Advisory Committee on Assisted Reproductive Technology

Consultation with the Minister of Health in respect of Guidelines on Embryo Donation

May 2008

Subject:	**EMBRYO DONATION**	
Date:	29 MAY 2008	**File Ref:** AD20-86-10
Attention:	HON STEVE CHADWICK, ASSOCIATE MINISTER OF HEALTH	

ADVICE AND RECOMMENDATIONS

Guidelines

ACART recommends that you:

(a)	**Note** the contents of this paper and its four appendices: • Appendix A: Background to this paper • Appendix B: Proposed Guidelines on Embryo Donation • Appendix C: Summary of submissions • Appendix D: Membership of ACART	Noted
(b)	**Note** that the new guidelines for embryo donation were approved by ACART on 9 May 2008 and will be issued by ACART following consultation with you.	Noted

Related issues: Communications

ACART recommends that you:

(c)	**Agree** to ACART publishing on its website this report to you	Yes/No
(d)	**Note** that ACART intends to publish the summary of submissions (Appendix B) in hard copy and on its website following consultation with you.	Noted

Sylvia Rumball

Sylvia Rumball
Chair, Advisory Committee on Assisted Reproductive Technology

Minister's signature:

Date:

PAPER

1. The purpose of this paper is for the Advisory Committee on Assisted Reproductive Technology (ACART) to consult with you over guidelines on embryo donation. ACART is an independent body and its functions include providing the Minister of Health with advice on aspects of, or issues arising out of, kinds of assisted reproductive procedures or human reproductive research.

2. Another function of ACART is to issue guidelines and advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on assisted reproductive procedures and human reproductive research. ACART is required, under section 41(2) of the Human Assisted Reproductive Technology Act 2004 (HART Act), to consult with the Minister of Health on proposed guidelines before issuing them to ECART.

3. Appendix A provides you with a background to the development of the proposed guidelines on embryo donation. These were approved by ACART on 9 May 2008, and are attached as Appendix B.

4. Development of the guidelines included consultation with interested parties and members of the public. The feedback is summarised in Appendix C.

5. The majority of submissions sought clarification of wording and inclusion of further detail. There were differing views about whether consent should be in writing; whether donation should be limited to one family; and whether embryos created from donated gametes should be able to be donated.

6. Issues raised outside the scope of the guidelines included concerns about the creation of surplus embryos through in vitro fertilisation treatment, and the need for education on embryo donation for users of fertility services and the public.

7. ACART's development of the guidelines reflected consideration of feedback, as well as its own further thinking. The guidelines provide for consent that is not in writing, as this is a general principle of law, and also provide for agreement between parties on storage and disposal of surplus embryos.

8. In response to specific feedback, ACART determined that increasing the potential for full genetic siblings in more than two families is not appropriate because of psycho-social, genetic, and medical risks for siblings in multiple families in a small population. The guidelines do not include provision for donation of embryos created from donated gametes because the use of donated eggs in conjunction with donated sperm is being considered in a separate workstream.

9. ACART also incorporated further thinking on informed consent into the guidelines. Informed consent is also being considered in a separate workstream. ACART has noted that public education is necessary to ensure that the option of embryo donation is known about in the wider community.

10. The guidelines provide for embryo donation as a means to address infertility. The views of many submitters indicate that a shift towards making embryo donation available for other reasons may be appropriate in the future. ACART will monitor this issue.

11. ACART has decided to include a requirement for police vetting for embryo recipients, in place of the current criminal record check. This responds to advice from the Police that vetting would assist the process of informed decision-making for donors, contribute to protecting the health and well-being of children born from assisted reproductive procedures, and be in line with other legislation and the adoption process.

Appendix A

Background to this Paper

1. Section 35(1)(a) of the Human Assisted Reproductive Technology Act 2004 (HART Act) provides that one of the functions of the Advisory Committee on Assisted Reproductive Technology (ACART) is to issue guidelines and advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on any matter relating to any kind of assisted reproductive procedure, and to keep such guidelines under review.

2. An assisted reproductive procedure ("a procedure") is defined as a procedure performed for the purpose of assisting human reproduction that involves:

   (i) The creation of an in vitro human embryo; or

   (ii) The storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo; or

   (iii) The use of cells derived from an in vitro human embryo; or

   (iv) The implantation into a human being of human gametes or human embryos;

   but does not include an established procedure pursuant to section 6 of the HART Act.

3. Section 41(2) of the HART Act provides that ACART is required to consult on proposed guidelines with the Minister of Health before issuing guidelines to ECART.

4. Section 83 of the HART Act provides that during the interim period (which commences on the day after the date on which the Act received the Royal assent, and ends on the third anniversary of that day) the Minister may issue a requirement requiring ECART to treat specified provisions of any document as guidelines issued by ACART.

5. On 2 August 2005 the Minister issued a requirement to ECART to treat the guidelines prepared for providers of fertility services by the National Ethics Committee on Assisted Human Reproduction ("the interim guidelines") as guidelines issued by ACART. The interim guidelines were prepared prior to the HART Act coming into force.

6. Pursuant to section 83 of the HART Act, the interim guidelines expired on 22 November 2007.

7. On 25 October 2007 ACART provided the former Minister of Health with a report outlining the background to the development of new guidelines for ECART under the HART Act. That report also consulted with the former Minister on guidelines for surrogacy arrangements involving providers of fertility services and guidelines on gamete donation between certain family members.

8. The Ministry of Health has advised that, while in its opinion the current provisions of the HART Act do not provide for the possibility of extending the interim period in section 83 beyond 21 November 2007, the HART Act allows ACART to reissue the interim guidelines in the form of “advice”.

9. ACART therefore issued the interim guidelines on embryo donation as advice to ECART on 22 November 2007.

Appendix B

Proposed Guidelines on Embryo Donation for Reproductive Purposes

1. When considering an application for embryo donation, ECART must be guided by the principles of the Human Assisted Reproductive Technology Act 2004:

   Section 4: Principles

   All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function:

   (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure:

   (b) the human health, safety, and dignity of present and future generations should be preserved and promoted:

   (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures:

   (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent:

   (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins:

   (f) the needs, values, and beliefs of Māori should be considered and treated with respect:

   (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

2. When considering an application for embryo donation:

   (a) ECART must determine that:

      (i) The embryos being donated are:

         - Existing embryos created as part of the donors' own IVF treatment.
         - Created from the donors' own gametes.
         - Surplus to the donors' own reproductive needs.

      (ii) Embryo donation is limited to producing full genetic siblings in no more than two families.

(iii) The recipient or the recipient's partner has a medical condition affecting his or her reproductive ability, or a medical diagnosis of unexplained infertility, that makes embryo donation appropriate.

(iv) The profile/s provided by the recipients for the donors include/s any police vetting information.

(v) Donor(s) and recipient(s) have received independent legal advice.

(vi) Legal reports indicate that the parties understand the legal issues associated with embryo donation.

(vii) There has been discussion, understanding, and agreement between the parties on matters relating to the use and storage of embryos and disposal of any unused embryos.

(viii) The parties understand that donors have the right to vary the agreed terms of donation or withdraw from the donation until the embryos have been placed in the uterus of the recipient woman.

(ix) Each party has received counselling in accordance with the Code of Practice for Assisted Reproductive Technology Units, or, when it comes into effect, the current Fertility Services Standard.

(b) ECART must take into account all relevant factors, including:

(i) Whether the donors have completed their family.

(ii) Whether there is written consent to the embryo donation.

(iii) Whether counselling has:

- Included implications counselling for all parties.
- Included joint counselling.
- Been culturally appropriate.
- Provided for whanau / extended family involvement.
- Provided for the inclusion of any children of the parties.

(iv) Whether counselling will be accessible to all parties throughout the donation process.

(v) Whether the residency of the parties safeguards the well-being of all parties, and especially any resulting child.

(vi) Whether the donors have been subjected to coercion or pressure.

(vii) Whether all parties have considered and discussed the implications of the following, and, in the professional opinion of counsellor/s and/or medical specialists, have understood:

- The rights and needs of any resulting child/ren, including their rights to access information about their genetic origins and contact the donors.
- Each other's needs, wishes, expectations, and plans regarding ongoing contact and information sharing.

- Any specific issues that may affect the health and well-being of any of the parties, and especially any resulting child.
- Each other's attitudes to openness about the donation, especially with any resulting child.
- The implications of any resulting child being born with disabilities or genetic disorders.
- The implications of possible termination of the pregnancy by the recipient/s.
- Issues relating to storage, use, and disposal of embryos.
- The requirements regarding information sharing under the Human Assisted Reproductive Technology Act 2004.
- That embryos may not be able to be refrozen if donors decide to withdraw from the donation after embryos have been thawed.
- Their reasons for wishing to donate and receive embryos.
- Their feelings now, and feelings they may experience in the future, concerning the donation of embryos.
- The impact of donating embryos on their existing child/ren.

Appendix C

Summary of Submissions on Embryo Donation for Reproductive Purposes

Introduction

On 6 July 2007 the Advisory Committee on Assisted Reproductive Technology (ACART) released a discussion document, *Advice on Aspects of Assisted Reproductive Technology: A consultation paper on policy issues*.

It included draft guidelines on surrogacy arrangements involving providers of fertility services, donation of gametes between certain family members, embryo donation, and pre-implantation genetic diagnosis (PGD), as well as proposed parameters for advice on related issues, including use of donated eggs and donated sperm, embryo splitting, import and export of donated gametes and embryos, and informed consent.

The discussion document was mailed to 272 individuals and groups that had previously registered interest with ACART, including government agencies, regional Te Puni Kōkiri offices, researchers, academics, providers of fertility services, fertility consumer groups, ethics committees, bioethics organisations and religious groups, and was emailed to other government agencies and organisations.

The consultation process was advertised in all major metropolitan newspapers on Wednesday 15 August 2007 and Saturday 18 August 2007, and in the *Sunday Star-Times* on 26 August 2007. A press release was sent out to 60 news outlets, including all radio and television stations.

ACART held consultation meetings with provider staff and representatives from Fertility NZ throughout August 2007.

A hui was held on 13 August 2007 and a public oral submissions hearing was held on 5 September 2007, both in Wellington.

Submissions closed on 7 September 2007. ACART received 48 submissions, including four oral submissions.

This document summarises the submissions received on the draft guidelines for embryo donation.

Embryo Donation for Reproductive Purposes

The majority of submissions supported embryo donation for reproductive purposes remaining an assisted reproductive procedure (ARP).

Reasons stated for supporting ethical review included:

- The procedure is very new.
- The need for "intense counselling" for couples.
- Case-by-case consideration [by ECART] is useful and should be continued with the intention of developing guidelines for clinics to use for straightforward scenarios. A target should be set for the number of cases that need to be reviewed before clinical guidelines can be developed (e.g. 20-30 cases).

Submitters who did not support ethical review stated that:

- Ethical review of every case is not necessary, but there should be an appeals process available.
- Ethical review is not necessary because it is a medical decision whether recipients need donor embryos.

Other comments and suggestions included:

- Embryo donation is "too much" for some people (because of the requirement to meet recipients and have counselling, and the impact on their children having full siblings).
- ACART should develop a "family lens" to take account of the collective interests of families and wider implications for whanau of assisted reproductive procedures.
- Couples with strong views about the status of embryos are particularly likely to be interested in embryo donation.

Responses to Question 3: What are your views on the proposed guidelines for embryo donation?

While there was a level of support for the guidelines, many submitters sought clarification of different aspects of the draft wording and further details of certain requirements, including counselling and medical and legal advice.

The majority of the submissions focused on one or more of the areas outlined below.

Counselling

Submissions on the counselling provisions for embryo donation included:

- Counselling should be available after the birth of the child.
- Joint counselling should not be mandatory where couples wish to make an "unconditional gift" of their embryos.

- The guidelines should specify that counselling must address issues around surplus embryos and disposal of embryos, so that couples understand that they have the option of donating to research, and that if they are donating to another couple it is clear who has the right of disposal.

Health and well-being of children

Many submitters considered that the guidelines should include provisions relating to children born from embryo donation. Suggestions included:

- Contact arrangements should be provided for.

  Suggestions for this ranged from a minimal arrangement involving a card and photo once a year, to provision for visitation during childhood. One submitter thought that the child should know the extended family of the donors, and others thought that the children of the donors and recipients should know each other.

- The potential impact on children should be addressed.

  Suggestions included providing for the child's rights by appointment of an advocate for the child; addressing the psychological effects on the child; a requirement for follow-up by child health providers; and stating that the potential child's rights are paramount in the guidelines.

- Counselling should involve donors and recipients meeting to discuss the children.

- The guidelines should include reference to the information-keeping provisions in the HART Act to ensure that children find out about their genetic origins.

Some submitters wanted more information about the impact on children born from embryo donation, stating that it should be possible to find this out from child psychologists or adoption research.

One submitter suggested that the age gap between potential offspring should be a consideration when determining if donation is appropriate.

Donation to more than one family

Many submitters considered that donation to more than one family should be permitted. The most commonly cited support for this was that adoption is not restricted to one family. Other reasons included that donor sperm is used more widely; that in Australia donation is permitted to more than one family; and that allowing donation to more than one family would afford donors and recipients the same rights as the general population.

Other submitters supported the restriction of donation to one family, noting that New Zealand's small population makes this appropriate.

One submitter suggested that provision needs to be made to ensure that donation has not occurred in any other jurisdiction.

Embryos from donated gametes
A number of submitters considered that embryos from donated gametes should be able to be donated if there was consent from the gamete donors.

Need for written consent
Requiring written consent for embryo donation was considered too restrictive by many submitters. Reasons cited included that it ignores the possibility of eyewitness testimony and that it imposes a higher standard than for medical procedures.

Donation when one partner is deceased
A number of submitters wanted embryos to be able to be donated without written consent if one donor was deceased. It was suggested that donors be given the option of relinquishing their decision to their surviving partner.

Other submitters did not support donation where one parent was deceased, irrespective of whether there was written consent, because of the needs of the potential child.

One submitter requested clarification on what happens if the recipients die, suggesting an additional guideline allowing ECART to be provided with evidence of agreement for storage.

Surplus embryos
Surplus embryos were a concern for many submitters. One submitter said "[i]t is tragic that procedures that result in the production of 'surplus' embryos… have been permitted at all. But donation … is better than destroying them … Within those considerations I believe the [embryo donation] guidelines are good and necessary."

Many other submitters suggested that surplus embryos should not be created in the first place and emphasis should be placed on this by ACART. Comments included that:

- Viewpoints are often clouded when decisions are made, meaning patients may not have properly considered the outcome (of having surplus embryos).
- The issue of surplus embryos is not discussed enough with patients.
- Some people will not consider donating embryos because to them, they are the children that they have tried so hard to have. They may find donation to research an option, but many will just wait the 10 years [the maximum period permitted for storage] as they do not know what else to do.
- Some religious couples create only the number of embryos that they will need – i.e. they use all their embryos.

Some submitters considered that embryo donation should be more widely available, and questioned why fertile couples could not be embryo donors or recipients. Other submitters considered that the option of embryo donation should be more widely communicated so that, for example, couples applying to adopt are advised of this option.

Education
Education was a key topic for many submitters who had been through IVF treatment personally. The general theme was that education was required so that patients and the general public would have a better understanding of embryo donation. Comments included:

- Education is important for people to make better-informed decisions.
- Normalising these issues for children from the outset is important and parents need to be educated that it is better for the child to know their genetic origins.
- There are thousands of surplus embryos in freezers, and people need to be educated that it is acceptable and possible to donate them.
- An equivalent of adoption "open days" could be run for people to come together and share their experiences.

One submitter suggested that embryo donation is becoming more common in Australia and that it will probably also become more common in New Zealand.

Opposition to the guidelines
Submitters who did not support the guidelines ranged from those who were opposed in principle, suggesting that donation of embryos was commodification and akin to donating a human being, to those who considered that the guidelines were unnecessarily cautious and that embryo donation should not be subject to ECART approval because the interim (NECAHR) guidelines are detailed and set out a careful process which could be followed by providers of fertility services.

Other concerns
Other issues raised included:

- Concern around the donation process, including that there is a mismatch between donors and recipients, in that if recipients assert their wishes there is a perception that they may lose their donors; that donors get to see all the recipients' details, making potential recipients very nervous about getting chosen; and that more stringent screening provisions should be in place for recipients.
- Embryo donors should have their own children before being permitted to donate.
- Issues around informed consent, including concerns that consent given under duress or pressure (particularly with regard to the creation of surplus embryos) may not be informed consent.
- A minimum number of embryos for donation could be considered, as many couples have only one embryo in storage. On the other hand, the viability of the embryos should also be considered.

Appendix D

Membership of ACART

Lay Members	**Expertise / Perspective**
Professor Sylvia Rumball (Chair, ACART)	Ethics
Professor Ken Daniels (Deputy Chair, ACART; Chair, Treatment Working Group)	Policy
John Forman	Disability
Dr Ian Hassall	Representative of the Commissioner for Children
Professor Mark Henaghan	Law
Cilla Henry	Maori
Maui Hudson	Maori
Professor Gareth Jones	Ethics
Christine Rogan	Consumer
Robyn Scott	Consumer
Non-lay members	
Dr Richard Fisher	Assisted Reproductive Procedures
Associate Professor Andrew Shelling	Human reproductive research