as it involves more than one person and the creation of biological/genetic relationships.

Arguments

- 156. ACART's sub-project on the informed consent processes within clinics suggests that current processes are working well. Accordingly, it may be considered that a light approach to the issues discussed in this document would be appropriate, perhaps involving Ministry of Health guidance to clinics.
- 157. The Standard sets out detailed requirements about information to be provided to patients and donors. ACART Guidelines address information and consent for those procedures that require ECART approval.
- 158. However, as discussed in our other proposals, current provisions lack specificity in some areas and there is a risk of inconsistent practice. The Standard is not easily accessible because it must be purchased or sighted at a fertility services provider's premises.

159. The HART Act provides for regulations to be made to specify requirements for informed consent.²⁶
160. The Act also provides for regulations to be made to address the use or destruction of *in vitro* gametes or *in vitro* embryos where one party, from whom such a gamete or embryo has been obtained or formed, withdraws consent to any course of action.²⁷ (This provision relates to Proposal h.)

Other jurisdictions

161. Overseas jurisdictions based on similar principles to the HART Act contain more detailed informed consent requirements in their regulatory frameworks.
- In the United Kingdom, Schedule 3 of the Human Fertilisation and Embryology Act 1990 (Consent to use of gametes or embryos), the **Human Fertilisation and Embryology Authority Code of Practice**, incorporates legislation. The Human Fertilisation and Embryology Authority (HFEA) has also issued guidance about interpretation. Mandatory requirements for standard consent forms are issued by the HFEA.
 - In Victoria (Australia), the **Assisted Reproductive Treatment Act 2008** includes informed consent requirements (Division 4). The Assisted Reproductive Procedures Regulations 2009 include counselling requirements in regard to procedures, donation, surrogacy and posthumous use.
 - In New South Wales, the **Assisted Reproductive Technology Act 2007** includes provisions about giving, modifying and revoking consent.

ACART's conclusion and reasoning

162. ACART proposes that regulations be developed for informed consent in the context of assisted reproductive procedures.
163. We note that Parliament has provided for regulations to be made on a number of matters about which the HART Act lacks detail, including informed consent.
164. The development of regulations under the HART Act would provide a legislated framework that draws together informed consent provisions into one place to support practice guidelines.
165. ACART found no evidence of significant problems associated with the informed consent process in clinics. However, we point out that informed consent to reproductive procedures is a sensitive area raising complex ethical issues, including the rights of donors and recipients and the creation of relationships.

²⁶ Section 76(1)(a)(i).

²⁷ Section 76(1)(a)(ii).

166. The development of regulations would assist in avoiding disputes and uncertainty by providing an accessible set of requirements. Regulations would also support equity, consistency and transparency for consumers and fertility service providers.
167. If the Minister of Health decides that regulations should be developed, the Ministry of Health would be responsible for developing these.
168. ACART's Guidelines and the Fertility Services Standard would be amended where necessary to be consistent with any regulations made about informed consent.

Question 9

- (a) Do you agree that requirements for informed consent should be set out in regulations?
- (b) Do you have any other comments?

Question 10

- (a) Do you have any general comments or suggestions about the requirements for informed consent?
- (b) Do you have any other comments or suggestions about the issues discussed in this consultation document?

Glossary

ACART	Advisory Committee on Assisted Reproductive Technology
ART	Assisted reproductive technology
The Code	Code of Health and Disability Services Consumers' Rights
Donor	A person from whose cells a donated embryo is formed or from whose body a donated cell is derived
ECART	Ethics Committee on Assisted Reproductive Technology
Embryo	Includes a zygote and a cell or group of cells that has the capacity to develop into an individual; but does not include stem cells derived from an embryo
Fertility Services Standard ('the Standard')	A document issued by Standards New Zealand that sets out the requirements for the safety and quality of fertility services in New Zealand. Clinics are audited and certified against the Standard
Gamete	Defined in the HART Act as: <ul style="list-style-type: none">(a) an egg or a sperm, whether mature or not; or(b) any other cell (whether naturally occurring or artificially formed or modified) that –<ul style="list-style-type: none">(i) contains only one copy of all or most chromosomes; and(ii) is capable of being used for reproductive purposes.
HART Act	Human Assisted Reproductive Technology Act 2004
HDC	Health and Disability Commissioner
<i>In vitro</i>	Fertilisation outside a living organism
IVF	<i>In vitro</i> fertilisation
Prospective parent	A person who hopes to become a parent following fertility treatment
Service provider	An ART provider, clinic or sperm bank
The Standard	Fertility Services Standard



Appendix 1: Members of ACART

Alison Douglass (Chair)

Associate Professor Mike Legge (Deputy Chair)

Dr Karen Buckingham

Jonathan Darby

Nikki Horne

Dr Kathleen Logan

Sue McKenzie

Dr Barry Smith

Further information about the members and ACART can be found on ACART's website (www.acart.health.govt.nz).

Appendix 2: Section 46 of the Human Assisted Reproductive Technology Act 2004²⁸

Advice to prospective donors

46 Providers must give advice to prospective donors and prospective guardians

- (1) A provider must ensure that, before a person consents to donating a donated embryo or a donated cell to or through the provider, or to any service performed or arranged by the provider that involves a donated embryo or a donated cell, the person is told the things described in subsection (3).
- (2) Before a provider performs or arranges the performance of a service that may result in the birth of a donor offspring, the provider must ensure that each prospective guardian of the donor offspring is told the things described in subsection (3).
- (3) The things are as follows:
 - (a) which information about donors is obtained and kept by providers:
 - (b) how long the information is kept:
 - (c) why the information is obtained and kept:
 - (d) which part of the information is forwarded to, and kept indefinitely by, the Registrar-General:
 - (e) the rights given by this Act to donor offspring, the guardians of donor offspring, and other people to obtain information about donors:
 - (f) the rights given by this Act to donors and other people to obtain information about donor offspring:
 - (g) the importance of telling offspring about the nature of their conception:
 - (h) the availability of counselling.
- (4) To avoid any doubt, this section does not limit any right or duty set out in the [Health and Disability Commissioner \(Code of Health and Disability Services Consumers' Rights\) Regulations 1996](#).

²⁸ The full Act can be found at www.legislation.govt.nz

Appendix 3: The Code of Health and Disability Services Consumers' Rights²⁹

The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996

1. Consumers have Rights and Providers have Duties:

- 1) Every consumer has the rights in this Code.
- 2) Every provider is subject to the duties in this Code.
- 3) Every provider must take action to –
 - a) Inform consumers of their rights; and
 - b) Enable consumers to exercise their rights.

2. Rights of Consumers and Duties of Providers:

The rights of consumers and the duties of providers under this Code are as follows:

RIGHT 1

Right to be Treated with Respect

- 1) Every consumer has the right to be treated with respect.
- 2) Every consumer has the right to have his or her privacy respected.
- 3) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Maori.

RIGHT 2

Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

²⁹ Further information about the Code is available on the website of the Health and Disability Commissioner: www.hdc.org.nz

RIGHT 3
Right to Dignity and Independence

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

RIGHT 4
Right to Services of an Appropriate Standard

- 1) Every consumer has the right to have services provided with reasonable care and skill.
- 2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
- 3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
- 4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.
- 5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 5
Right to Effective Communication

- 1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.
- 2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

RIGHT 6
Right to be Fully Informed

- 1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –
 - a) An explanation of his or her condition; and
 - b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
 - c) Advice of the estimated time within which the services will be provided; and
 - d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
 - e) Any other information required by legal, professional, ethical, and other relevant standards; and

- f) The results of tests; and
 - g) The results of procedures.
- 2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.
 - 3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about –
 - a) The identity and qualifications of the provider; and
 - b) The recommendation of the provider; and
 - c) How to obtain an opinion from another provider; and
 - d) The results of research.
 - 4) Every consumer has the right to receive, on request, a written summary of information provided.

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

- 1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
- 2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
- 3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.
- 4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
 - a) It is in the best interests of the consumer; and
 - b) Reasonable steps have been taken to ascertain the views of the consumer; and
 - c) Either, –
 - i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
 - ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
- 5) Every consumer may use an advance directive in accordance with the common law.

- 6) Where informed consent to a health care procedure is required, it must be in writing if –
 - a) The consumer is to participate in any research; or
 - b) The procedure is experimental; or
 - c) The consumer will be under general anaesthetic; or
 - d) There is a significant risk of adverse effects on the consumer.
- 7) Every consumer has the right to refuse services and to withdraw consent to services.
- 8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.
- 9) Every consumer has the 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.
- 10) 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:
 - (a) With the informed consent of the consumer; or
 - (b) For the purposes of research that has received the approval of an ethics committee; or
 - (c) For the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:
 - (i) A professionally recognised quality assurance programme;
 - (ii) An external audit of services;
 - (iii) An external evaluation of services.

RIGHT 8
Right to Support

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

RIGHT 9
Rights in Respect of Teaching or Research

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

RIGHT 10
Right to Complain

- 1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.
- 2) Every consumer may make a complaint to –
 - a) The individual or individuals who provided the services complained of; and
 - b) Any person authorised to receive complaints about that provider; and
 - c) Any other appropriate person, including –
 - i. An independent advocate provided under the Health and Disability Commissioner Act 1994; and
 - ii. The Health and Disability Commissioner.
- 3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
- 4) Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.
- 5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
- 6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that –
 - a) The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
 - b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of –
 - i. Independent advocates provided under the Health and Disability Commissioner Act 1994; and
 - ii. The Health and Disability Commissioner; and
 - c) The consumer's complaint and the actions of the provider regarding that complaint are documented; and
 - d) The consumer receives all information held by the provider that is or may be relevant to the complaint.
- 7) Within 10 working days of giving written acknowledgement of a complaint, the provider must, –
 - a) Decide whether the provider –
 - i. Accepts that the complaint is justified; or
 - ii. Does not accept that the complaint is justified; or

- b) If it decides that more time is needed to investigate the complaint, –
 - i. Determine how much additional time is needed; and
 - ii. If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.
- 8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of –
 - a) The reasons for the decision; and
 - b) Any actions the provider proposes to take; and
 - c) Any appeal procedure the provider has in place.

3. Provider Compliance

A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.

The onus is on the provider to prove it took reasonable actions.

For the purposes of this clause, “the circumstances” means all the relevant circumstances, including the consumer’s clinical circumstances and the provider’s resource constraints.

4. Definitions

In this Code,

“**Advance directive**” means a written or oral directive –

- (a) **By which a consumer makes a choice about a possible future health care procedure; and**
- (b) That is intended to be effective only when he or she is not competent:

“**Choice**” means a decision –

- (a) To receive services:
- (b) To refuse services:
- (c) To withdraw consent to services:

“**Consumer**” means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer:

“**Discrimination**” means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993:

“**Duties**” includes duties and obligations corresponding to the rights in this Code:

“**Ethics committee**” means an ethics committee –

- (a) established by, or appointed under, an enactment; or
- (b) approved by the Director-General of Health.

“Exploitation” includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence:

“Optimise the quality of life” means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances:

“Privacy” means all matters of privacy in respect of the consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates:

“Provider” means a health care provider or disability services provider:

“Research” means health research or disability research:

“Rights” includes rights corresponding to the duties in this Code:

“Services” means health services, or disability services, or both; and includes health care procedures:

“Teaching” includes training of providers.

5. Other Enactments

Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

6. Other Rights

An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.



Appendix 4: Extracts from the Fertility Services Standard and the Fertility Services Audit Workbook

This appendix has been removed for copyright reasons. Please contact the ACART Secretariat (acart@moh.govt.nz) for further information.

Feedback form

Please provide your contact details below.

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

We will place all feedback on ACART's website, except where we are asked that feedback be withheld in full or part for reasons of confidentiality. We will remove contact information from all feedback.

I **request** that my feedback be withheld in full or part from publication on ACART's website. (If you wish a part to be withheld, please clearly indicate which part.)

Please note that all feedback may be requested by any member of the public under the Official Information Act 1982 (the Act). If there is any part of your feedback that you consider should be properly withheld under the Act, please make this clear in your feedback, noting the reasons.

If information from your feedback is requested under the Act, the Ministry of Health (the Ministry) will release your feedback to the person who requested it. The Ministry will remove your name and/or contact details from the feedback if you check one or both of the following boxes. Where feedback is on behalf of an organisation, the Ministry will not remove the name of the organisation.

I **do not** give permission for my name to be released to any person under the Official Information Act 1982.

I **do not** give permission for my contact details to be released to any person under the Official Information Act 1982.

We will acknowledge all feedback.



Questions for response

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 No

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

Yes No

Please give reasons for your views.

Question 2: Form of consent

- (a) Do you agree that consent to all assisted reproductive processes, where consent is required, must be in writing?

Yes No

- (b) Do you have any other comments?

Yes No

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?

Yes No

(b) Do you have any other comments?

Yes No

Please give reasons for your views.

Question 4: Placing conditions on donor consent

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

Yes No

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

Yes No

(c) Do you have any other comments?

Yes No

Please give reasons for your views.

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?

Yes No

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

Yes No

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

Yes No

Please give reasons for your views.

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?

Yes No

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

Yes No

Please give reasons for your views.

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?

Yes No

- (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?

Yes No

Please give reasons for your views.

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?

Yes No

- (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?

Yes No

Please give reasons for your views.

Question 9: Form of requirements for informed consent

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

Yes No

- (b) Do you have any other comments?

Yes No

Please give reasons for your views.

Question 10: Comments or suggestions

- (a) Do you have any general comments or suggestions about the requirements for informed consent?

- (b) Do you have any other comments or suggestions about the issues discussed in this consultation document?