



Advisory Committee on Assisted Reproductive Technology

**Annual Report
2006–2007**

Including the 2006/07 Annual Report of
the Ethics Committee on Assisted
Reproductive Technology



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Part One: 2006/07 Annual Report of the Advisory Committee on Assisted Reproductive Technology

Chair's Foreword

It is with pleasure that I submit the second annual report of the Advisory Committee on Assisted Reproductive Technology (ACART) to the Minister of Health.

During the 2006/07 fiscal year, the Committee has furthered its work programme as defined under the Human Assisted Reproductive Technology Act 2004 (the HART Act).

The Committee undertook extensive public consultation and presented the Minister of Health with advice on human reproductive research on 30 June 2007. The submissions made to the Committee were assessed within a larger analysis that informed ACART's advice. Other factors taken into account included the potential scientific and medical benefits, international literature on the ethics of embryo research, New Zealand policy and practice in related areas, and policy and practice in other jurisdictions. In forming its advice, ACART was also guided by the principles of the HART Act.

Significant work has been undertaken in preparation for public consultation in late 2007 as an input to ACART's advice to the Minister of Health on assisted reproductive procedures. Work has also started on developing advice on the use of previously cryopreserved eggs and establishing a monitoring regime.

Another focus for the Committee has been on maintaining relationships – with the Minister of Health, the Ministry of Health, the Ethics Committee on Assisted Reproductive Technology, and other ethics committees. In particular, ACART and Toi te Taiao: the Bioethics Council worked together on embryo research, with Toi te Taiao facilitating public dialogue in the lead-up to ACART's consultation on human reproductive research. ACART has also worked to develop its relationship with Māori, to ensure that its consultation processes are effective for Māori.

I appreciate the significant contribution of all Committee members to the work programme over 2006/07, and look forward to the challenges ahead.

Sylvia Rumball

Chair, Advisory Committee on Assisted Reproductive Technology

Purpose of this Report

Section 42(3) of the Human Assisted Reproductive Technology Act 2004 (the HART Act) requires the Advisory Committee on Assisted Reproductive Technology (ACART), as soon as practicable after each 12-month period ending on 30 June, to give the Minister of Health a report on:

- its progress in carrying out its functions
- the number and kinds of decisions given by the Ethics Committee on Assisted Reproductive Technology (ECART) in that period.

Background

The HART Act

The HART Act provides a legislative framework that prohibits some procedures, 'establishes' others and requires that others be subject to ethical review. It identifies areas where further advice is required, as well as procedures for developing this advice.

The HART Act established two committees: the Advisory Committee on Assisted Reproductive Technology and the Ethics Committee on Assisted Reproductive Technology.

ACART's functions

ACART's functions, as set out in section 35 of the HART Act, are to:

- issue guidelines and advice to ECART on any matter relating to any kind of assisted reproductive procedure or human reproductive research, and keep such guidelines and advice under review
- advise the Minister of Health on aspects of, or issues arising out of, kinds of assisted reproductive research and, without limitation, advice as to whether:
 - the HART Act or another enactment should be amended to prohibit or provide for any kind of assisted reproductive procedure or human reproductive research
 - any kind of procedure or treatment should be declared an established procedure on the basis of the information, assessment, advice and ethical analysis required under section 6 of the HART Act
 - any established procedure should be modified or should cease to be an established procedure
 - a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research
 - regulations should be made under section 76 of the HART Act to regulate the performance of any kind of assisted reproductive procedure or the conduct of any kind of human reproductive research
- liaise with the ethics committee on general and specific matters relating to assisted reproductive procedures or human reproductive research
- consult with anyone who, in the opinion of ACART, is able to assist it to perform its functions
- perform any other function that the Minister of Health assigns to it by written notice.

For the purposes of performing the above functions, ACART must monitor:

- the application, and health outcomes, of assisted reproductive procedures and established procedures
- developments in human reproductive research.

ECART's functions

ECART's role is to consider and determine 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 or advice given by ACART.

Work Programme

The HART Act

ACART's work programme over the past year has been largely defined by requirements set out in the HART Act.

Section 37 requires ACART to provide the Minister of Health with information, advice and, if it thinks fit, recommendations on the following matters in relation to the use of gametes and embryos in human reproductive research:

- cloned embryos
- donations of human embryos
- genetic modification of human gametes and human embryos
- human gametes derived from fetuses or deceased people
- hybrid embryos
- requirements for informed consent
- the import into or export from New Zealand of in vitro human gametes or embryos.

Section 38 requires ACART to provide the Minister of Health with information, advice and, if it thinks fit, recommendations on the following matters in relation to human assisted reproductive technology:

- donation of embryos
- embryo splitting
- gametes derived from deceased people
- requirements for informed consent
- selection of embryos using pre-implantation genetic analysis
- the import into or export from New Zealand of in vitro donated cells or embryos.

In addition, the Minister of Health has asked for advice on the use of eggs and ovarian tissue that have been previously cryopreserved. While cryopreservation of eggs and ovarian tissue are established procedures under the HART Act, they cannot be subsequently used.

Currently, ECART considers applications for approvals for assisted reproductive procedures or human reproductive research based on interim guidelines. These interim guidelines cover:

- in vitro fertilisation (IVF) surrogacy
- storage, use and disposal of sperm from a deceased man
- within-family gamete donation
- pre-implantation genetic diagnosis
- embryo donation for reproductive purposes
- research on gametes and non-viable embryos.

Under the HART Act, these interim guidelines lapse in November 2007. ACART must, therefore, have advised the Minister of Health on human reproductive research and assisted reproductive procedures, and any new requirements must be in place by November 2007.

ACART's advice to the Minister of Health may include recommendations that aspects of human reproductive research and assisted reproductive procedures be:

- prohibited
- placed under a moratorium
- allowed to proceed subject to review by ECART on the basis of any requirements agreed to by the Minister of Health and set out in new guidelines
- declared established procedures and able to proceed without ECART review.

Progress made in 2006/07

ACART was established in August 2005. Additional members were appointed during the 2006/07 fiscal year to bring its membership up to 12.

Over 2006/07 ACART has further developed its work programme to ensure that it fulfils its requirements under the HART Act.

ACART has established the following workstreams:

1. advice to the Minister of Health on human reproductive research (as required under section 37 of the HART Act)
2. advice to the Minister of Health on assisted reproductive procedures (section 38) and guidelines and advice for ECART (section 35(1)(a))
3. advice to the Minister of Health on new assisted reproductive procedures (section 6)
4. establishment of monitoring regimes (sections 35(2), 30, 42(3)(b))
5. advice to the Minister of Health on how to respond to aspects of human reproductive research and assisted reproductive procedures (section 35(1)(b))
6. governance
7. administration.

Progress on these workstreams and on other work undertaken by ACART during 2006/07 is outlined below.

Advice to the Minister of Health on human reproductive research

Section 37 of the HART Act requires ACART to advise the Minister of Health on future policy for human reproductive research in New Zealand.

On 15 December 2006 ACART issued a public discussion paper entitled *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand*. Submissions closed on 2 March 2007.

ACART received 345 written submissions, and heard nine oral submissions at meetings in Wellington and Auckland in early March 2007. In addition, approximately 160 people attended eight public consultation meetings, hui and fono. New Zealanders held a wide range of views on the use of gametes and embryos in human reproductive research. Views varied not only across the population as a whole, but also within specific social, cultural and ethnic groups.

In forming its advice, ACART was guided by the principles of the HART Act. With regard to the submissions it received, ACART considered both the strength of public opinion and the strength of the arguments made. It took account of the submissions within a larger analysis that informed its advice to the Minister of Health. Other factors taken into account include the potential scientific and medical benefits, the international literature on the ethics of embryo research, New Zealand policy and practice in related areas, and policy and practice in other jurisdictions.

ACART provided the Minister of Health with advice on human reproductive research on 30 June 2007. Further information on ACART's advice and the response of the Minister of Health will be available from ACART's website.

Advice to the Minister of Health on assisted reproductive procedures

Section 38 of the HART Act requires ACART to advise the Minister of Health on future policy for assisted reproductive procedures in New Zealand.

During the 2006/07 fiscal year ACART undertook a substantial amount of work to prepare a discussion paper, *Advice on Aspects of Assisted Reproductive Technology: A Consultation Paper on Policy Issues*. This consultation paper includes draft guidelines for the review of assisted reproductive procedures.

The discussion document on aspects of assisted reproductive technology will be released for public consultation on 6 July 2007, with a closing date for submissions of 17 August 2007. ACART will also be hearing oral submissions. ACART will advise the Minister of Health on future assisted reproductive technology policy in late 2007.

Advice to the Minister of Health on new assisted reproductive procedures

Cryopreservation of eggs and ovarian tissue are established procedures under the HART Act. Under the current legislative regime, however, although eggs and ovarian tissue can be preserved in this manner, they cannot be used subsequently.

The Minister of Health has asked that ACART give priority to preparing advice on the use of eggs and ovarian tissue that have been previously cryopreserved. To date, ECART has received one application for the use of previously cryopreserved eggs. In the absence of guidelines, ECART has referred the issue to ACART.

ACART intends to use the issue of previously cryopreserved eggs to pilot a methodology for considering new assisted reproductive procedures. After this pilot, it will consider the use of previously cryopreserved ovarian tissue and in vitro maturation.

The methodology is set out in section 6 of the HART Act, which deals with the provision of advice on declaring a new established procedure. It seems reasonable that any new assisted reproductive procedure should be considered as a potential established procedure and, therefore, submitted to the rigorous process set out in section 6. In this process, ACART must provide the Minister of Health with a report that sets out:

- information about the procedure or treatment
- an assessment, drawn from the published and peer-reviewed research, of the known risks and benefits to health of the procedure or treatment
- advice as to whether, in its expert opinion, the known risks to health of the procedure or treatment fall within a level of risk that is acceptable in New Zealand

- an ethical analysis of the procedure or treatment
- advice as to whether, in its expert opinion, the Minister should recommend that the procedure or treatment be declared an established procedure.

ACART has commissioned a report summarising the techniques involved in cryopreserving and using cryopreserved eggs and the outcomes from using cryopreserved eggs. ACART has commenced its analysis as set out above.

ACART intends to consult on the use of cryopreserved eggs in late 2007 and advise the Minister on policy for their use by the end of 2007.

Establishment of monitoring regimes

Section 35(2) of the HART Act requires ACART to monitor the application and health outcomes of assisted reproductive procedures and established procedures, and developments in human reproductive research. In order to fulfil its functions, ACART must also monitor developments in assisted reproductive technology.

In addition, ACART's Terms of Reference require it to monitor the decisions of ECART to ensure that they fall within the guidelines, as set by ACART. To assist in this monitoring process, section 30 of the HART Act requires ECART, as soon as practicable after it has granted an approval, to give ACART a copy of the approval and the relevant proposal. Section 42(3)(b) of the HART Act requires ACART to report in its annual report on the number and kinds of decisions given by ECART during the year.

At present, ACART monitors the application of assisted reproductive procedures through requiring clinics to submit an annual return reporting progress on applications approved by ECART. The application of assisted reproductive procedures in New Zealand from 1 June 2006 to 30 June 2007 is set out in Appendix 1. This information is limited to those procedures that require ECART review. ACART has also asked clinics to list procedures that they may be interested in pursuing in the future. One clinic reported the need to consider third-party donation in surrogacy, such as surrogacy with a donated egg or a donated embryo.

The outcomes of assisted reproductive procedures are currently monitored through self-reporting by fertility clinics, which submit information on all babies born as a result of assisted reproductive technology to the Australia and New Zealand Assisted Reproductive Database (ANZARD). This information feeds into Australia's National Perinatal Statistics Unit annual report.

ACART currently monitors ECART's decisions through receiving a copy of those decisions and related applications, and through its Chair's ex officio attendance at ECART meetings.

In addition, ACART refers to the international literature to monitor the application and health outcomes of assisted reproductive procedures and developments in assisted reproductive technology and human reproductive research.

A comprehensive approach to monitoring is currently being developed.

Advice to the Minister of Health on how to respond to aspects of human reproductive research and assisted reproductive procedures

ECART referred the issue of menopause as a medical condition to ACART for its consideration. ACART intends to add the issue of age and assisted reproductive technology to its future work programme.

Governance

The governance workstream focuses on the development and maintenance of ACART's internal policies and its relationships with external parties.

Communications is a key area of work within the governance workstream. The following activities in this area were undertaken during the 2006/07 fiscal year.

Conference presentations

The Chair gave a presentation on the *Development of Policy Advice concerning the Use of Gametes and Embryos in Human Reproductive Research* to the Medico Law Conference in Wellington, New Zealand, held on 11–12 April 2007.

Conference attendance

ACART members and/or Secretariat members attended the following conferences:

- Fertility Society of Australasia Annual Meeting in Sydney, Australia, 22–25 October 2006
- University of Sydney Law School seminar on Law and Genetics in Sydney, Australia, 24 November 2006
- International Federation on Fertility and Sterility 19th World Congress on Fertility and Sterility in Durban, South Africa, 29 April – 3 May 2007
- Medico Law Conference in Wellington, New Zealand, 11–12 April 2007
- Human Fertilisation and Embryology Authority Annual Conference, London, United Kingdom, 5 June 2007.

Panel discussions

The Chair and various Committee members participated in three panel discussions as part of the consultation on human reproductive research on 8, 13 and 27 February 2007.

Media interactions

The Chair had media interviews about the consultation on human reproductive research as follows:

- a Māori TV documentary (in which Mihi Namana was also interviewed), 9 February 2007
- a *Sunday Star Times* feature article, 16 February 2007
- a *Dominion Post* health feature article, 14 February 2007
- Newstalk ZB, 7 February 2007
- Newstalk ZB, 8 February 2007
- Radio Live, 7 February 2007.

Website

In relation to the Committee's work, the ACART website serves as a key point of contact with fertility service providers, consumers and other interested parties. It has been used extensively during public consultation for the distribution of the consultation document, contact with the Secretariat, provision of details of public meetings, fono and hui, and media releases.

During the 2006/07 fiscal year ACART revised its website to make it more user-friendly. It also adopted a new address – www.acart.health.govt.nz.

Administration

The administration workstream involves the day-to-day operations of ACART as well as annual activities, such as the preparation and release of the annual report.

Other work

The Chair was invited to represent ACART on the Joint Accreditation System of Australia and New Zealand Technical Committee. The first meeting is scheduled for 11 July 2007.

ACART Membership

Table 1: A summary of ACART members

	Expertise / perspective	Year that term of office expires (beginning 23 June)
Lay members		
Prof Sylvia Rumball (Chair)	Ethics	2008
Prof Ken Daniels* (Deputy Chair)	Policy	2009
Prof Gareth Jones	Ethics	2008
Dr Mavis Duncanson	Office of the Commissioner for Children	Resigned November 2006
Christine Rogan	Consumer	2008
David Tamatea	Māori	2007
Mihi Namana	Māori	2007
John Forman	Disability	2007
Philippa McDonald	Law	2007
Prof Mark Henaghan*	Law	2009
Non-lay members		
Assoc Prof Andrew Shelling*	Human reproductive research	2009
Dr Richard Fisher	Assisted reproductive procedures	2007

* Appointed 23 August 2006.

Table 1 summarises the membership of ACART during the 2006/07 fiscal year, along with each member's area of expertise and expiry date of term of office. Further biographical information is contained in Appendix 4.

Table 2: Member attendance at ACART meetings 2006/07

Member	Meetings attended							Total
	14 July 2006	8 September 2006	24 November 2006	9 February 2007	13 April 2007	11 May 2007	8 June 2007	
Sylvia Rumball (Chair)	X	X	X	X	X	X	X	7/7
Ken Daniels (Deputy Chair)	NA	X	X	X	X	X	X	6/6
Gareth Jones	A	X	X	X	A	X	X	5/7
Mavis Duncanson	X	X	X	NA	NA	NA	NA	3/3
Christine Rogan	X	X	X	X	X	X	X	7/7
David Tamatea	X	X	X	X	X	X	X	7/7
Mihi Namana	X	X	A	A	X	X	X	5/7
John Forman	A	X	X	X	X	X	X	6/7
Philippa McDonald	X	X	X	X	X	X	X	7/7
Mark Henaghan	NA	X	X	X	X	X	X	6/6
Andrew Shelling	NA	X	X	X	X	A	X	5/6
Richard Fisher	X	X	X	X	X	X	A	6/7
Total members present	7/9	12/12	11/12	10/11	10/11	10/11	10/11	

NA Not appointed

A Apologies

X Present

Secretariat members

Ian Hicks	Analyst (August 2005 – present)
Willow Mckay	Analyst (October 2005 – present)
Barbara Nicholas	Contractor (until August 2006)
Sally Stewart	Senior Analyst (August 2006 – present)

Ethics Committee Decisions

This report covers ECART's decisions for the 2006/07 fiscal year.

Between 1 July 2006 and 30 June 2007, ECART considered 15 full applications and one Stage 1 application for IVF surrogacy; five applications for within-family gamete donation; one application for embryo donation for reproductive purposes; and one application for the use of sperm from a deceased man. The details of these decisions are set out in Appendix 1.

Applications were received from five of the six fertility clinics in New Zealand.

In total, 19 of the applications that ECART considered were approved. Of this total, 11 were approved outright, six were approved subject to conditions and two were deferred and subsequently approved.

The primary reason for which ECART deferred applications was to receive more information from the principal medical specialist about the birth mother's medical condition that precludes normal reproduction.

ECART declined two applications; one for surrogacy and one for the use of sperm from a deceased man. The primary reasons for declining the applications were that:

- informed consent had not been properly collected
- not all the parties involved were permanently resident in New Zealand
- there were concerns for the wellbeing of any future child
- the parties involved had known each other for a limited period
- there were concerns in regard to the motivations of some of the parties involved.

ECART reviewed one application for within-family gamete donation where it did not have the authority to make a decision as the application was for an established procedure under the HART Act.

ECART also referred the issue of whether menopause falls under the definition of a medical condition to ACART for its consideration.

Appendix 1: Applications Considered by ECART 2006/07

Procedure	Date first reviewed	Date of final decision	Decision	Date commenced	Comment
Within-family gamete donation	13/06/06	15/08/06	Deferred (13 June 2006) to seek legal advice on ECART's jurisdiction to consider this application – as it involved the use of donated sperm in conjunction with donated eggs. Subsequently approved subject to further counselling and legal advice due to the complex nature of the application.	October 2006	Opted to have treatment in Australia. Twin pregnancy.
IVF surrogacy	15/08/06	15/08/06	Approved.	November 2006	Fresh single embryo transfer. Pregnant.
IVF surrogacy	15/08/06	13/03/07	Approved subject to: <ul style="list-style-type: none"> the children of intending father be involved in implications counselling prior to treatment commencing not more than one fresh embryo be transferred, or not more than two frozen embryos be transferred, due to the increased risk to the birth mother. <p>The second condition was reviewed at two later meetings (10/10/07 and 28/11/06); and was varied to approve the transfer of two fresh embryos to the surrogate mother provided:</p> <ul style="list-style-type: none"> the surrogate mother still consents to the surrogacy arrangement after she has received advice, from a suitably qualified medical practitioner who is independent of the intending parents and the supervising medical team, on the likelihood of twins and the possible harm and negative consequences – to herself and the twins – associated with such a transfer. 	March 2007	Fresh embryo transfer, thaw of frozen embryos. Not pregnant.
Within-family gamete donation	10/10/06	10/10/06	Approved.	March 2007	No pregnancy and no embryos stored.
IVF surrogacy	10/10/06	10/10/06	Approved subject to the birth mother being given further legal advice about her legal situation if the intended parents do not adopt the child.	May 2007	Thawed embryo transfer. Pregnant.

Procedure	Date first reviewed	Date of final decision	Decision	Date commenced	Comment
Within-family gamete donation	10/10/06	28/11/06	Deferred to request more information from the medical specialist about the birth mother's medical condition that precludes normal reproduction or unexplained infertility that has not responded to other treatments. Subsequently approved.	May 2007	Single embryo transfer. Pregnant.
IVF surrogacy	10/10/06	10/10/06	Approved.	February 2007	Fresh embryo transfer, no spare embryos. Not pregnant.
The use of sperm from a deceased man	28/11/06	28/11/06	Declined due to the intending mother not residing in New Zealand and consent not having been obtained from the deceased man.	N/A	
IVF surrogacy	28/11/06	28/11/06	Approved.	March 2007	Three embryo transfers. No pregnancy.
IVF surrogacy	28/11/06	28/11/06	Approved.	Not commenced	Waiting for birth mother's hormones to settle down.
Within-family gamete donation	28/11/06	28/11/06	Approved.	May 2007	Donor insemination and positive pregnancy.
IVF surrogacy	28/11/06	28/11/06	Approved subject to the intending parents meeting with Child, Youth and Family, all parties being made aware of the increased risk of foetal abnormality due to the intending mother's age and further legal advice being sought by the intending parents.	Due to start late 2007	
IVF surrogacy	13/03/07	13/03/07	Approved.	April 2007	Surrogate pregnant – single foetal heart on scan.
IVF surrogacy	13/03/07	13/03/07	Approved subject to changes to the Surrogacy agreement.	April 2007	Outcome unsuccessful. Plans to begin second IVF cycle.
Embryo donation for reproductive purposes	13/03/07	13/03/07	Approved.	June 2007	Single embryo transfer. Pregnant – yet to have a scan.
IVF surrogacy	13/03/07	13/03/07	Approved.	Not commenced	Delayed due to health of surrogate.
IVF surrogacy	8/05/07	8/05/07	Approved.	Not commenced	

Procedure	Date first reviewed	Date of final decision	Decision	Date commenced	Comment
IVF surrogacy	8/05/07	8/05/07	Approved subject to the intending parents being informed of the requirements around payment of costs in s 14 of the HART Act.	Not commenced	
Within-family gamete donation	8/05/07	8/05/07	Approved.	Not commenced	
Within-family gamete donation	8/05/07	8/05/07	ECART had no authority to review this application as it was for an established procedure under the HART Act.	N/A	
IVF surrogacy	8/05/07	8/05/07	Approved subject to the birth parents taking further legal advice on the requirements of section 14 of the HART Act; and the issue of life insurance for the birth mother.	Not commenced	
IVF surrogacy	8/05/07	8/05/07	Declined due to concerns for the wellbeing of any future child, the parties involved having known each other for a limited period, and concerns in regard to the motivations of some of the parties involved.	N/A	
IVF surrogacy	8/05/07	N/A	This application was for a stage one application. No final decision was made. Stage 2 application in progress.	N/A	

Appendix 2: Information on Applications

Table 3: Applications for surrogacy using *in vitro* fertilisation 1997–2007

This table sets out the numbers and outcomes of surrogacy applications between 1997 and 2007.

Year	Number approved ^{†∞}	Number declined [†]	Number deferred
1997	1	0	0
1998	2	1*	4
1999	4	0	3
2000	5	1	2
2001	6	1	1
2002	1	0	3
2003	5	0	3**
2004	5 [^]	0	1
2005	15	4	0
2006	16	0	1
2007	14	1	0
Total	74	8	18

Notes

† The number of 'approved' and 'declined' applications for each year may include some applications that were deferred in previous years.

* In 1999 the National Ethics Committee on Assisted Human Reproduction considered a variation to the original application in 1998 and approved it.

** One application was subsequently withdrawn.

∞ Includes applications approved outright and applications approved subject to conditions.

[^] Includes two applications that were provisionally approved in 2004 and then granted final approval in 2005.

Table 4: Applications approved by ECART by ethnicity September 2005–May 2007

	Number in ethnic group	Total
IVF surrogacy		
Intending mother		31
European	26	
Asian	5	
Intending father		31
European	31	
Birth mother		31
European	25	
Māori	5	
Asian	1	
Birth father		20
European	16	
Māori	4	
Within-family gamete donation		
Recipient woman		7
European	6	
Middle Eastern	1	
Recipient woman's partner		7
European	5	
Māori	1	
Middle Eastern	1	
Donor egg		4
European	2	
Māori	1	
Middle Eastern	1	
Donor sperm		3
European	2	
Māori	1	
Embryo donation		
Donor woman		1
European	1	
Donor man		1
European	1	
Recipient woman		1
European	1	
Recipient man		1
European	1	
Total		138
European	117	
Māori	12	
Asian	6	
Middle Eastern	3	

Table 5: Summary of new applications by type of application

Year	Surrogacy	Innovative treatment	Within-family gamete donation	Embryo donation	Use of sperm from a deceased man	Clinical research	Non-clinical research	Total
1 January– 31 December 1998	6	3	–	–	–	1	–	10
1 January– 31 December 1999	4	7	–	–	–	3	–	14
1 January– 31 December 2000	6	1	–	–	–	2	1	10
1 January– 31 December 2001	4	4	–	–	–	3	–	11
1 January– 31 December 2002	4	4	–	–	–	2	1	11
1 January– 31 December 2003	6	9	–	–	–	1	2	18
1 January– 31 December 2004	6	9	–	–	–	1	1	17
1 January 2005– 30 June 2006	31	2*	4	–	–	2	–	39
1 July 2006– 30 June 2007	17	–	5	1	1	–	–	24
Total	84	39	9	1	1	15	5	154

* Referred to ACART as no guidelines existed.

Appendix 3: Terms of Reference – Advisory Committee on Assisted Reproductive Technology

The Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research ('the Advisory Committee on Assisted Reproductive Technology' or ACART) is established under section 32 of the Human Assisted Reproductive Technology (HART) Act 2004. These Terms of Reference outline the role and functions of ACART.

Functions of ACART

ACART has the following functions:

- 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 or human reproductive research and to keep such guidelines and advice under review
- to provide the Minister of Health with advice on aspects of, or issues arising out of, kinds of assisted reproductive procedure or human reproductive research and, without limitation, advice as to whether:
 - the HART Act should be amended to prohibit or provide for any kind of assisted reproductive procedure or human reproductive research
 - any kind of procedure or treatment should be declared an established procedure, on the basis of the information, assessment, advice, and ethical analysis required to declare a procedure to be an established procedure under section 6 of the HART Act
 - any established procedure should be modified or should cease to be an established procedure
 - a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research
 - regulations should be made under section 76 of the HART Act to regulate the performance of any kind of assisted reproductive procedure or the conduct of any kind of human reproductive research.
- to liaise with ECART on general and specific matters relating to assisted reproductive procedures or human reproductive research
- to consult with any persons who, in the opinion of ACART, are able to assist it to perform its functions
- any other function that the Minister of Health assigns to ACART by written notice.

For the purposes of performing the above functions, ACART must monitor:

- the application, and health outcomes, of assisted reproductive procedures and established procedures
- developments in human reproductive research.

ACART should also monitor the decisions of ECART to ensure that they fall within the guidelines as intended by ACART. If, after consideration of one of ECART's decisions, ACART considers that the decision falls outside of its guidelines, ACART should inform ECART of this.

Guiding principles

ACART shall be guided by the following principles:

- the health and wellbeing 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
- the human health, safety, and dignity of present and future generations should be preserved and promoted
- 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
- 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
- donor offspring should be made aware of their genetic origins and be able to access information about those origins
- the needs, values, and beliefs of Māori should be considered and treated with respect
- the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

Guidelines

ACART may issue guidelines to ECART only after it has:

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

When ACART issues guidelines to ECART, it must:

- give copies of the guidelines to the Minister, the Director-General of Health, to ECART, and to providers; and
- publish the guidelines on the internet and in any other publications (if any) that the Committee thinks appropriate; and
- give public notice of the issue of the guidelines by publishing in any publication that it considers appropriate for the purpose a notice that states:
 - the date and subject matter of the guidelines
 - the internet website on which they are published.

Specific advice

ACART must, within time frames agreed with the Minister, provide the Minister with information, advice, and if it thinks fit, recommendations on the following matters in relation to the use of gametes and human embryos in human reproductive research:

- cloned embryos
- donations of human embryos
- genetic modification of human gametes and human embryos
- human gametes derived from foetuses or deceased persons
- hybrid embryos
- requirements for informed consent
- the import into, or export from, New Zealand of *in vitro* human gametes or *in vitro* human embryos.

ACART must, within the time frames agreed with the Minister, provide the Minister with information, advice, and if it thinks fit, recommendations on the following matters in relation to human assisted reproductive technology:

- donations of human embryos
- embryo splitting
- gametes derived from deceased persons
- requirements for informed consent
- selection of embryos using pre-implantation genetic diagnosis
- the import into, or export from, New Zealand of *in vitro* donated cells or *in vitro* donated gametes.

ACART may give advice on the above areas only after it has:

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

Public meetings on proposed significant advice

If, in the opinion of ACART, a significant number of persons wish to make oral submissions on a proposal to give specific advice on any of the above human reproductive research or human assisted reproductive technologies, ACART must hold as many meetings as are required to enable those submissions to be made.

ACART must:

- notify the persons who wish to make oral submissions of the time and place of any meeting to be held
- publish a notice on the internet and in any other publication the committee thinks appropriate that states the time, place, and purpose of any such meeting and that will be held in public.

Consultation

Before ACART gives advice to the Minister or issues guidelines to ECART, it must consult on the proposed advice or guidelines with:

- any members of the public that the committee considers appropriate
- appropriate government departments and agencies
- any other person or group that the committee considers appropriate.

Composition and membership

The Minister may appoint any person to be a member of ACART and must, before doing so, consult any persons who, in the Minister's opinion, are able to provide advice on prospective appointees who have the required expertise and the ability to reflect relevant perspectives and concerns, including, without limitation, the perspectives and concerns of women.

Guiding principle

The primary guiding principle for appointing members to ACART is to ensure that ACART has the appropriate expertise, skills, knowledge and perspectives to provide advice and guidelines of the highest quality.

Member numbers

ACART must consist of not fewer than 8 and not more than 12 members appointed by the Minister of Health.

Lay/non-lay membership

At least half of the members of ACART must be lay members.

For the purposes of these Terms of Reference, a layperson is a person who, at no time during the person's membership of ACART or in the three years before becoming a member of ACART:

- is a health practitioner within the meaning of the Health Practitioners Competence Assurance Act 2003; or
- is involved in health research; or
- is employed by or associated with, or has a pecuniary interest in, a fertility service provider.

Ex-officio attendance

The chairperson of ACART, or a member of ACART nominated by the chairperson of ACART for the meeting may attend each meeting of the National Ethics Committee on Assisted Reproductive Technologies (ECART). The ACART member or Chair attending the Advisory Group meeting is not a member of the committee.

The chairperson of ECART, or a member of ECART nominated by the chairperson of ECART for the meeting may attend each meeting of ACART. ECART member or Chair attending the ACART meeting is not a member of the committee.

Member categories

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 the ability to articulate issues from a disability perspective
- one or more members with the ability to articulate the interests of children who, at the time of his or her appointment, holds the office of Children's Commissioner or is a representative or employee of the person who holds that office
- one or more members with expertise in relevant areas of the law.

Whole committee requirements

Members should possess an attitude that is accepting of the values of different professions and community perspectives, and it is important that ACART be comprise people from a range of backgrounds and ethnicities. All members of ACART are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, Advisory Committee members are not in any way the representatives of those groups. They are appointed in their own right, to participate in the work of ACART as equal individuals of sound judgement and relevant experience.

Terms and conditions of appointment

Members of ACART are appointed by the Minister of Health for a term of office of up to three years. The terms of office of members of ACART will be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years.

Persons who have served six consecutive years as members of the previous National Ethics Committee on Assisted Human Reproduction (NECAHR) shall not be immediately eligible for appointment to ACART.

A person may not be a member of ACART and ECART simultaneously.

Unless a person sooner vacates their office, every appointed member of ACART shall continue in office until their successor comes into office. Any member of ACART may at any time resign as a member by advising the Minister of Health in writing.

The Minister may, by written notice, terminate the appointment of a member or chairperson of the advisory committee.

The Minister may from time to time alter or reconstitute ACART, or discharge any member of ACART, or appoint new members to ACART for the purpose of decreasing or increasing the membership or filling any vacancies.

Chairperson and Deputy Chairperson

The Minister may appoint any person to be a chairperson of ACART and must, before doing so, consult any persons who, in the Minister's opinion, are able to provide advice on prospective appointees who have the required expertise and the ability to reflect relevant perspectives and concerns, including, without limitation, the perspectives and concerns of women.

ACART may appoint one of its members to be Deputy Chairperson.

The Chairperson will preside at every meeting of ACART at which they are present.

Duties and responsibilities of a member

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of ACART. This is intended to aid members of ACART by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect ACART and its members.

As an independent statutory body, ACART has an obligation to conduct its activities in an open and ethical manner. ACART has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference and in accordance with the HART Act.

General

ACART members should have a commitment to work for the greater good of the Committee.

There is an expectation that members will make every effort to attend all ACART meetings and devote sufficient time to become familiar with the affairs of ACART and the wider environment within which it operates.

Members have a duty to act responsibly with regard to the effective and efficient administration of ACART and the use of ACART funds.

Conflicts of interest

ACART members must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect ACART and its members and will ensure that it retains public confidence.

Members attend meetings and undertake committee activities as independent persons responsible to ACART as a whole. Members are not appointed as representatives of professional organisations and or particular community bodies. ACART should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.

Members should declare, and the committee regularly review their actual and potential conflicts of interest. ACART must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

Confidentiality and information sharing

The public has a right to be informed about the issues being considered by ACART. The chairperson of ACART must ensure that the agenda and minutes are published on the internet as soon as possible after they are confirmed by the members of the committee. ACART should have procedures in place regarding the release of information and processing requests for information.

Individual members must observe the following duties in relation to ACART information. These provisions ensure that ACART as a whole maintains control over the appropriate release of information concerning issues before it.

- Meetings of ACART, including agenda papers and draft minutes, are confidential. Members must ensure that the confidentiality of ACART business is maintained.
- Members are free to express their own view within the context of committee meetings or the general business of ACART.
- Members must publicly support a course of action decided by ACART. If unable to do so, members must not publicly comment on decisions.
- At no time should members individually divulge details of ACART matters or decisions of ACART to persons who are not ACART members. Disclosure of ACART business to anyone outside ACART must be on the decision of ACART, or at the discretion of the Chairperson of ACART between meetings. In choosing to release or withhold information, the Committee must comply with the Official Information Act 1982 and the Privacy Act 1993.
- ACART members must ensure that ACART documents are kept secure to ensure that the confidentiality of committee work is maintained. Release of committee correspondence or papers can only be made with the approval of ACART.

Meetings of the Committee

Meetings shall be held at such times and places as ACART or the Chairperson of ACART decides.

When ACART has 12 members, at least seven members must be present to constitute a majority. When the number of appointed members is less than 12, a quorum is the minimum number constituting a majority. The quorum must include a reasonable representation of members with health practitioner, research, ethical and community/consumer expertise, knowledge and perspectives.

Every question before any meeting shall generally be determined by consensus decision-making. Where a consensus cannot be reached a simple majority vote will apply. In such circumstances, the Chairperson shall have the casting vote.

Subject to the provisions set out above, ACART may regulate its own procedures.

Reporting requirements

ACART must, as soon as practicable after each 12-month period ending on 30 June, give the Minister of Health a report:

- on its progress in carrying out its functions; and
- on the number and kinds of decisions given by ECART in that period.

Fees and allowances

Members of ACART are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

The Chairperson will receive \$430 per day (plus half a day's preparation fee) and an allowance of two extra days per month to cover additional work undertaken by the Chairperson. The attendance fee for members is set at \$320 per day (plus half a day's preparation fee). The Ministry of Health pays actual and reasonable travel and accommodation expenses of ACART members.

Servicing of ACART

ACART will agree a work programme with the Minister of Health. ACART will be serviced by permanent staff, sufficient to meet the Committee's statutory requirements, who will be based in the Ministry of Health.

Appendix 4: Biographies of ACART Members

Professor Sylvia Rumball (Chair) 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; through 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 2005. 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 Inc.

Dr Mavis Duncanson is the Principal Advisor – Research and Policy in the Office of the Children’s Commissioner and, until November 2006, was the Commissioner’s representative on ACART. The Commissioner is required by statute to raise awareness and understanding of and act as an advocate for children’s interests, rights and welfare, and monitor application of the United Nations Convention on the Rights of the Child by Crown agencies. Dr Duncanson is a public health physician with previous experience in communicable disease and fire safety research.

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 a member 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 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 Ngai Tahu elders to assist with the completion of their ancestral meeting house by managing the Marae Development Project under the Department of Labour. After the completion of this project in 1987, she stayed on with the Department of Labour 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 Department of Labour. 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 District Health Board. 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 *Human Reproduction*, 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 the Department of Obstetrics and Gynaecology at the University of Auckland, where he is extensively involved in teaching reproduction, genetics and cancer. Dr Shelling has recently served as President of the New Zealand branch of the Human Genetics Society of Australasia. He has recently been appointed as 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.

Part Two: 2006/07 Annual Report of the Ethics Committee on Assisted Reproductive Technology

Chair's Foreword

I am pleased to present the second annual report of the Ethics Committee on Assisted Reproductive Technology (ECART).

ECART has continued to review applications for assisted reproductive procedures using the interim guidelines that were developed by the National Ethics Committee on Assisted Human Reproduction. The guidelines were developed before the implementation of the Human Assisted Reproductive Technology Act 2004 (the HART Act), and are often overly prescriptive, constraining ECART's ability to make considered decisions in relation to people's individual circumstances. The Advisory Committee on Assisted Reproductive Technology (ACART) has been informed of issues with the interim guidelines where applicable.

ECART is legally required to operate with the interim guidelines until November 2007. Before then, ACART will consult publicly and advise the Minister of Health on future policy for assisted reproductive procedures in New Zealand, and issue any new guidelines. ECART will have input as part of ACART's wider consultation.

These new guidelines will be firmly based in the principles of the HART Act and should allow ECART greater flexibility in reviewing applications. I am confident that more flexible guidelines will enable ECART to function more effectively as an ethics committee.

I wish to thank ECART members for their hard work during 2006/07 and look forward to another successful year in 2007/08.

Philippa Cunningham
Chair, Ethics Committee on Assisted Reproductive Technology

Purpose of this Report

The Terms of Reference of the Ethics Committee on Assisted Reproductive Technology (ECART) require it to submit an annual report to the Minister of Health. The annual report must include information on:

- members
- assisted reproductive technology applications reviewed (which, as the Advisory Committee on Assisted Reproductive Technology, ACART, has the legislative responsibility for reporting on ECART's decisions, are set out in Appendix 1 of ACART's report)
- training
- complaints received
- issues causing ECART difficulty in reviewing applications
- issues referred to ACART.

Introduction

ECART was established under the Human Assisted Reproductive Technology Act 2004 (the HART Act).

The functions of ECART are to:

- consider and determine applications for assisted reproductive procedures or human reproductive research
- keep under review any approvals previously given, including those applications approved prior to the existence of ECART and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals
- liaise with ACART on matters relating to assisted reproductive procedures and human reproductive research, and to forward to the advisory committee reports received under section 19(5) of the HART Act together with any comments or requests for advice that ECART considers appropriate
- consult with any persons who, in the opinion of the committee, are able to assist it to perform its functions
- perform any other functions that the Minister of Health assigns to the committee by written notice.

ECART can only consider applications for approval for activities covered in guidelines or advice issued or given by ACART. If such guidelines or advice do not exist, ECART must decline the application and refer the matter to ACART.

Progress in 2006/07

ECART met five times over the 2006/07 fiscal year to review 23 applications for assisted reproductive procedures. Three new members were appointed to ECART during this period; their individual experience lies in counselling, being a consumer of assisted reproductive technology, or the needs, values and beliefs of Māori.

Since its establishment in August 2005, ECART has reviewed applications for assisted reproductive procedures based on guidelines that were developed under the previous regulatory regime. The HART Act made provisions for these guidelines to be treated as interim guidelines up until 21 November 2007. ECART has found the interim guidelines to be overly prescriptive and has felt that they have constrained its ability to ethically review applications.

A summary of the number and kinds of decisions made by ECART is included in ACART's annual report as required by the HART Act. This summary is contained in Appendix 1 of that report.

In ECART's review of applications, a number of issues arose in relation to the interim guidelines. These issues have been forwarded to ACART to inform its advice to the Minister of Health on assisted reproductive procedures. These issues are:

- the requirement that a surrogate and intended parents be family members or close friends, and the difficulty of defining 'close friend'
- the need for the *Guidelines on Within-family Gamete Donation* to require review of legal reports in complex situations (i.e., where both sets of gametes are donated)
- that surrogacy may be more usefully defined as 'medically facilitated surrogacy' rather than 'in vitro fertilisation (IVF) surrogacy' for the purposes of ethical review
- menopause as a medical condition necessitating IVF surrogacy – in particular, the interface between advanced maternal age and the requirement in surrogacy arrangements that there be a medical condition precluding normal reproduction or preventing the intending mother from becoming pregnant, or that makes pregnancy potentially damaging to her or the resulting child
- the requirement that all parties involved (intending parents, birth parents and donors) be permanent residents in New Zealand
- the exclusion of arrangements using donated sperm in conjunction with donated eggs (unless the arrangements are within-family).

Training

During the 2006/07 fiscal year each member of ECART was taken on a tour of a fertility clinic.

A full training day is scheduled for late 2007 for all new and existing members.

ECART Membership

	Expertise / perspective	Term of office expires 23 June
Lay membership		
Philippa Cunningham (Chair)	Law	2008
Eamon Daly	Disability	2008
Lynley Anderson	Ethics	2008
Sharron Cole	Consumer	2007
Maui Hudson	Māori	2007
Huia Tomlins-Jahnke*	Māori	2009
Hazel Irvine†	Counselling	2009
Jackie Freeman†	Consumer	2009
Non-lay membership		
Dr Christine Forster (Deputy Chair)	Assisted reproductive research	2007
Prof John Hutton	Human reproductive procedures	2008

* Appointed 12 October 2006

† Appointed 23 August 2006

Member attendance at ECART meetings 2006/07

Member	Meetings attended					Total
	15 August 2006	10 October 2006	28 November 2006	13 March 2007	8 May 2007	
Lynley Anderson	X	X	X	X	X	5/5
Philippa Cunningham	X	X	X	A	X	4/5
Sharron Cole	X	X	X	X	A	4/5
Eamon Daly	X	X	X	A	A	3/5
Christine Forster	X	X	X	X	X	5/5
Jackie Freeman	NA	X	X	X	X	4/4
Maui Hudson	X	X	X	X	X	5/5
John Hutton	X	X	X	X	A	4/5
Hazel Irvine	NA	X	X	X	X	4/4
Huia Tomlins-Jahnke	NA	NA	X	X	X	3/3
Total members present	7/7	9/9	10/10	8/10	7/10	

NA Not appointed

A Apologies

X Present

Complaints

ECART received no complaints between 1 July 2006 and 30 June 2007.

ECART has no formal appeals process similar to that of the health and disability ethics committees. This issue is one that ACART has referred to the Minister of Health.

Appendix 1: ECART Terms of Reference

Public Authority of the Ethics Committee on Assisted Reproductive Technology (ECART)

ECART is established and designated under section 27 of the Human Assisted Reproductive Technology (HART) Act 2004. These Terms of Reference outline the role and functions of ECART.

Relations with other public sector organisations

ECART shall liaise with other relevant ethics committees on matters of common interest, such as cases where jurisdiction is unclear. ECART shall inform the Ministry of Health and the Advisory Committee on Assisted Reproductive Technology (ACART) of any matters that arise in its operation that potentially have policy significance.

Functions of ECART

ECART has the following functions:

- to consider and determine applications for assisted reproductive procedures¹ or human reproductive research²
- to keep under review any approvals previously given, including those applications approved prior to the existence of ECART, and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals
- to liaise with ACART on matters relating to assisted reproductive procedures and human reproductive research and, to forward to the advisory committee reports received under section 19(5) of the HART Act together with any comments or requests for advice that ECART considers appropriate
- to consult with any persons who, in the opinion of the committee, are able to assist it perform its functions
- any other functions that the Minister of Health assigns to the committee by written notice.

¹ “Assisted reproductive procedure”

(a) means 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; but

(b) does not include an established procedure.

² “Human reproductive research” means research that uses or creates a human gamete, a human embryo, or a hybrid embryo.

Guiding principles

ECART shall be guided by the following principles:

- the health and wellbeing 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
- the human health, safety, and dignity of present and future generations should be preserved and promoted
- 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
- 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
- donor offspring should be made aware of their genetic origins and be able to access information about those origins
- the needs, values, and beliefs of Māori should be considered and treated with respect
- the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

Operation of ECART

ECART must operate:

- in accordance with the HART Act and any other enactment
- in accordance with these Terms of Reference
- in accordance with any guidelines or advice issued by ACART or transitional guidelines gazetted by the Minister of Health under section 79 of the Human Assisted Reproductive Technology Act; and
- in accordance with Chapters 1–4 of the *Operational Standard for Health and Disability Ethics Committees*; and
- expeditiously, having regard, in particular, to the effect that undue delay may have on the reproductive capacity of individuals.

On any point of conflict, the guidelines issued by ACART will have precedence over the *Operational Standard*.

Composition and membership

Guiding principle

The primary guiding principle for appointing members to ECART is to ensure that ECART has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality in accordance with its functions as defined by the HART Act.

Member numbers

ECART must consist of not fewer than eight and not more than 12 members appointed by the Minister of Health.

Lay/non-lay membership

At least one half of the total membership of ECART shall be lay persons, including a lay Chairperson and a non-lay Deputy Chairperson.

For the purposes of these Terms of Reference, a lay person is a person who, at no time during the person's membership of ECART or in the three years before becoming a member of ECART:

- is a health practitioner within the meaning of the Health Practitioners Competence Assurance Act 2003; or
- is involved in health research; or
- is employed by or associated with, or has a pecuniary interest in, a provider.

Member categories

ECART's lay membership shall include:

- one or more members with the ability to articulate issues from a consumer perspective
- one or more members with the ability to articulate issues from a disability perspective
- one or more members with expertise in ethics
- one or more members with expertise in law.

ECART's non-lay membership shall include:

- one or more members with expertise in assisted reproductive procedures
- one or more members with expertise in human reproductive research.

Ex-officio attendance

The chairperson of ECART, or a member of ECART nominated by the chairperson of ECART for the meeting may attend each meeting of ACART. The ECART member or Chair attending the ACART meeting is not a member of the committee.

The chairperson of ACART, or a member of ACART nominated by the chairperson of ACART for the meeting may attend each meeting of ECART. The ACART member or Chair attending the ECART meeting is not a member of the committee.

Whole committee requirements

At any time, consistent with the requirements for district health boards under the New Zealand Public Health and Disability Act 2000, ECART shall have at least two Māori members. Māori members should have a recognised awareness of te reo Māori, and an understanding of tikanga Māori. All members of ECART are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important that ECART be comprised of people from a range of backgrounds and ethnicities.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, ECART members are not in any way the representatives of those groups. They are appointed in their own right, to participate in the work of ECART as equal individuals of sound judgement, relevant experience, and adequate training in ethical review.

Terms and conditions of appointment

Members of ECART are appointed by the Minister of Health for a term of office of up to three years. The terms of office of members of ECART shall be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years.

After serving the maximum six-year term, members shall not be considered for reappointment until at least three years after their retirement from ECART or any other health and disability ethics committee.

Persons who have served six consecutive years as members of the previous National Ethics Committee on Assisted Human Reproduction (NECAHR) shall not be eligible for appointment to ECART until at least three years after their retirement from NECAHR. Persons who have served less than six years on NECAHR will be eligible to be appointed to ECART for a term that is equal to six years minus the term already served by that person on NECAHR, or a shorter period.

A person may not be a member of ECART and ACART simultaneously.

Unless a person sooner vacates their office, every appointed member of ECART shall continue in office until their successor comes into office. Any member of ECART may at any time resign as a member by advising the Minister of Health in writing.

The Minister may, by written notice, terminate the appointment of a member or chairperson of the advisory committee.

The Minister may from time to time alter or reconstitute ECART, or discharge any member of ECART, or appoint new members to ECART for the purpose of decreasing or increasing the membership or filling any vacancies.

Chairperson and Deputy Chairperson

The Minister must appoint a lay member of ECART to be its Chairperson. The terms and conditions of appointment for members of ECART also apply to the person appointed as Chair. The Chairperson shall preside at every meeting of ECART at which they are present.

ECART may appoint a non-lay member as Deputy Chairperson.

The Chairperson and Deputy Chairperson may act with the delegated authority of ECART between meetings.

Duties and responsibilities of a member

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of ECART. This is intended to aid members of ECART by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect ECART and its members.

General

ECART members should have a commitment to protecting the interests of human participants, including a potential child when this is appropriate, while promoting excellence in research and innovative practice.

There is an expectation that members will make every effort to attend all ECART meetings and devote sufficient time to become familiar with the affairs of ECART and the wider environment within which it operates.

Members have a duty to act responsibly with regard to the effective and efficient administration of ECART and the use of ECART funds.

Conflicts of interest

ECART members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect ECART and its members and will ensure it retains public confidence.

ECART members attend meetings and undertake ECART activities as independent persons responsible to ECART as a whole. Members are not appointed as representatives of professional organisations or particular community bodies. ECART should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.

Members should declare, and the committee regularly review their actual and potential conflicts of interest. ECART must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

When ECART members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or undertaking an activity consistent with the committee's functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of ECART who has a proposal before ECART or who has an involvement in the proposal such as a supervisory role shall not take part in ECART's assessment of that proposal. The member may be present to answer questions about a proposal but should take no part in the discussion surrounding the consideration of the proposal or any decision relating to the proposal. This will allow the proposal to be considered in a free and frank manner.

ECART must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

Confidentiality and information sharing

Agendas and minutes of all ECART meetings should be available to the public. Copies of applications may be made available to individuals outside ECART on request, subject to the Official Information Act 1982.

It is desirable for the members of ECART to have an opportunity to discuss issues arising from applications with key contacts and support people prior to the consideration of proposals. This process should be encouraged. However, due to the need to protect any personal information, names or identifying details should not be circulated or made known outside ECART. ECART will need to consider the Privacy Act 1993 and the Health Information Privacy Code 1994 in developing these processes.

Within ECART, members' expertise in particular communities of interest should be consulted and provide advice on the appropriate consultative process for all ethical issues concerning that community.

Committee meetings

Meetings of ECART shall be held as regularly as needed, as determined by the workload.

When ECART has 12 members, at least seven members must be present to constitute a quorum. When the number of appointed members is less than 12, a quorum is the minimum number constituting a majority. The quorum must include a reasonable representation of members with health practitioner, research, ethical and community/consumer expertise, knowledge and perspectives.

As part of the accountability to the public they protect, it is desirable for the meetings of ECART to be open to the public. Meetings of ECART should therefore be:

- i. open meetings for the discussion of broad issues, particularly if ECART is reviewing human reproductive research
- ii. closed meetings when necessary to ensure the privacy and confidentiality of participants
- iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.

Information about the dates and times of committee meetings, including the closing date for the agenda, should be made available to the public.

Subject to the provisions set out in this document, ECART may regulate its own procedures.

Decision-making process

Wherever possible, ECART should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions.

In relation to specific research or specific treatment involving Māori participants, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend an ECART meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

On occasion, individual members may wish to abstain from some or all of the decision making process because of strong moral or religious reasons. Such abstentions shall not affect the approval process.

Advice from ACART

At any stage in its deliberations, ECART may seek advice from ACART on the interpretation of ACART's guidelines.

ECART actions

ECART may give its written approval:

- for the performance of assisted reproductive procedures by a nominated person; or
- for the conduct of human reproductive research by a nominated person.

ECART may not give its approval unless it is satisfied that the activity proposed to be undertaken under the approval is consistent with relevant guidelines or relevant advice issued or given by the advisory committee.

ECART may cancel an approval, in whole or in part, if it is satisfied:

- that one or more conditions stated in the approval have been breached; or
- that the activity undertaken, or purportedly undertaken, under the approval:
 - is inconsistent with any relevant guidelines and advice issued by the advisory committee on or before or after the date on which the approval was given; or
 - is inconsistent with the description set out in the application in which the approval was sought; or
 - breaches or has breached the HART Act or regulations made under section 76 of the HART Act; or
- that, since giving the approval, the ethics committee has become aware that the activity to which the approval relates poses a serious risk to human health and safety.

The actions of ECART in relation to applications are set out in sections 19 to 23 of the HART Act.

For each application it reviews, ECART must state to the applicant whether its action is to Approve, Approve subject to conditions, Defer, or Decline that application. It should state its grounds for any action to Defer or Decline. For any action to Approve subject to conditions, ECART should specify the conditions, the grounds for these, and its process for assessing whether these conditions are subsequently met. In all cases, it should state which matters its action is based upon, and which are instead matters of comment, information, or advice to its applicant.

As soon as practicable after ECART grants an approval, it must give a copy of the approval and the relevant proposal to ACART.

Expert advice and consultation

Members may wish to consult on ethical issues with, for example, individuals, groups, iwi and hapū, and this should be encouraged and supported. Consultation should be carried out in a timely manner.

Where the Chairperson or quorum of ECART members believes there is insufficient expertise on ECART to assess an application or an issue, the committee should seek additional expert advice.

Advice may be sought from recognised experts with:

- i. specialist knowledge in the field of assisted reproductive technology
- ii. knowledge of the experiences and perspectives of people with infertility
- iii. knowledge of the experiences and perspectives of people with disabilities
- iv. awareness of gender health perspectives
- v. consumer and/or research participant perspectives
- vi. an understanding of community health issues
- vii. an understanding of relevant cultural perspectives
- viii. an understanding of developing Māori research methodologies
- ix. expertise in te reo Māori
- x. expertise in ethical theory
- xi. expertise in child and family health and wellbeing.

It should be noted that the above list gives examples, without restricting the range of external expertise that may be sought.

Where external consultation has taken place or advice has been sought, this should be documented, and recorded where appropriate in ECART's decision on a proposal.

Training for members

Training should be provided for new members and chairpersons within six months of appointment to ECART. Reasonable expenses incurred in attending training will be paid for, but a meeting fee is not paid for training.

Reporting requirements

The following provides a checklist of requirements for annual reporting. Annual reports should be submitted to the Minister of Health and will be tabled by the Minister of Health in the House of Representatives.

The annual report shall include information on the membership of ECART, including any change in ECART's membership or other substantive changes ECART or its chairperson feels should be noted.

The annual report should also include a list of the assisted reproductive technology proposals reviewed in the preceding year outlining the following details:

- i. the research title or the type of treatment
- ii. principal investigator
- iii. institution where the research is to be/has been undertaken
- iv. date of first review
- v. date of final outcome
- vi. outcome (which will be one of: approved, approved subject to conditions, deferred, declined)
- vii. for each protocol deferred or declined, the reasons for the decision.

The annual report shall also include:

- i. a list of training undertaken by ECART members, and a statement on processes for orientation and training of new ECART members
- ii. a list of complaints received by ECART (if any), the actions taken to resolve the complaint and a comment on the outcome of the complaint(s)
- iii. any areas of review that caused difficulty for ECART in making a decision on any particular protocol(s), and any questions on policy or other matters ECART referred to ACART for comment or guidance.

In compiling annual reports, ECART should take care not to provide information that would involve a breach of the Privacy Act 1993 and/or the Health Information Privacy Code 1994.

Fees and allowances

Members of ECART are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

The Chairperson shall receive an attendance fee of \$330 per day (plus half a day's preparation fee). The attendance fee for members is set at \$250 per day (plus half a day's preparation fee). The Chairperson and Deputy Chairperson shall receive an allowance of up to one extra day each per month to cover additional work undertaken under the delegated authority of ECART. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of ECART members.

Servicing of ECART

The Ministry of Health shall employ staff and provide resources to service, advise, and administer ECART out of the allocated budget for ethics committees.

Appendix 2: ECART Member Biographies

Philippa Cunningham (Chair) is a District Court Judge based in Auckland. Prior to her appointment in March 2007, Philippa practised as a barrister mainly in the areas of civil and family law, including some medical cases. Philippa trained and worked as a nurse prior to taking up law 22 years ago. She has a Diploma in Professional Ethics from the University of Auckland. Philippa has had an interest in the protection and promotion of health consumers' rights since her involvement in the Cervical Cancer Inquiry in 1988 as junior counsel to Judge Silvia Cartwright. Philippa was a member of the National Ethics Advisory Committee from December 2001 to 2004 and a member of NECAHR from mid 2002 until its disestablishment in July 2005.

Dr Christine Forster (MNZM) (Deputy Chair) is a general practitioner in Auckland. Prior to medical training, she was a researcher in the area of reproductive endocrinology. Other former roles have included Chair of the Abortion Supervisory Committee for six years, NECAHR member and member of the Auckland Regional Ethics Committee. Christine completed the Diploma in Professional Ethics in 2004. She is married with four children.

Lynley Anderson is employed as a lecturer at the Bioethics Centre at Otago University. As part of her role, she teaches ethics and professional development within the medical, physiotherapy, dentistry and midwifery schools at Otago. Lynley was the former and founding editor of the *Journal of Bioethical Inquiry* and the *New Zealand Bioethics Journal*. She is on the University Human Ethics Committee of Otago and was the Chair of the Ethics Committee of the New Zealand Society of Physiotherapists. She is married with three sons.

Sharron Cole has an extensive background of community work in health. She holds a Masters degree in history and a Diploma in Health Education. Sharron is Deputy Chief Families Commissioner, Deputy Chair of the Hutt Valley District Health Board, Deputy Chair of the Midwifery Council, an independent advisor on medical misadventure to the Accident Compensation Corporation (ACC), a member of the ACC Purchasing Guidance Advisory Group and the ACC Research Ethics Committee, a member of the PHARMAC Consumer Advisory Committee, a member of the Down Syndrome Screening Advisory and the HIV/Antenatal Screening Advisory Groups to the Ministry of Health, and Patron and a Life Member of Parents Centres New Zealand. She is a past Chair of the Wellington Regional Health Authority Ethics Committee and past Chair of the National Chairs of Ethics Committees Group. She lives in Petone and is married with four adult children.

Eamon Daly is an ethics researcher/advisor for information privacy and information and communication technologies. Prior to this Eamon has been a teaching assistant in the Department of Philosophy at the University of Canterbury (2003), a researcher/advisor for the Office of Hon Ruth Dyson (2001/02) and a lecturer in ethics at Christchurch Polytechnic (1996). Eamon is studying for a PhD in philosophy at the University of Canterbury, and holds a Bachelor of Science (1991) and a Master of Science (1996) from that university. He has also been on research scholarships with the University of Canterbury, University of California and London School of Economics. Eamon was Chair of the Assisted Human Reproduction Working Group of Toi te Taiao: the Bioethics Council (2002–2003) and he is a member of the Human Rights Review Tribunal (2003 – present). He is an elected member of the Disabled Persons Assembly National Executive Committee (2002 – present) and an ethicist on the University of Canterbury Biosafety Committee (2002 – present).

Jackie Freeman (BEd, Dip Teaching) is a part-time teacher who has taught mainly primary school children for 15 years. For the last 12 years, Jackie has been a consumer of fertility services in New Zealand. Jackie is an active member of the Fertility New Zealand Executive. She is the key contact/representative for the Canterbury region and works closely with other assisted reproductive technology consumers by facilitating contact groups and offering support. Recently Jackie has taken on a role as a consumer auditor for the Reproductive Technology Accreditation Committee accreditation process. She is married with three daughters.

Maui Hudson lives in Auckland and is married with three young children. His iwi affiliations are with Whakatōhea, Ngaruahine and Te Mahurehure. Maui trained as a physiotherapist and holds professional qualifications from Auckland University of Technology in physiotherapy, ethics and Māori health. He currently works for the Institute of Environmental Science and Research Ltd in a Māori development position that involves providing cultural and ethical advice to researchers. Maui was previously a member of the Auckland Regional Health and Disability Ethics Committee.

Professor John Hutton (PhD, FRANZCOG, CREI) is a subspecialist in reproductive medicine and the Medical Director of Fertility Associates Wellington, which he established in 1993. He is also (part-time) Professor of Reproductive Medicine at the Wellington School of Medicine and Health Sciences where, previously, he was Professor of Obstetrics and Gynaecology.

Hazel Irvine is a registered nurse, midwife, ACC registered counsellor and psychotherapist. She was a founding member in 1979 of a women's health collective offering information, counselling and advocacy to women. Hazel has worked in the public hospital system as a nurse-midwife and as a manager. She has also had several years of private practice as a nurse-therapist, her main clientele being women, couples and families coping with fertility issues, pregnancy loss, childbirth and postnatal depression. In 1991 a Lion's Fellowship enabled Hazel to investigate independent nurse practitioners in the United Kingdom. In 1996 she travelled to the United Kingdom on a Churchill Fellowship to study the implementation of professional supervision for nurses and midwives.

In 2004 Hazel was a member of a technical group formed by the Abortion Supervisory Committee to produce guidelines for mifepristone medical abortion in New Zealand. She currently lives in Wellington with her partner and three sons, and is a Sea Scout leader and a keen gardener. She has a private practice offering professional supervision, counselling and psychotherapy and also works part time as a midwife and a gynaecology nurse at Wellington Hospital.

Associate Professor Huia Tomlins-Jahnke is affiliated with Ngāti Kahungunu, Ngai Tahu, Ngāti Toa Rangatira and Ngāti Hine. She is currently an Associate Professor of Māori Education in the College of Education at Massey University. Huia trained as a teacher and holds professional qualifications in education (BEd, MEd Hons). She worked for 12 years as a lecturer in Te Pūtahi-a-Toi, School of Māori Studies at Massey University, which has a strong health research and development focus. She has extensive experience in iwi research and has completed a PhD in which she investigated the nature of tribal service provision in health and social services. She has expertise in Māori theoretical, methodological and ethical frameworks and in working with Māori communities. Huia is Deputy Chair of the Massey University Human Ethics Committee and a member of the Social & Human Sciences Sub Commission of the New Zealand National Commission for UNESCO, which has as a key focus the ethics of knowledge production. Huia is also a member of the Sub Commission's Pacific Ethics Consultation Steering Committee. She is a recent appointee to Toi te Taiao.