

# **Advice on Aspects of Assisted Reproductive Technology:**

A consultation paper  
on policy issues

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# Chair's foreword

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Approximately one in five couples will find it difficult to conceive at some stage during their reproductive lives. The difficulty or inability to create or complete a much-wanted family can be a deeply personal experience that can cause grief and disempowerment to those who face it.

A range of reproductive technologies is available to assist couples to have a child, and this consultation paper canvasses your views on the policy aspects of some of the reproductive technologies used for this purpose.

While most reproductive technologies are used for the treatment of infertility, one procedure may also be used to prevent the inheritance of a genetic disease or disorder, and this paper also seeks your opinion on the policy dimensions of evolving aspects of preimplantation genetic diagnosis.

The Advisory Committee on Assisted Reproductive Technology (ACART) must provide the Minister of Health with advice on the above matters as well as some related policy issues. This policy advice will include draft guidelines for the Ethics Committee on Assisted Reproductive Technology (ECART) to use when reviewing applications to perform assisted reproductive procedures.

In formulating this advice, ACART must consult with interested parties and the public on these matters and take any submissions into account.

This consultation paper has been prepared to assist you in your thinking. Please take the time to consider the questions raised at the end of this paper – your responses will help us to decide what to recommend to the Minister.

I look forward to receiving your views on these very important issues.



Sylvia Rumball  
**Chair, Advisory Committee on Assisted Reproductive Technology**





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# 1. Introduction

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The Human Assisted Reproductive Technology Act (the HART Act) was passed in 2004, bringing together all aspects of assisted reproductive technology under a single regulatory framework.

However, it left a number of policy areas open for future consideration, some of which are covered in this consultation paper.

Two committees were established by the HART Act:

- the Advisory Committee on Assisted Reproductive Technology (ACART)
- the Ethics Committee on Assisted Reproductive Technology (ECART).

ACART's role is to consult the public on these policy areas and advise the Minister of Health on the policy New Zealand should adopt. ACART is particularly interested in seeking Māori views on the issues raised in this consultation paper.

This consultation paper covers:

- human assisted reproductive technology under the HART Act (chapter 2)

- policy advice and ethical review of assisted reproductive procedures, including draft guidelines for comment (chapter 3)
- further areas of assisted reproductive technology, on which ACART would like to gauge public opinion before advising the Minister of Health (chapter 4)
- how to contribute your views (chapter 5).

**ACART is seeking written submissions in response to this consultation paper, holding meetings with interested parties, and hearing oral submissions.**

Chapter 5 of this paper sets out how you can have your say, and a set of questions has been provided at the end of this paper to help you to structure your submission. All submissions will be analysed and taken into consideration by ACART when preparing its advice to the Minister of Health. The analysis of submissions will be made publicly available in due course.

**Submissions close on 17 August 2007.**

## Abbreviations and terms used

Assisted reproductive technology is a complex topic and this paper uses a number of technical terms. Where a technical term is used in the text for the first time, it is given in **heavy black type**. You will also find its meaning explained in the Glossary at the end of the document.

Where a name is used frequently, we have used abbreviations. Some of the most common abbreviations are:

**ACART** Advisory Committee on Assisted Reproductive Technology

**ECART** Ethics Committee on Assisted Reproductive Technology


**HART Act** Human Assisted Reproductive Technology Act 2004

**IVF** *in vitro* fertilisation

**PGD** preimplantation genetic diagnosis.

Some other abbreviations are used, but you will find them explained in the surrounding text.





## 2. Human assisted reproductive technology under the HART Act

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A range of reproductive technologies is available to treat infertility<sup>1</sup>. Some reproductive technologies may also be used to prevent a genetic disease.

These guidelines were mainly in the form of specific rules, which had to be met before an application could be approved. It was NECAHR's role to assess applications against these rules.

### Before the HART Act

Prior to the HART Act, assisted reproductive treatment and research were managed through ethical review, guidelines for fertility clinics, and fertility clinics abiding by a Code of Practice.

Some aspects were managed by the **National Ethics Committee on Assisted Human Reproduction** (NECAHR) – an ethical review and policy body established in 1993 and disestablished in 2005 as a result of the HART Act. From 2000 to 2005 NECAHR developed guidelines<sup>2</sup> for fertility clinics to use when applying for ethical approval to perform procedures covering:

- IVF **surrogacy**
- the storage, use and disposal of sperm from a deceased man
- within-family **gamete** (eggs or sperm) donation
- **embryo** donation
- **PGD** (preimplantation genetic diagnosis).

### The HART Act 2004

The HART Act (see Appendix 1) is New Zealand's first legislation to specifically address the practice of assisted reproductive technology. The Act establishes a legal framework for the practice of assisted reproductive technology, including treatment procedures and research. Central to this framework was the establishment of ACART and ECART.

Other key changes brought about by the passing of the HART Act were the:

- definition of some assisted reproductive procedures as prohibited, some as able to go ahead under the direction of fertility clinics, and some as having to be approved by ECART
- establishment of a donor register so that, when they are adults, the children born from donor eggs, sperm or embryos can access the identity of, and information about their genetic donor/s (whakapapa)<sup>3</sup>

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1 Infertility is commonly defined as not becoming pregnant after one year of trying to conceive, and is a medical condition recognised by the World Health Organization. Sometimes no reason can be found for failure to conceive. Approximately one in five couples experience difficulty in conceiving at some stage during their reproductive lives.

2 These guidelines will lapse on 21 November 2007 and are available at: <http://www.ecart.health.govt.nz>.

3 Whakapapa is acknowledged by the requirement to collect and store information in the donor register about the ethnicity and whānau, iwi and hapū affiliations (if known) of the donor.

- requirement that ACART report annually to Parliament
- introduction of a regime to enforce the HART Act, with punishable offences for anyone who contravenes the Act
- inclusion of fertility services as specified health and disability services that are regulated under the Health and Disability Services (Safety) Act 2001. This has resulted in the development of the **Fertility Services Standard**, which sets out the safety and quality measures all New Zealand fertility clinics must meet, including specific provisions for Māori<sup>4</sup>.

## Principles of the HART 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:

- a) The health and wellbeing of children born as a result of the performance of an assisted reproductive procedure should be an important consideration in all decisions about that procedure.
- b) The human health, safety, and dignity of present and future generations should be preserved and promoted.
- c) While all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and wellbeing of women must be protected in the use of these procedures.
- d) No assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given **informed consent**.
- e) Donor offspring should be made aware of their genetic origins and be able to access information about those origins.
- f) The needs, values, and beliefs of Māori should be considered and treated with respect.
- g) The different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

Both ACART and ECART are guided by the principles of the HART Act.

<sup>4</sup> These provisions are included in the Fertility Services Standard available through Standards New Zealand: <http://www.standards.co.nz>.

In relation to principle (f), ACART acknowledges that the following concepts are inherent in the use of assisted reproductive technology:

- wairua
- whakapapa
- whanaungatanga
- mauri
- mana
- kaitiakitanga and tino rangatiratanga.

These concepts are described in Appendix 2.

## ACART

ACART's role under the HART Act is to:

- issue guidelines and advice to ECART on any matter relating to any kind of **assisted reproductive procedure** or **human reproductive research**
- provide the Minister with advice on aspects of, or issues arising out of, different kinds of assisted reproductive procedures or human reproductive research
- monitor the application, and health outcomes, of assisted reproductive procedures and established procedures, and developments in human reproductive research.

## ECART

ECART's role under the HART Act is to consider and decide on applications for approvals for assisted reproductive procedures or human reproductive research, and keep under review approvals previously given. Approval can only be given if the activity is consistent with guidelines established or advice given by ACART.

## The four categories of human assisted reproductive technology

Assisted reproductive technology procedures fall into four categories under the HART Act; those that are:

- declared an '**established procedure**'
- prohibited
- an 'assisted reproductive procedure', requiring review by ECART
- subject to a moratorium.

These are all described in detail below.

### Established procedures

Established procedures, although they do not need approval from ECART, must be undertaken by fertility clinics that are guided by the principles of the HART Act and bound by the Fertility Services Standard. The application and health outcomes of established procedures are monitored by ACART.

The **Human Assisted Reproductive Technology (HART) Order in Council 2005** declared established procedures to be:

- **artificial insemination**
- **assisted hatching**
- **blastocyst** culture
- egg **cryopreservation**
- embryo cryopreservation
- ovarian tissue cryopreservation
- sperm cryopreservation
- **gamete intra fallopian transfer (GIFT)**
- **intracytoplasmic sperm injection (ICSI)**
- ***in vitro* fertilisation (IVF)**

- collection of eggs for purposes of donation (with exceptions)
- collection of sperm for purposes of donation (with exceptions)
- **preimplantation genetic diagnosis** (PGD) (with exceptions).

Exceptions to some of these established procedures were detailed in the HART Order in Council and are set out in Appendix 1.

## Prohibited procedures and actions

The HART Act makes it illegal to:

- artificially form, for reproductive purposes, a **cloned embryo**
- artificially form, for reproductive purposes, a **hybrid embryo**
- implant into a human being a cloned embryo
- implant into a human being an animal gamete or embryo
- implant into a human being a hybrid embryo
- implant into an animal a human gamete or human embryo
- implant into an animal a hybrid embryo
- implant into a human being a genetically modified gamete, human embryo, or hybrid embryo
- implant into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.

The Act also prohibits the commercial supply of human embryos or human gametes, and the giving or receiving of **valuable consideration** for participation in a surrogacy arrangement.

In addition, it is an offence under the Act to:

- store an ***in vitro*** human embryo or an *in vitro* human gamete for more than 10 years, unless ECART has approved storage for a longer period
- select an embryo on the basis of sex, unless it is used to prevent or treat a **familial sex-linked genetic disorder** (such as **haemophilia**)
- collect gametes (eggs or sperm) from an individual under 16 years of age, unless the purpose of collecting the gamete is to preserve the fertility of that individual
- cause the development of an *in vitro* embryo outside the body beyond 14 days after its formation.

## Assisted reproductive procedures

Assisted reproductive procedures may only be undertaken after ECART has given its consideration and approval on a case-by-case basis. The current assisted reproductive procedures that must be considered by ECART are:

- surrogacy
- embryo donation for reproductive purposes
- donation of gametes (egg or sperm) between certain family members
- uses of PGD that are exceptions to the established procedures (listed in Appendix 1).

## Procedures subject to a moratorium

The Governor-General can impose a moratorium<sup>5</sup> of 18 months on any kind of reproductive procedure, based on the recommendation of the Minister of Health. ACART might advise the Minister that a moratorium should be imposed on a procedure in order to allow more time to develop advice or guidelines.

A moratorium can only be extended once, for a further 18 months, and procedures under moratorium cannot be performed or considered for approval by ECART.


## Focus of this consultation

This consultation is about one of these categories of human assisted reproductive technology, that is, assisted reproductive procedures (chapter 3) and related issues, including import and export and informed consent (chapter 4).

ACART does not propose to advise the Minister on established or prohibited procedures because these were considered relatively recently, either in the passing of the HART Act itself or in the HART Order in Council.

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5 A moratorium is the temporary prohibition or suspension of an activity.



# 3. Guidelines for the ethical review of assisted reproductive procedures under the HART Act

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Guidelines for the ethical review of assisted reproductive procedures must reflect the HART Act's seven guiding principles (listed on page 4). This includes taking into account the needs, values and beliefs of Māori (see Appendix 2).

These guidelines must also take account of New Zealand's broader regulatory context, including human rights, health consumer protection and family law legislation. In developing these guidelines ACART has sought to balance public policy on new technologies and individuals' rights to make their own reproductive choices.

In undertaking review of applications for use of assisted reproductive procedures, ECART must ensure that its decisions implement the guidelines developed by ACART.

ACART is responsible for monitoring the decisions of ECART to ensure that they are consistent with ACART's guidelines, as well as for monitoring the application and outcome of assisted reproductive procedures and established procedures.

## Procedures requiring ECART approval

The procedures that currently require ECART review are:

- surrogacy
- embryo donation for reproductive purposes
- donation of gametes (egg or sperm) between certain family members
- certain uses of PGD.

While ACART could potentially advise the Minister that any of the above procedures no longer require ECART review, the Committee's thinking is that currently these procedures should continue to require ECART review, for the following reasons:

- these procedures are still relatively new in New Zealand and we have limited experience of the outcomes of these procedures
- these procedures – particularly where third parties are involved – are complex and involve significant **psycho-social** issues. Requiring them to have ECART review will maintain consistency with the recent decision to exclude practices with significant psycho-social issues from being established procedures, under the HART Order in Council 2005.

However, ACART proposes to monitor the application of all the proposed guidelines and, within the next four years, revisit the possibility of one or more of the above procedures no longer requiring ECART review.

See *question 1* to comment on whether you agree that these procedures should continue to be subject to guidelines and ECART review.

## The proposed guidelines for ECART

On the assumption that the above procedures continue to be subject to ethical review, ACART has drafted guidelines for ECART. These guidelines have been developed from the principles of the Act, taking account of the needs, values and beliefs of Māori (see Appendix 2).

For each procedure the first guideline establishes the conditions that must be met in order for an application to be accepted for review (**prerequisite**). These prerequisites have been developed to ensure that the principles of the Act are met when and if these procedures are undertaken.

In addition to providing guidelines to ECART, ACART will also instruct ECART to develop application forms that collect information to enable an assessment of each application for consistency with the principles of the HART Act.

### Clinic-assisted surrogacy

A surrogacy arrangement involves a woman agreeing to become pregnant on the basis that she will surrender

custody of a child born as a result of the pregnancy. **Clinic-assisted surrogacy** is when a surrogacy arrangement is facilitated by a fertility clinic, whether by IVF or donor insemination.

From 1997 to 2006, 60 applications for surrogacy were approved and seven declined. As of April 2007 a total of five live births have been reported by fertility clinics. Further detail of these past applications is included in Appendix 3.

### Proposed guidelines for clinic-assisted surrogacy

1. ECART may only approve applications for clinic-assisted surrogacy that meet the following prerequisites:
  - a) Permanent legal arrangements regarding the care of the potential child have been agreed to by all parties.
  - b) The surrogate has had an opportunity to reconsider her involvement in the surrogacy arrangement after undergoing implications counselling<sup>6</sup>.
  - c) Each of the parties has received independent legal advice.
  - d) Each of the parties has received independent medical advice.
  - e) Each of the parties has received independent counselling.
  - f) All parties have attended a joint counselling session.
2. ECART must review applications for clinic-assisted surrogacy to ensure consistency with the principles of the HART Act.

See *question 2* to comment on the proposed guidelines for clinic-assisted surrogacy.

<sup>6</sup> Implications counselling provides the opportunity to discuss and consider potential psycho-social, legal and medical implications of the surrogacy arrangement for the surrogate and her family (where appropriate this includes cultural counselling).



## Embryo donation for reproductive purposes

Embryo donation for reproductive purposes is the donation, by a couple who have 'surplus' embryos following IVF treatment, of one or more of their embryos to an infertile couple or person.

During *in vitro* fertilisation it is normal to collect a number of eggs from the woman receiving treatment and for these to be fertilised with the sperm of her partner. One embryo (or sometimes two) is transferred to the woman, and the remaining embryos are frozen. If a pregnancy is not achieved following the IVF cycle, the frozen embryos can be thawed and transferred to the woman. If a pregnancy is achieved, the frozen embryos can be used to achieve subsequent pregnancies.

Couples may have 'surplus' embryos left once their family is complete. At some stage, because embryos can only be stored for 10 years, a decision has to be made about the remaining embryos.

Although embryo donation has been an option for couples since August 2005, there has been only one application for this, which was approved by ECART in March 2007.

ACART has proposed prerequisite (g), see right, to restrict couples from donating embryos to more than one couple<sup>7</sup>. The donation of embryos to more than one couple increases the number of children and families genetically related and, given New Zealand's small population, might result in medical, legal, social or emotional difficulties for the families involved.

## Proposed guidelines for embryo donation

1. ECART may only approve applications for embryo donation that meet the following prerequisites.
  - a) The embryos being donated are existing embryos that were created from the donors' own gametes and are 'surplus' to the donors' own reproductive needs.
  - b) Donor couples have had an opportunity to reconsider the donation after undergoing implications counselling.
  - c) Each of the parties has received independent legal advice.
  - d) Each of the parties has received independent medical advice.
  - e) Each of the parties has received independent counselling.
  - f) Written consent for the donation of embryos has been given by both partners of a donor couple. If one partner of a potential donor couple is deceased, embryo donation can only proceed if prior written consent to embryo donation had been obtained from the deceased person.
  - g) The donor couple has not previously donated any 'surplus' embryos to another couple that have resulted in a live birth.
  - h) All parties have attended a joint counselling session.
2. ECART must review applications for embryo donation to ensure consistency with the principles of the HART Act.

See *question 3* to comment on the proposed guidelines for embryo donation.

<sup>7</sup> In submissions to the 2004 NECAHR public consultation on embryo donation, strong arguments were made to restrict the donation of embryos to one couple only.



## Donation of gametes between certain family members

A donor may donate an egg to a woman who is infertile and a donor may donate sperm to a man who is infertile or to a woman who does not have a male partner. The collection of eggs and sperm for donation are established procedures.

In most cases, the donation of eggs and sperm is also an established procedure and may go ahead without referral to ECART, under the guidance of fertility clinics. There are, however, exceptions to this as follows:

- donation of sperm from a family member, other than the patient's brother or cousin
- donation of eggs from a family member, other than the patient's sister or cousin
- donation of eggs or sperm from a sibling or cousin of the patient, when the donor or patient was under 20 at the time of the donation.

In these cases, donations between family members are required to be referred to ECART for ethical review.

From 2003 to 2006, 12 applications for donation of gametes between certain family members were approved and one was declined.

## Proposed guidelines for donation of gametes between certain family members

1. ECART may only approve applications for donation of gametes between certain family members that meet the following prerequisites.
  - a) Each of the parties has received independent medical advice.
  - b) Each of the parties has received independent counselling.
  - c) All parties have attended a joint counselling session.
2. ECART must not approve applications for donation of gametes between the following family members:
  - i) father and daughter
  - ii) mother and son
  - iii) brother and sister
  - iv) uncle and niece
  - v) aunt and nephew
  - vi) grandfather and granddaughter
  - vii) grandmother and grandson.
3. ECART must review applications for donation of gametes between family members to ensure consistency with the principles of the HART Act.

See *question 4* to comment on the proposed guidelines for donation of gametes between certain family members.

## Uses of PGD that are reviewed by ECART<sup>8</sup>

Preimplantation genetic diagnosis (PGD) involves testing the embryo to investigate if it is unaffected by a particular **genetic mutation** before being implanted in the uterus. PGD can identify a range of genetic diseases and chromosomal disorders. PGD is an alternative to prenatal diagnosis (such as **amniocentesis**) because it allows couples to make decisions at the embryonic rather than the foetal stage.

PGD involves the following steps:

- the creation of an embryo via *in vitro* fertilisation (IVF)
- obtaining one or more cells from the embryo between day three and five of development
- testing the cells to determine if the cells that come from the embryo contain the particular genetic mutation under investigation (or has an abnormal chromosome rearrangement)
- the subsequent transfer of unaffected embryos to a woman's uterus.

PGD can only be used in conjunction with IVF and is often used by fertile couples whose offspring are at risk of inheriting a genetic disease or chromosomal disorder. It can be used for the benefit of:

- a) the potential child only, or
- b) the potential child and the existing sibling of the potential child, or
- c) solely the existing sibling of the potential child.

Each of these scenarios is examined below, along with recommendations.

### (a) PGD to benefit the potential child only

The most common use of PGD is to benefit the potential child. However, it is possible to use PGD to select and implant an embryo with a genetic disease present in one of the parents. In ACART's opinion this use of PGD is inconsistent with the principles of the HART Act and this view is reflected in prerequisite (a) below.

#### Proposed guidelines for those uses of PGD that are reviewed by ECART

1. ECART may only approve applications for preimplantation genetic diagnosis that meet the following prerequisites.
  - a) Preimplantation genetic diagnosis is not used for the purpose of selecting an embryo with a genetic disease.
  - b) Genetic counselling has been received by the couple.
  - c) Medical advice has been received by the couple.
2. ECART must review applications for preimplantation genetic diagnosis to ensure consistency with the principles of the HART Act.

See *question 5* to comment on the proposed guidelines for used PGD that are reviewed by ECART.

<sup>8</sup> The uses of PGD that are exceptions to the established procedures are listed in Appendix 1.

**(b) PGD to benefit the potential child and the existing sibling of the potential child**

PGD and **human leukocyte antigen (HLA) tissue typing** can be used when an existing child has a disease that could be treated with a transplant (for instance, of stem cells from the umbilical cord blood or bone marrow) from a sibling who is a suitable tissue match. This process ensures that future transplants of the potential child's cells are much less likely to be rejected by the existing child's immune system, and also that the potential child will not carry the same disease as the existing child.

Currently in New Zealand HLA tissue typing can only be undertaken when PGD is needed to test the embryo for a **familial single-gene disease** or a **familial sex-linked disease**. Internationally the use of PGD with HLA tissue typing is very rare and it has not yet been used in New Zealand.

Proposed guideline for PGD\* using HLA tissue typing

1. ECART may only approve applications for preimplantation genetic diagnosis using human leukocyte antigen (HLA) tissue typing that meet the following prerequisite:
  - a) HLA tissue typing will only be undertaken for the benefit of a genetic sibling of the potential child.

\* In this circumstance PGD is being undertaken for the benefit of the potential child *and* the existing sibling of the potential child.

See *question 6* to comment on the proposed guideline for PGD using HLA tissue typing.

**(c) PGD to benefit solely the existing sibling of the potential child**

PGD and tissue typing can also be used for the sole purpose of finding a tissue match for an existing child, although this is not currently allowed in New Zealand. Parents who have a child with **leukaemia**, for example, could use PGD and HLA tissue typing to select an embryo to be a tissue match for their affected child. Once born, the baby's umbilical cord blood and/or bone marrow could be used in the treatment of their older sibling.

In 2004 the **Human Fertilisation and Embryology Authority (HFEA)**, the United Kingdom's regulatory body, extended its policy on PGD to allow embryos to be tested for tissue typing solely for the benefit of the potential child's existing sibling.

Applications to use PGD and tissue typing in the United Kingdom are considered by the HFEA on a case-by-case basis. The HFEA has set out a number of criteria<sup>9</sup> such applications are expected to meet, including:

- a statement from the clinician treating the existing child
- evidence that all possible alternative treatments have been investigated
- fertility centres have established arrangements to contact patients and families for long-term follow-up studies
- it is provided by a multidisciplinary team consisting of reproductive specialists, embryologists, clinical geneticists, genetic counsellors, molecular geneticists and counsellors

9 The HFEA guidance on preimplantation and tissue typing was released in August 2004 and is available at: <http://www.hfea.gov.uk/en/599.html>

- genetic and implications counselling are provided to all family members
- patients are provided with relevant information<sup>10</sup>
- the clinical decision to undertake PGD and tissue typing has considered the welfare of the potential child and any other child who might be affected by the birth.<sup>11</sup>

If the use of PGD in New Zealand were to be extended to allow the testing of embryos solely for tissue typing for an existing child with a disease, this would be a significant extension of what is currently allowed, because the benefit is not to the embryo but to the existing child. This use of PGD raises important issues to consider, including:

- the possibility that there could be significant psycho-social implications for a child created for the purpose of treating an existing child
- the implications of the transplant of stem cells from the umbilical cord or bone marrow to the affected child being unsuccessful
- the possibility of the resulting child being pressured to donate other tissue (ie, a kidney)
- the possibility that HLA tissue typing may be the only available way to successfully treat the existing child.

ACART would like to gauge public opinion on this extended use of PGD and tissue typing, before it develops advice to the Minister on this matter.

See *question 7* to comment on whether New Zealand policy should be extended to allow the use of PGD and tissue typing for the sole purpose of finding a tissue match for an existing child, where there is no benefit to the embryo.

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10 The specific information the HFEA expects patients to be provided with is detailed in the HFEA guidance.

11 The specific issues that are expected to have been considered in the clinical decision to undertake PGD with tissue typing are detailed in the HFEA guidance.

## 4. Advice on related issues

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In addition to developing new guidelines for ECART to use in reviewing applications to perform assisted reproductive procedures, ACART must also advise the Minister on:

- the use of donated eggs with donated sperm for reproductive purposes
- embryo splitting
- the import and export of donated gametes or embryos
- informed consent.

This advice must reflect the principles of the Act, including the needs, values and beliefs of Māori (see Appendix 2).

### The use of donated eggs with donated sperm for reproductive purposes

Some people may be unable to have a child without the use of both donated eggs and donated sperm, unless they are able to obtain a donated embryo. However, overseas research and New Zealand experience shows that few couples are likely to donate 'surplus' IVF embryos for reproductive purposes.

Donated eggs and donated sperm may be needed where:

- both partners of a heterosexual couple are infertile
- a person is infertile and does not have a partner
- both partners of a same-sex couple are infertile.

The use of donated eggs with donated sperm would involve obtaining both sperm and eggs from donors, fertilising the donor eggs with the donor sperm,

and implanting the resulting embryo/s into the intending mother or surrogate. Neither of the intending parents would be the genetic parent of the resulting child. At present there are no guidelines to allow such an arrangement to proceed.

ACART is, in this consultation, distinguishing between the use of donated eggs with donated sperm and embryo donation to explore whether there is a difference between the use of an already existing embryo and the intentional creation of an embryo from donor eggs and donor sperm.

ACART's primary concern is whether there are any adverse implications to the health and wellbeing of the potential child of being born from two donor gametes, particularly where the genetic parents may never have been in a relationship together.

Issues to consider include whether:

- the process of gaining information about donors may be significantly more difficult for a child born from two sets of donor gametes
- the potential child is more likely to have half-siblings of whom they are unaware
- it would be discriminatory against people in the circumstances described above if the use of donated eggs with donated sperm was prohibited.

ACART welcomes your views on the use of donated eggs with donated sperm.

See *question 9* to comment on whether the use of donated eggs with donated sperm should be allowed.

## Embryo splitting

Early *in vitro* embryos can be split into two identical embryos. Embryo splitting might be an option for people undergoing IVF treatment who have a limited number of embryos.

ACART understands that embryo splitting is not a procedure fertility clinics are interested in using in the foreseeable future, so it does not intend to provide any specific recommendations to the Minister of Health at this stage. If, in the future, fertility clinics show an interest in using embryo splitting, then ACART will provide further advice to the Minister on the procedure.

See *question 10* to comment on whether you think it is necessary for ACART to give specific advice on embryo splitting to the Minister of Health.

## Import into, or export from, New Zealand of *in vitro* donated human gametes or *in vitro* donated human embryos

The HART Act prohibits the commercial supply of gametes and embryos and there are significant penalties for anyone breaching this prohibition. It leaves open, however, the possibility for allowing the import and export of donated gametes and embryos where there has been no commercial transaction.

Some people may have had IVF treatment using donated gametes or embryos, or donor insemination, in New Zealand and then moved overseas with their child. Some may move here who

have had IVF treatment overseas. In all these cases, if these people want to have another child and complete their family, their donated gametes and embryos may be in another country.

Currently, the import and export of donated gametes and embryos is not allowed to proceed. ACART's preliminary thinking is that such people should be able to import and export gametes and embryos that have been donated to them in order that their children can be genetically related. ACART believes, however, that any import or export must meet the requirements relating to gametes and embryos donated within New Zealand which were established by the HART Act.

Any future guidelines or regulations for the import and export of donated *in vitro* gametes and embryos would be in addition to legal constraints such as the prohibition on commercial supply. They would need to ensure that:

- donor offspring are made aware of their genetic origins and are able to access information about those origins
- both the donor/s and recipient/s of the gametes or embryos have made an informed choice and given informed consent
- the human health, safety and dignity of present and future generations are preserved and promoted.

There are two possible ways that the import and export of donated *in vitro* gametes and embryos might be controlled to meet the above requirements.

- (a) ACART could recommend to the Minister that regulations be established under the HART Act. Such regulations can only be made by the Governor-General on the



recommendation of the Minister, after the Minister has received advice from ACART; or

- (b) ACART could recommend to the Minister that it issue guidelines for ECART to review applications to import or export of *in vitro* donated gametes or embryos on a case-by-case basis.

ACART's current view is that it would be sufficient to develop guidelines for ECART to review applications for the import and export of donated gametes and embryos (option b) because:

- guidelines are flexible and adaptable to change in the rapidly advancing area of assisted reproductive technology
- there are strong penalties for breaching guidelines
- the process for developing guidelines would be open, as they would require public consultation.

See *questions 11 and 12* to comment on the import and export of *in vitro* donated gametes or embryos, to or from New Zealand.

## Informed consent

### General requirements

Currently, informed consent relating to assisted reproductive technology undertaken in New Zealand is addressed in three ways:

- informed consent is integral to the HART Act and is explicitly referred to in the Act's principles
- some requirements for informed consent in the area of assisted reproductive technology are detailed in the Fertility Services Standard

- fertility services and associated health professionals are subject to the Code of Health and Disability Services Consumers' Rights 1996, which confers 10 rights on consumers of health and disability services, including the right to be fully informed and the right to make an informed choice and give informed consent.

There are, however, some aspects of assisted reproductive technology which ACART believes may not be adequately covered, including the donation of gametes and embryos and clarification of the potential use, storage and destruction of donated gametes and embryos where a donor has withdrawn consent.

Therefore, ACART proposes to recommend to the Minister that requirements for informed consent, specific to assisted reproductive technology, be prescribed in regulations under the HART Act.

See *questions 13 and 14* to comment on informed consent.

### Gametes from deceased persons

The collection of gametes from deceased persons for reproductive purposes is being considered under the consent framework of the Human Tissue Bill.<sup>12</sup> However, the subsequent use of gametes from deceased persons falls under the HART Act.

ACART's current view is that the use of gametes from deceased persons should only proceed where an individual has given written consent prior to their death. ACART has formed this view in line with principle (d) of the HART Act, which

<sup>12</sup> The Human Tissue Bill is currently before the Health Select Committee.

emphasises the importance of informed consent in every application of assisted reproductive technology.

ACART proposes to advise the Minister that, where written consent is not given prior to death, the use of gametes from deceased persons for reproductive purposes should be prohibited under the HART Act.

See *question 15* to comment on whether you agree that the use of gametes from deceased persons be prohibited unless they have given their prior written consent.





## 5. How to contribute your views

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Your feedback is important to help ACART advise the Minister of Health on future policy for assisted reproductive technology in New Zealand. Please take this opportunity to have your say. You may make a submission on your own behalf or as a member of an organisation. A summary of the submissions will be released after ACART has provided its advice to the Minister of Health.

ACART welcomes your views on any or all of the issues raised. However, there are some key questions we would like you to think about and comment on. These questions are set out in a detachable submission form at the back of this document.

There are a number of ways you can contribute to this consultation.

1. Make a formal oral submission or speak to your written submission. If you wish to do this, please advise the ACART Secretariat as soon as possible, but no later than **17 August 2007**, by emailing them at [acart@moh.govt.nz](mailto:acart@moh.govt.nz), or phoning 04 496 2000.
2. Write down your comments on the detachable pages at the end of this document and post to:  
The Secretariat  
Advisory Committee on Assisted Reproductive Technology  
PO Box 5013  
WELLINGTON.
3. Download the submission form in Word format from: [www.acart.health.govt.nz](http://www.acart.health.govt.nz), save it to your computer, fill it in and email it to [acart@moh.govt.nz](mailto:acart@moh.govt.nz).
4. Email your comments to [acart@moh.govt.nz](mailto:acart@moh.govt.nz).

The closing date for submissions is **17 August 2007**.

All submissions will be considered before ACART decides what advice to give to the Minister of Health.

Additional copies of this discussion paper are available from the ACART website [www.acart.health.govt.nz](http://www.acart.health.govt.nz) or from:

Wickliffe Press  
PO Box 932  
Dunedin  
Phone: (04) 496 2277  
Email: [moh@wickliffe.co.nz](mailto:moh@wickliffe.co.nz)

When ordering this discussion paper from Wickliffe, please quote **HP 4420**.



# Glossary

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**Advisory Committee on Assisted Reproductive Technology (ACART)**

The advisory committee established under New Zealand's Human Assisted Reproductive Technology Act 2004.

**Amniocentesis**

A medical test intended to detect a disorder in the foetus during pregnancy, which involves removing a sample of amniotic fluid from around the foetus via a fine needle inserted through the abdomen and the wall of the uterus.

**Artificial insemination**

A procedure in which sperm is artificially introduced into a woman's body.

**Assisted hatching**

A procedure that involves thinning or making a hole in the outer covering or membrane of an embryo in order to help the embryo implant itself in the uterine lining.

**Assisted reproductive procedure**

The HART Act defines an assisted reproductive procedure as a procedure performed for the purpose of assisting human reproduction that involves:

- the creation of an *in vitro* human embryo; or
- the storage, manipulation or use of an *in vitro* human gamete or an *in vitro* human embryo; or
- the use of cells derived from an *in vitro* human embryo; or
- the implantation into a human being of human gametes or human embryos.

**Blastocyst**

The appearance of the embryo at day five or six. The spherical blastocyst is made up of an outer ring of cells (the trophoctoderm), which encloses a fluid-filled cavity and an interior cluster of cells (the inner cell mass).

**Blastocyst culture**

A procedure in which the culture of an embryo or embryos outside the body is prolonged so that embryos might develop to the stage of a blastocyst.

**Clinic-assisted surrogacy**

A surrogacy arrangement that is facilitated by a fertility clinic, whether by IVF or donor insemination.

**Cloned embryo**

A human embryo that is a genetic copy (whether identical or not) of a living or dead human being, a still-born child, a human embryo or a human foetus.

**Cryopreservation**

The freezing and storage of tissue and cells at extremely low temperatures.

**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.

|  |   |
|--|---|
| <b>Embryo splitting</b>  | A procedure that involves splitting an early preimplantation embryo to increase the number of embryos.  |
| <b>Established procedure</b>   | A procedure that is declared established under section 6 of the HART Act, and therefore does not require approval from ECART.   |
| <b>Ethics Committee on Assisted Reproductive Technology</b>                | The ethics committee established under New Zealand's Human Assisted Reproductive Technology Act 2004.   |
| <b>Familial sex-linked disease</b>   | A disease caused by defects in the X or Y chromosomes, which can often be traced through multiple generations of a family.  |
| <b>Familial single-gene disease</b>  | A disease caused by defects in one particular gene, which can often be traced through multiple generations of a family.   |
| <b>Fertility Services Standard</b>   | A standard issued under the Health and Disability Services (Safety) Act 2001 that sets out the safety and quality measures all fertility services provided by New Zealand fertility clinics must meet.  |
| <b>Foetus</b>  | The early human form from week eight until the birth of a child.  |
| <b>Gamete</b>  | An egg or a sperm, whether mature or not, or any other cell (whether naturally occurring or artificially formed or modified) that (i) contains only one copy of all or most chromosomes and (ii) is capable of being used for reproductive purposes.                        |
| <b>Gamete intrafallopian transfer (GIFT)</b>                               | A technique that involves combining eggs and sperm outside the body and immediately placing them into the fallopian tubes (through laparoscopic surgery) to achieve fertilisation.  |
| <b>Gene</b>  | A section of the DNA molecule that contains a distinct package of genetic material and is located in a specific site on a chromosome.   |
| <b>Genetic mutation</b>  | A change in genetic material, usually a single gene, resulting in new or rearranged hereditary determinants and associated with disease (or risk of disease).   |
| <b>Haemophilia</b>   | An inherited lifelong blood condition carried on the X chromosome, in which an essential clotting factor is either partly or completely missing. This causes a person with haemophilia to bleed for longer than normal, and in some cases bleeding can occur without cause. |
| <b>Human Assisted Reproductive Technology (HART) Act 2004</b>              | An Act to secure the benefits of, and regulate, assisted reproductive technology and human reproductive research.   |
| <b>Human Assisted Reproductive Technology (HART) Order in Council 2005</b> | A supplementary order which declared certain medical procedures to be established procedures under section 6 of the HART Act, and in doing so specified those procedures that do not require approval from ECART under the HART Act.  |

|  |   |
|--|---|
| <b>Human Fertilisation and Embryology Authority (HFEA)</b> | The United Kingdom's independent regulator overseeing safe and appropriate practice in fertility treatment and embryo research. Online at <a href="http://www.hfea.gov.uk">http://www.hfea.gov.uk</a>   |
| <b>Human leukocyte antigen (HLA) tissue typing</b>         | The immune system recognises proteins on cells as either foreign or self, and the HLA proteins are the major proteins that identify as foreign and self. If the potential donor (ie, the embryo) and the recipient have matching HLA proteins, it is likely that the recipient's immune system will not reject a transplant (ie, umbilical cord blood) from the potential donor   |
| <b>Human reproductive research</b>                         | Research that uses or creates a human gamete, a human embryo, or a hybrid embryo.   |
| <b>Hybrid embryo</b>                                       | The HART Act defines a hybrid embryo as one that is formed: <ul style="list-style-type: none"> <li>• by fusing a human gamete with a non-human gamete; or</li> <li>• by fusing or compacting a cell of a human embryo with the cell of a non-human embryo; or</li> <li>• by fusing or compacting a cell or cells of a human embryo with the cell or cells of another human embryo; or</li> <li>• by transferring the nucleus of a human cell into a non-human egg or a non-human embryo; or</li> <li>• by transferring the nucleus of a non-human cell into a human egg or human embryo.</li> </ul> |
| <b>Informed consent</b>                                    | A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.  |
| <b>Interim guidelines</b>                                  | Guidelines developed by NECAHR for its use in reviewing applications from fertility clinics to undertake certain assisted reproductive treatment procedures. These were declared to be guidelines for use by ECART pursuant to the transitional provisions of the HART Act.   |
| <b>Intracytoplasmic sperm injection (ICSI)</b>             | A procedure in IVF where one selected sperm is injected into the cytoplasm of an egg to achieve fertilisation.  |
| <b><i>In vitro</i></b>                                     | In relation to an embryo, a foetus, gamete or cell, means an embryo, foetus, gamete or cell that is outside a living organism.  |
| <b><i>In vitro</i> fertilisation (IVF)</b>                 | The uniting of egg and sperm outside the body (in the laboratory).  |
| <b><i>In vitro</i> maturation (IVM)</b>                    | The act of culturing and maturing eggs (oocytes) that have been collected at an immature state.   |
| <b>Leukaemia</b>   | A group of blood diseases characterised by malignancies (cancer) of the blood-forming tissues.  |

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|---|--|
| <b>Minister</b>   | The Minister of Health.  |
| <b>National Ethics Committee on Assisted Human Reproduction</b> | An ethical review and policy body that was established in 1993 to manage some aspects of assisted reproductive technology prior to the HART Act.   |
| <b>Prerequisite</b>   | Required as a prior condition.   |
| <b>Psycho-social</b>  | Involving both the social and psychological aspects of a person's life.  |
| <b>Surrogacy</b>  | An arrangement under which a woman agrees to become pregnant for the purpose of surrendering custody of a child born as a result of the pregnancy. |
| <b>Valuable consideration</b>                                   | Includes an inducement, discount, or priority in the provision of a service.   |



# Further reading

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Advisory Committee on Assisted Reproductive Technology. 2006. *Annual Report 2005–2006*. Wellington: ACART.

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Human Fertilisation and Embryology Authority. 2002. *The Patient's Guide to IVF Clinics*. London: HFEA.

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Human Genome Research Project. 2006. *Choosing Genes for Future Children: Regulating preimplantation genetic diagnosis*. Dunedin: Human Genome Research Project. URL: <http://www.otago.ac.nz/law/genome/resources/RegulatingPGD.pdf>

Standards New Zealand. 2007. *Fertility Services Standard* (NZS8181:2007). Wellington: Standards New Zealand.

## Legislation

Human Assisted Reproductive Technology (HART) Act 2004. URL: [http://www.legislation.govt.nz/browse\\_vw.asp?content-set=pal\\_statutes](http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes)

Human Assisted Reproductive Technology (HART) Order in Council 2005. URL: [http://www.legislation.govt.nz/browse\\_vw.asp?content-set=pal\\_statutes](http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes)

## Interim guidelines

National Ethics Committee on Assisted Human Reproduction. 2005. *Guidelines on Embryo Donation for Reproductive Purposes*. Wellington: NECAHR. URL: <http://www.ecart.health.govt.nz/moh.nsf/indexcm/ecart-guidelines-embryodonation>

National Ethics Committee on Assisted Human Reproduction. 2005. *Guidelines on Preimplantation Genetic Diagnosis*. Wellington: NECAHR. URL: <http://www.ecart.health.govt.nz/moh.nsf/indexcm/ecart-guidelines-preimplantation>

National Ethics Committee on Assisted Human Reproduction. 2005. *Guidelines on IVF Surrogacy*. Wellington: NECAHR.

URL: <http://www.ecart.health.govt.nz/moh.nsf/indexcm/ecart-guidelines-ivfsurrogacy>

National Ethics Committee on Assisted Human Reproduction. 2005. *Guidelines on Within Family Gamete Donation*. Wellington: NECAHR.

URL: <http://www.ecart.health.govt.nz/moh.nsf/indexcm/ecart-guidelines-gametedonation>

National Ethics Committee on Assisted Human Reproduction. 2005. *Guidelines for the Storage, use and Disposal of Sperm from a Deceased Man*. Wellington: NECAHR. URL:

<http://www.ecart.health.govt.nz/moh.nsf/indexcm/ecart-guidelines-spermdeceased>



# Appendix 1: The HART Act

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This appendix summarises some key parts of the HART Act which are relevant to this consultation.

## Purposes of the HART Act

The HART Act has a number of purposes. These are:

- a) to secure the benefits of assisted reproductive procedures, established procedures, and human reproductive research for individuals and for society in general by taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research
- b) to prohibit unacceptable assisted reproductive procedures and unacceptable human reproductive research
- c) to prohibit certain commercial transactions relating to human reproduction
- d) to provide a robust and flexible framework for regulating and guiding the performance of assisted reproductive procedures and the conduct of human reproductive research
- e) to prohibit the performance of assisted reproductive procedures (other than established procedures) or the conduct of human reproductive research without the continuing approval of the ethics committee

- f) to establish a comprehensive information-keeping regime to ensure that people born from donated embryos or donated cells can find out about their genetic origins.

## ACART membership

The Minister of Health appoints members to ACART. The HART Act specifies that ACART's membership must include:

- one or more members with expertise in assisted reproductive procedures
- one or more members with expertise in human reproductive research
- one or more members with expertise in ethics
- one or more Māori members with expertise in Māori customary values and practice and the ability to articulate issues from a Māori perspective
- one or more members with the ability to articulate issues from a consumer perspective
- one or more members with expertise in relevant areas of the law
- one or more members with the ability to articulate the interests of children.

At least half the members of ACART must be laypersons.



## Changes to the classification of procedures

ACART has the authority to recommend to the Minister of Health at any time that:

- an established procedure become an assisted reproductive procedure
- an established procedure become a prohibited procedure
- an assisted reproductive procedure become an established procedure
- an assisted reproductive procedure become a prohibited procedure
- an assisted reproductive procedure be subject to a moratorium.


## Exceptions to the list of established procedures

The HART Order in Council 2005 declared the following exceptions to established procedures:

- the use of donated eggs that:
  - (a) have been donated by a family member (other than a sister or cousin) of the patient
  - (b) have been donated by a sister or cousin of the patient, if either the donor or patient was under 20 at the time of donation
  - (c) are used with donated sperm.

- the use of donated sperm that:
  - (a) has been donated by a family member (other than a brother or cousin) of the patient
  - (b) has been donated by a sister or cousin of the patient, if either the donor or patient was under 20 at the time of donation
  - (c) is used in conjunction with donated eggs.
- the collection of immature eggs or the use of eggs that have been matured by *in vitro* maturation (IVM).
- the use of sperm that was collected from a person who has died since the sperm was collected, and who did not give specific consent for the use of the sperm.
- the use of preimplantation genetic diagnosis for purposes other than the prevention or treatment of a genetic disorder by:
  - (a) diagnosis of a familial single-gene disorder
  - (b) sex determination
  - (c) diagnosis of familial chromosomal disorders
  - (d) diagnosis of non familial chromosomal disorders (aneuploidy testing).

The above procedures are subject to ethical review by ECART.



# Appendix 2: Tikanga and potential implications of assisted reproductive technology: ACART's current understanding

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## Wairua

The spirit within all things, wairua is the counterpoint to the physical element of existence (Barlow 1994). A key debate may be around when wairua enters the embryo – whether wairua takes hold at conception, during the embryonic stage, during the foetal stage or at birth. Some may hold the view that the wairua enters the embryo as soon as the sperm and the egg come together to form the zygote, while others may consider the wairua only enters when the new child is welcomed to the world at birth.

## Whakapapa

Whakapapa is the genealogical descent of all living things from the gods to the present time (Barlow 1994). Te ao Māori has its roots deeply entrenched in whakapapa, with a focus on the importance of relationships between tangata whenua (people of the land) and the natural world. A key concern for some Māori may be whether whakapapa would be disrupted through the use of some assisted reproductive procedures, such as embryo donation.

## Whanaungatanga

Whanaungatanga relates to an obligation of care and support among relatives. This suggests the importance of whānau considerations in any decision made involving donation of embryos or gametes to others or the acceptance of gametes or embryos from others, especially given that the whānau may be affected by the decision made by an individual.

## Mauri

Mauri is the life force that permeates all things in te ao Māori – every living thing has a mauri. There may be some questions about the effect of preimplantation genetic diagnosis on the mauri of the embryo.

## Mana

Mana implies authority, influence and prestige as well as the recognition that these qualities can be collective as well as individual, and may extend to include whānau, hapū, and iwi. There may be some concerns over who has the mana to make decisions in relation to Māori donating or receiving gametes or embryos. Māori may be concerned over whether the choice to donate or receive gametes or embryos should be left to individuals or with a larger social grouping.

## Kaitiakitanga and tino rangatiratanga

There is a distinct relationship between kaitiakitanga (guardianship) and tino rangatiratanga (self determination). This may relate to guardianship over genetic information or protecting the wellbeing of the embryo, the intending parents, the whānau or future generations. Tino rangatiratanga involves the authority to make decisions about the future at both an individual and a collective level.



# Appendix 3: Surrogacy applications

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## Surrogacy applications, 1997–2006

| Year  | Number approved <sup>a, b</sup> | Number declined <sup>a</sup> | Number deferred |
|-------|---------------------------------|------------------------------|-----------------|
| 1997  | 1                               | 0                            | 0               |
| 1998  | 2                               | 1 <sup>d</sup>               | 4               |
| 1999  | 4                               | 0                            | 3               |
| 2000  | 5                               | 1                            | 2               |
| 2001  | 6                               | 1                            | 1               |
| 2002  | 1                               | 0                            | 3               |
| 2003  | 5                               | 0                            | 3 <sup>e</sup>  |
| 2004  | 5 <sup>c</sup>                  | 0                            | 1               |
| 2005  | 15                              | 4                            | 0               |
| 2006  | 16                              | 0                            | 1               |
| Total | 60                              | 7                            | 18              |

Notes:

- a The number of 'approved' and 'declined' applications for each year may include some applications that were deferred in previous years.
- b Includes applications approved outright and applications approved subject to conditions.
- c Includes two applications that were provisionally approved and granted final approval in 2005.
- d In 1999 NECAHR considered a variation to the original application and approved it.
- e One application was subsequently withdrawn.

Source: ACART Annual Report 2005–2006.



# Appendix 4: Members of ACART

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## **Professor Sylvia Rumball**

(Chairperson) is Assistant to the Vice Chancellor (Ethics and Equity) at Massey University. She has a PhD in chemistry and for many years taught chemistry and undertook research in structural biology at Massey University. She has extensive international, national and local experience on ethics committees through past membership of the UNESCO International Bioethics Committee, the Health Research Council Ethics Committee, and the Massey University Human Ethics Committee; current membership of the Ethics Advisory Panel of the Environmental Risk Management Authority and the MASH Trust Ethics Committee; as past Chair of the National Ethics Committee on Assisted Human Reproduction; and as current Chair of the Massey University Human Ethics Chairs Committee. Professor Rumball is also a member of the Massey University Council and the International Council for Science Committee on Freedom and Responsibility in Science. In 1998 she was made an Officer of the New Zealand Order of Merit for services to science. She is also the recipient of a Palmerston North City Council Civic Award, a Distinguished Alumni Award from the University of Canterbury and a New Zealand Science and Technology medal.

**Professor Ken Daniels** (Deputy Chair) is Adjunct Professor in the School of Social Work and Human Services at the University of Canterbury. He was appointed to establish social work education and training at Canterbury in 1975 and retired in 2004. For over 30 years he has been actively involved in studying, writing, counselling and policy development in the psychosocial

aspects of assisted reproductive technology. His particular focus has been on the children and families that result from assisted reproductive technology. He served for nine years on the National Ethics Committee on Assisted Human Reproduction, the last three as Deputy Chair. Professor Daniels has carried out research in a number of countries and has been used as a policy consultant in several overseas jurisdictions. He has published extensively, and his book *Building a Family with the Assistance of Donor Insemination* is used by parents and professionals throughout the world. Professor Daniels is also Deputy Chair of Richmond, New Zealand.

**Professor Gareth Jones** is Deputy Vice-Chancellor (Academic and International) at the University of Otago, where he is also Professor of Anatomy and Structural Biology. He qualified in medicine and neuroscience (BSc Hons, MBBS) at University College London, and has DSc and MD degrees from the University of Western Australia and University of Otago in science and bioethics respectively. He was made Companion of the New Zealand Order of Merit in 2004 for his contributions to science and education. He has published extensively in neuroscience, anatomy education and bioethics. His recent books include: *Speaking for the Dead: Cadavers in biology and medicine* (2000), *Stem Cell Research and Cloning* (editor, 2004), *Medical Ethics* (co-author, 4th edition, 2005), *Designers of the Future* (2005), and *Bioethics* (2007).

**Dr Richard Fisher** is a gynaecologist with a sub-specialty practice in reproductive medicine. He is a co-founder of Fertility Associates and has been an active advocate for infertile couples for 20 years. He is the only New Zealander to have been elected President of the Fertility Society of Australia. Dr Fisher is a member of a number of professional associations and of the Institute of Directors. He is married and has four children. Dr Fisher brings a medical professional viewpoint to ACART, which is tempered by recognition of the need for community involvement and decision-making in this area.

**John Forman** is a parent of adult twins with a rare genetic disorder, Alpha Mannosidosis, and his family experience with physical and intellectual disability has drawn him into a range of health and disability sector networks in the past 30 years. He has also spent many years in disability support service provision, mainly in community mental health. Since the late 1990s John has focused on the development of patient-family support networks in New Zealand and internationally, with an emphasis on partnership with health professionals, policy agencies and researchers to promote prevention, treatments and cures for rare disorders. He has volunteer roles on the board of several local and international advocacy groups. His paid role is as Executive Director of the New Zealand Organisation for Rare Disorders, where he advocates for increased application of genome knowledge and biotechnology to control health and disability problems, with a sharp eye on the ethical issues to ensure safety for the patient and their family.

**Professor Mark Henaghan** is Professor and Dean of Law at Otago University and Principal Investigator of the New Zealand Law Foundation sponsored Human Genome Project, Law and Ethics for the Future. Professor Henaghan's primary research interests are in family law and medico-legal law involving children.

**Philippa McDonald** is from Te Aupōuri and Ngāti Porou. She has worked in law and policy in Australia and New Zealand. She was a member of the Human Rights Review Tribunal for 10 years and of the research ethics committees of Victoria University Council. Ms McDonald is Vice President of the Post Polio Support Society and a Trustee of the Disability Resources Trust, Wellington. She is a founder member of Te Aupōuri ki Pōneke Trust. She was a member of the National Ethics Committee on Assisted Human Reproduction for one year before it was replaced by ACART and ECART in 2005.

**Mihi Namana** has a formal training as a secondary school teacher and spent four years teaching at Kingswell College in Invercargill. In the early 1980s she worked extensively with Ngāi Tahu elders to assist with the completion of their ancestral meeting house by managing the Marae Development Project under the Labour Department. After the completion of this project in 1987, she stayed on with the Labour Department as a liaison officer working with gangs. In 1989 she was appointed as a cultural advisor for the South Canterbury, Dunedin and Southland branches of the Labour Department. By 1991 Ms Namana and her husband had moved to the Wairarapa, where she worked as a career consultant for secondary schools in the Wairarapa and Wellington regions. In 1996 she became principal of the local kura kaupapa, a position she held until her diagnosis with cancer in 1998. In 2000 she was

appointed to her current position of Iwi and Māori Health Co-ordinator for the Wairarapa DHB. In 2003 Ms Namana was made a Companion of the Queen's Service Order for community service.

**Christine Rogan** has worked to actively promote health for 15 years. She is a past President and life member of the Auckland Infertility Society and became the first National Development Officer for the New Zealand Infertility Society (now Fertility New Zealand). Currently she is a health promotion advisor with a non-government public health organisation. In addition, Ms Rogan is a non-medical Performance Assessment Committee member for the Medical Council and the Dental Council. She has a tertiary qualification in social sciences from Massey University and lives on the North Shore of Auckland with her daughter.

**Associate Professor Andrew Shelling** is head of the Medical Genetics Research Group, which is primarily interested in understanding the molecular changes that occur during the development of genetic diseases, focusing on infertility and reproductive cancers, but also including cardiac disorders and inflammatory bowel disease. He is currently an Associate Editor for the *Human Reproduction* journal, which is one of the leading journals in the area of reproductive research. Dr Shelling has a special interest in understanding the cause of premature menopause, and his research is internationally recognised for identifying genetic causes of this common cause of infertility. He initiated the development of a support group for women with premature menopause in New Zealand. Dr Shelling is currently Deputy Head of Department of Obstetrics and Gynaecology, and is extensively involved in teaching reproduction, genetics and cancer at the University of Auckland.

Dr Shelling has recently served as President of the New Zealand branch of the Human Genetics Society of Australasia. He has recently been appointed to be a Trustee for the Nurture Foundation for Reproductive Research.

**David Tamatea** is a New Zealand Māori with Taranaki iwi affiliations, is married to Olivia, and has two daughters and 10 grandchildren. He has been actively involved in a number of administrative and governance bodies for many years, and also has a wide breadth of experience and contacts in the community health and disability sectors. In 1998 Mr Tamatea completed the National Certificate in Human Services (Disability Support). He is a positive and proactive person who likes to be involved with helping people. He has the skills and ability to motivate and encourage others, particularly those facing barriers or with a disability.







# Submission form

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Please provide your contact details.

|  |  |
|--|--|
| <b>Name:</b>   |  |
| <b>If this submission is made on behalf of an organisation please name it:</b>                             |  |
| <b>Brief description of organisation (if applicable):</b>  |  |
| <b>Address/email:</b>  |  |
| <b>Interest in this topic (eg, user of fertility services, health professional, member of the public):</b> |  |

Please note that all correspondence may be requested under the Official Information Act 1982. If there is any part of your correspondence that you consider should properly be withheld under the Act, please point this out, noting the reasons why you would want it to be withheld.

If your submission is requested under the Official Information Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, as opposed to an organisation, the Ministry will remove your personal details from the submission if you check the following box.

I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged by ACART, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Do you wish to receive a copy of the summary of submissions?

Yes

No

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**Question 1:**

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**Do you agree that the following procedures should remain subject to guidelines developed by ACART, and review by ECART:**

- clinic-assisted surrogacy
- embryo donation for reproductive purposes
- donation of gametes between certain family members
- certain uses of PGD?

Please give reasons for your views.

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**Question 2:**

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**What are your views on the proposed guidelines for clinic-assisted surrogacy?**

Please give reasons for your views.

*(See page 9 of the consultation paper)*

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**Question 3:**

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**What are your views on the proposed guidelines for embryo donation?**

Please give reasons for your views.

*(See page 10 of the consultation paper)*

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**Question 4:**

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**What are your views on the proposed guidelines for donation of gametes between certain family members?**

Please give reasons for your views.

*(See page 11 of the consultation paper)*

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**Question 5:**

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**What are your views on the proposed guidelines for used PGD that are reviewed by ECART?**

Please give reasons for your views.

*(See page 12 of the consultation paper)*

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**Question 6:**

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**What are your views on the proposed guideline for PGD using HLA tissue typing?**

Please give reasons for your views.

*(See page 13 of the consultation paper)*

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**Question 7:**

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**What are your views on whether the use of PGD should be extended to allow the testing of embryos solely for tissue typing for an existing child with a disease?**

Please give reasons for your views.

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**Question 8:**

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**Do the guidelines proposed in chapter 3 adequately address the needs, values and beliefs of Māori?**

Please give reasons for your views.

**Kei te tika te whakaritenga o ngā rārangi tohutohu e pā ana i nga tikanga Māori i te wahanga 3?**

Homai ou whakaarō.

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**Question 9:**

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**What are your views on whether an embryo for reproductive purposes should be allowed to be created using a donated egg and donated sperm?**

Please give reasons for your views.

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**Question 10:**

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**Do you agree that embryo splitting requires no specific recommendation to the Minister of Health (which will mean that it is unable to proceed, although it will not be prohibited)?**

Please give reasons for your views.

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**Question 11:**

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**Do you agree that the import and export of donated *in vitro* embryos and gametes should be allowed, provided that the prohibitions and principles of the HART Act are met?**

Please give reasons for your views.

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**Question 12:**

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**Do you agree that requirements for the import and export of donated *in vitro* embryos or gametes should be set out in guidelines developed by ACART, rather than regulations?**

**Yes/ No**

Please give reasons for your views.

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**Question 13:**

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**Do you agree that it is necessary to prescribe requirements for informed consent in regulations?**

**Yes/No**

Please give reasons for your views.

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**Question 14:**

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**What specific requirements for informed consent would you like to see?**

Please give reasons for your views.



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**Question 15:**

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**Do you agree that, where written consent is not given prior to death, the use of gametes from deceased persons for reproductive purposes should be prohibited?**

**Yes/No**

Please give reasons for your views.

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**Question 16:**

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**Does the advice proposed in chapter 4 adequately address the needs, values and beliefs of Māori?**

Please give reasons for your views.

**Kei te tika ngā tohutohu e pā ana ki ngā tikanga Māori i te wahanga 4?**

Homai ou whakaarō.

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**Question 17:**

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**What are your views on the Tikanga outlined in Appendix 2?**

Please give reasons for your views.

**He aha ōu whakaarō mo te Tikanga i roto te tāpiritanga 2?**

Homai ou whakaarō.

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**Question 18:**

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**Are there any other Tikanga that ACART should take into consideration?**

Please give reasons for your views.

**He Tikanga ano hei whakaarohanga mā ACART?**

Homai ou whakaarō.

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**Question 19:**

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**Do you have any further comments to make that have not been covered in the questions set out above?**

