Advisory Committee on Assisted Reproductive Technology
Annual Report 2008/09

Citation: ACART. 2009. *Advisory Committee on Assisted Reproductive Technology. Annual Report 2008–09.* Wellington: Advisory Committee on Assisted Reproductive Technology.

Published in December 2009
by the Advisory Committee on Assisted Reproductive Technology.
PO Box 5013, Wellington, New Zealand

ISBN: 978-0-478-33939-0 (online)
ISBN: 978-0-478-33940-6 (print)
HP: 4970

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

Contents

Chair's Foreword

On behalf of the Advisory Committee on Assisted Reproductive Technology (ACART) I am pleased to present this annual report for the 2008/09 reporting year.

ACART's terms of reference require it to develop advice for the Minister of Health across a very broad area, including the use of assisted reproductive technologies in both treatment and research. It is also charged with developing guidelines for the Ethics Committee on Assisted Reproductive Technology (ECART) and undertaking a broad monitoring role.

In this, the fourth year of ACART's existence, the committee's workload has continued to be high. The work programme required the committee to work simultaneously in a number of areas.

In July 2008 ACART released a consultation document on the use of frozen eggs in fertility treatment. The collection and freezing of eggs was declared to be an established procedure in New Zealand in 2005. ACART proposed that the use of frozen eggs in fertility treatment become an established procedure.

Also in July 2008 ACART released its consultation paper on pre-implantation genetic diagnosis (PGD) with HLA tissue typing. Draft guidelines were subsequently developed, and remain under consideration.

This year, ACART considered the technical report on in vitro maturation (IVM) that was commissioned in May 2008. This report identified the benefits and risks of the collection of immature eggs, the maturation of the eggs through IVM and the subsequent use of these eggs for fertility treatment. ACART will provide advice to the Minister later in 2009 on the use of IVM in fertility treatment.

ACART has continued work in the last year on the use of donated eggs with donated sperm for reproductive purposes. ACART is currently consulting with the Minister on guidelines for the use of donated eggs with donated sperm.

ACART's role in monitoring developments in human reproductive research was assisted by reports provided by a Scanning Panel, set up in 2008 for one year.

As in earlier years, ACART interacted closely with ECART, the Ministry of Health and providers of fertility services in the course of its work programme. The insights provided assisted ACART greatly in implementing its responsibilities under the Human Assisted Reproductive Technology Act 2004.

ACART has also appreciated opportunities to meet and discuss ACART initiatives with the Minister. Since the work programme for each reporting year is dependent on ministerial approval, these meetings are of particular significance for ACART's strategic direction and future work programmes.

In undertaking its extensive 2008/09 work programme the committee has been very ably supported by the secretariat. I wish to record my thanks here for their high level of professionalism.

I wish to thank the Ministry of Health for their ongoing support. I am also very grateful to ACART members for their outstanding commitment to the committee's work and their willingness to

provide both time and expertise. Without such involvement the progress achieved would not have been possible. I particularly wish to thank those members who completed their terms during this period.

I also wish to express my appreciation to those who have assisted ACART's work by responding to requests for submissions. Members of various groups and organisations and individual members of the public have been most helpful, and their input has greatly enhanced ACART's understanding of complex issues.

I look forward to continuing ACART's important work in the coming year.

Sylvia Rumball
Chair, Advisory Committee on Assisted Reproductive Technology

Introduction

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 provide the Minister of Health with a report on:

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

Background

ACART was established under section 32 of the HART Act. ACART's current membership, with biographical information, is shown in Appendix 1.

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, provide 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 (that is, a procedure which does not require ECART approval) 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.

ACART's terms of reference are detailed in Appendix 2.

ACART Work During 2008/09

Background

ACART has established the following work streams:

- advice to the Minister of Health on human reproductive research (as required under section 37 of the HART Act)
- advice to the Minister of Health on assisted reproductive technology (section 38)
- consultation with the Minister of Health on guidelines for assisted reproductive procedures (section 41(2))
- advice to the Minister of Health on new assisted reproductive procedures (section 6)
- monitoring (sections 35(2), 30, 42(3)(b)
- advice to ECART (section 35(1)(a))
- governance and administration.

Work on specific projects within these broad areas requires the approval of the Minister of Health prior to commencement.

ACART's processes

ACART met five times during this reporting year to formulate advice and make decisions on specific projects. Member attendance at these meetings is shown in Appendix 3.

Projects were progressed through working groups acting under the delegated authority of ACART. Working groups undertook in-depth thinking on issues and provided ACART with minutes of their meetings, along with reports and recommendations.

ACART steered the working groups on an ongoing basis, and a full ACART committee meeting approved or declined each of their final outputs – whether a report, recommendation, consultation paper, guidelines for ECART, advice to ECART or advice to the Minister.

Further information on working groups' membership and projects undertaken is detailed in Appendix 4.

Progress made in 2008/09

Advice to the Minister of Health on human reproductive research

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

ACART provided the Minister of Health with advice on human reproductive research on 29 June 2007 following extensive public consultation in the 2006/07 financial year. No further work was undertaken in the 2008-09 reporting year. Any further ACART work in this area depends on ministerial approval.

Advice to the Minister of Health on assisted reproductive technology

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

- requirements for informed consent

- the import into or export from New Zealand of in vitro donated cells or embryos.

In the previous reporting year, ACART undertook preliminary work on requirements for informed consent and import/export of embryos. This work continued in 2008/9.

Consultation with the Minister of Health on guidelines for assisted reproductive procedures

Selection of embryos using pre-implantation genetic diagnosis

In July 2008, ACART released its consultation paper on pre-implantation genetic diagnosis (PGD) with HLA tissue typing.

Following consultation, ACART developed guidelines for consideration by the Minister of Health. If the guidelines are issued, they will replace the existing guidelines on PGD with HLA tissue typing that were developed prior to enactment of the HART Act.

Embryo donation

Guidelines on embryo donation were issued in November 2008.

Use of donated eggs with donated sperm for reproductive purposes

ACART completed consultation on draft guidelines during the 2008/09 year, and is currently consulting with the Minister on guidelines.

Advice to the Minister of Health on new assisted reproductive procedures

The use of frozen eggs

In June 2005 the collection and cryopreservation (freezing) of human eggs was declared to be an established procedure, meaning that it could be undertaken by a fertility clinic. However, the subsequent use of frozen eggs was specifically excluded from this established procedure because the risks could not be adequately assessed, due to the newness of the technique. When ACART was established, the former Minister of Health asked, among other things, for advice on the use of frozen eggs in fertility treatment.

In July 2008, ACART produced a discussion document for consultation on the use of frozen eggs in fertility treatment. ACART proposed that the use of frozen eggs in fertility treatment become an established procedure.

Following consultation, ACART provided advice to the Minister that the use of frozen eggs in fertility treatment be approved and classified as an established procedure. The Minister agreed. An amendment to the Human Assisted Reproductive Technology Order 2005 (the HART Order) accordingly came into effect on 10 July 2009.

In vitro maturation (IVM)

ACART considered a technical report, commissioned in May 2008, on the risks and benefits of the collection of immature eggs and the use of eggs that have been matured through IVM.

This procedure was of particular consumer interest because of the potential benefit for women at risk from high doses of drugs used in conventional in vitro fertilisation.

ACART formed a preliminary view that it was safe to undertake the collection of immature eggs and that the use of eggs matured by IVM should be declared an established procedure.

A discussion document was released for sector consultation in January 2009. The consultation phase has been completed, an analysis of submissions has taken place, and ACART intends to provide advice to the Minister later in 2009 on whether to remove the exclusion from using IVM as an established procedure.

If ACART advises the Minister that IVM should become an established procedure and the Minister agrees, the HART Order would require amendment.

Use of cryopreserved ovarian tissue

Under the HART Act, ovarian tissue may be frozen but not used. ECART referred an enquiry to ACART in December 2008 about the use of previously frozen ovarian tissue.

ACART has agreed to seek a technical report on the use of cryopreserved ovarian tissue.

Monitoring

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. ACART's terms of reference also require it to monitor ECART's decisions, to ensure they fall within the guidelines set by ACART. The secretariat summarises ECART's decisions for each committee meeting to assist ACART in carrying out this role.

Both committees have an interest in clarifying the scope of current monitoring processes. The committees would also like to be able to perform their respective monitoring functions from a more robust information base that supports improved analysis of treatment outcomes.

A joint ACART–ECART project is in the early stages of determining what can and should be monitored by ACART and ECART in their respective monitoring roles.

To date, the outcomes of assisted reproductive treatments have been monitored through the annual report of the Australia and New Zealand Assisted Reproduction Database (ANZARD). ACART also monitored international trends through the reports of organisations such as the European Society of Human Reproduction and Embryology and the International Federation of Fertility Societies.

ACART's Horizon Scanning Network was established as a pilot in early 2008. The network met twice and provided individual reports which focused on developments in human reproductive research. ACART is currently evaluating the pilot project and considering how to proceed in this area.

In addition, to help ensure that its work programme is focused on the needs of consumers and providers of fertility services, ACART asked fertility services providers, ECART and the Ministry of Health to indicate any procedures they consider New Zealanders might wish to pursue in the next three years. No emerging issues were reported to ACART during the 2008/09 reporting year.

Advice to ECART

Matters of significance forwarded to ACART from ECART

ECART forwarded a number of matters to ACART during 2008/09. The significant

matters received in the period, and the consequent actions taken during the 2008/09 period, is set out below.

Advice on individual applications

ECART asked ACART to consider whether it was possible to develop processes which would allow ECART to consider applications which did not meet the provisions of the current guidelines.

ACART agreed to work with ECART on a joint project to consider whether there is a need for such processes.

IVM

ECART referred an application to ACART under section 18(2) regarding IVM of eggs from unstimulated ovaries. This was noted in the ACART agenda in September 2005.

ACART's subsequent work is described on page 6.

The use of frozen eggs

ECART referred an application to ACART under section 18(2) regarding the use of frozen eggs in infertility treatment. This was noted in the ACART agenda in July 2006.

ACART provided advice to the Minister in December 2008 that the use of frozen eggs in infertility treatment be approved. The Minister agreed with the advice, and the use of frozen eggs is now an established procedure.

Applications involving a combination of assisted reproductive procedures

ACART considered whether applications that combine more than one assisted reproductive procedure can be considered by ECART (for example, surrogacy with embryo donation). ACART provided advice to ECART on applications for combined assisted reproductive procedures on 24 November 2008. The secretariat provided letters to providers, the Ministry and Fertility New Zealand notifying the advice and the date it came into effect. The advice is available on the ACART website.

The use of donated sperm with donated egg

ECART referred letters from clinics/patients seeking approval to use donated egg and donated sperm.

ACART is currently consulting with the Minister on guidelines for the use of donated sperm with donated egg.

Use of cryopreserved ovarian tissue

ECART referred an enquiry about the use of previously frozen ovarian tissue.

ACART's subsequent work is described on page 6.

Familial relationships

ECART sought advice on the use of the HART Order definitions of cousin, patient and family member in relation to the guidelines on donation of eggs or sperm between certain family members. ACART referred the matter to the Ministry of Health and the HART Order has been amended to clarify the relationships concerned.

Potential donation of embryos formed from donated eggs

ECART referred a letter noting that the embryo donation guidelines do not currently allow the donation of embryos that have been created with donated gametes. ECART queried when these guidelines would be reconsidered to allow flexibility in decision-making in cases deemed 'exceptional circumstances'.

In response, ACART informed ECART that the embryo donation guidelines would be reviewed in three years (subject to work programme agreement with the Minister of Health).

Matters raised with the Ministry of Health

ACART raised a number of matters with the Ministry of Health during 2008/09. A list of significant matters and responses (as at the time of publishing) is set out below.

Familial relationships

ACART noted in the 2007-2008 reporting year that there existed potential for confusion in the definitions in the HART Order around familial relationships. ACART received a letter from the Ministry of Health in July 2009 noting that the HART Order had been amended to clarify interpretation.

Extension of storage of gametes and embryos beyond 10 years

ACART sought clarification about ACART's role under the HART Act in the matter of extension of storage of gametes and embryos beyond 10 years.

On 27 July 2009 the Minister of Health requested ACART to develop guidelines for determining extended storage applications under section 10 of the Act.

Governance

Conference attendance

ACART members attended the following conferences:

- Fertility Society of Australia, 19–22 October 2008
- European Society of Human Reproduction and Embryology Conference, 7–9 July 2008.

Publications

ACART published several documents in the 2008/09 financial year in addition to consultation documents noted earlier.

The *Risk Acceptability Framework used by the Advisory Committee on Assisted Reproductive Technology* is used by ACART to determine whether the risks associated with a procedure are acceptable for the purposes of recommending to the Minister that it be declared an established procedure.

In September 2008, ACART agreed to add further guidance to the interpretation of words in accordance with definitions given in the HART Act 2004 and HART Order 2005. The following guidelines have been updated to reflect this:

- *Guidelines on Donation of Eggs or Sperm Between Certain Family Members* (November 2008)
- *Guidelines on Surrogacy Arrangements Involving Providers of Fertility Services* (November 2008).

The following guidelines were issued to ECART:

- *Embryo Donation for Reproductive Purposes* (November 2008).

ACART consulted with the Minister as follows:

- *Consultation with the Minister of Health in Respect of Guidelines on Embryo Donation* (November 2008)
- *Use of Frozen Eggs in Fertility Treatment* (December 2008).

The following advice was issued to ECART:

- *Advice on Combined Assisted Reproductive Procedures* (November 2008).

Website

ACART's website, http://www.acart.health.govt.nz, serves as a key point of contact for fertility service providers, consumers and other interested parties.

Ethics Committee Decisions 2008/09

Between 1 July 2008 and 30 June 2009 ECART considered 30 applications for assisted reproductive procedures. There were:

- 18 applications for surrogacy
- nine applications for gamete donation between certain family members
- three applications for embryo donation for reproductive purposes.

Of these, 19 were approved outright, nine were approved subject to conditions and two were deferred. One of the deferred applications was subsequently approved by the Sub-Committee and the other deferred application was declined. The details of these decisions are set out in the ECART Annual Report.

Summary information on applications from 1 January 1997 to 30 June 2009 submitted to ECART and its predecessor, the National Ethics Committee on Assisted Human Reproduction, is contained in Appendix 5.

Appendix 1: ACART Membership and Biographies

ACART membership

ACART members

Professor Sylvia Rumball – Chair

Adjunct Professor Ken Daniels – Deputy Chair

Dr Richard Fisher

John Forman

Dr Ian Hassall

Professor Mark Henaghan

Cilla Henry

Maui Hudson

Professor Gareth Jones

Bishop Richard Randerson

Robyn Scott

Associate Professor Andrew Shelling

Secretariat members

Vicky Baynes policy analyst (January 2008 – present)

Betty-Ann Kelly senior analyst (February 2008 – present)

Sally Stewart senior analyst (August 2006 – December 2008)

Biographies of ACART members

Sylvia Rumball CNZM (Chair)

Professor Sylvia Rumball is Assistant to the Vice Chancellor (Research Ethics) 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 and ethics-related bodies through past membership of the UNESCO International Bioethics Committee, the New Zealand National Commission for UNESCO, the Health Research Council Ethics Committee, the Massey University Human Ethics Committee and the MASH Trust Ethics Committee; through current membership of the Ethics Advisory Panel of the Environmental Risk Management Authority; as past chairperson of the National Ethics Committee on Assisted Human Reproduction (NECAHR); and as current chairperson of the Massey University Human Ethics Chairs Committee.

Professor Rumball is also a member of the International Council for Science (ICSU) Committee on Freedom and Responsibility in Science, a former member of the Massey University Council, an auditor for the New Zealand Universities Academic Audit Unit and a member of the board of the National Centre for Advanced Bioprotection Technologies.

In 1998 she was made an Officer of the New Zealand Order of Merit for services to science, and in 2008 she was promoted to Companion. 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.

Ken Daniels (Deputy Chairperson)

Ken Daniels is adjunct professor in the School of Social Work and Human Services at the University of Canterbury. He was appointed to establish social work education and training at Canterbury in 1975 and retired in 2004. For over 30 years he has been actively involved in studying, writing, counselling and policy development in the psychosocial aspects of assisted reproductive technology (ART). His particular focus has been on the children and families that result from ART.

He served for nine years on NECAHR – the last three as deputy chairperson. Professor Daniels has carried out research in a number of countries and has worked 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 chairperson of Richmond New Zealand.

Richard Fisher

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. Richard is a member of a number of professional associations and is a member of the Institute of Directors in New Zealand Inc. He is married and has four children. Richard brings a medical professional's viewpoint to ACART, which is tempered by his recognition of the need for community involvement and decision-making in this area.

John Forman

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 over 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.

John has volunteer roles on the boards of several local and international advocacy groups. He is employed as Executive Director of the New Zealand Organisation for Rare Disorders, where he advocates for the increased application of genome knowledge and biotechnology to control health and disability problems, with a sharp eye on ethical issues to ensure safety for patients and their families.

Ian Hassall

Dr Ian Hassall is a paediatrician and children's advocate. He was New Zealand's first Commissioner for Children from 1989 to 1994. His career has entailed working for children and their families as clinician, strategist, researcher and advocate. He is at present research associate at the Institute of Public Policy at Auckland University of Technology (AUT).

Dr Hassall teaches in the Master of Arts (Children and Public Policy) course at AUT. He is engaged in research and advocacy work the aim of reducing the risk of violence and harm to children and placing their interests centrally in government decision-making. He is married to Jenny, is father to four children and grandfather to six. He is the Children's Commissioner's nominee to ACART.

Mark Henaghan

Mark Henaghan is professor and dean of law at the University of Otago and principal investigator of the Human Genome Project, Law and Ethics for the Future, which is sponsored by the Law Foundation New Zealand. The project has produced four major reports: *Choosing Genes for Future Children: Regulating pre-implantation genetic diagnosis* and *Genes, Society and the Future,* volumes 1, 2 and 3. Professor Henaghan's primary research interests are family law and medico-legal law involving children. Professor Henaghan is on the editorial boards of the *Journal of Human Rights* and the *Child and Family Law Quarterly* (both based in the United Kingdom).

Cilla Ruruhira Henry QSM

Cilla Henry grew up under the mantle of the kīngitanga movement, deeply entrenched in Waikato kawa (protocol) and tikanga (teachings). Her hapū connections are Ngāti Wairere and Ngāti Hako Hauraki. Cilla is married with three children and five mokopuna.

Cilla is a Māori specialist consultant in the bicultural theory model for the Department of Corrections – Psychological Services Hamilton, working with Māori inmates at Waikeria Prison, and a trustee of the Health Consumer Service Trust. She is a member of the National Council of Women, and is the Māori Women's Welfare League representative on the Care and Protection Resource Panel for Children (Child Youth and Family Service). Cilla is passionate about the care, protection and wellbeing of children.

Cilla was appointed a justice of the peace (JP) in 1996, and received the Queens Service Medal for public service in 2003.

Maui Hudson

Maui Hudson (JP) lives in Rotorua, and his iwi affiliations are with Whakatōhea, Ngā Ruahine and Te Māhurehure. Maui has professional qualifications from AUT in physiotherapy, ethics and Māori health, and currently works for the Institute of Environmental Science and Research Ltd (ESR) in a Māori development position. In this role he is responsible for internal development, providing cultural and ethical advice to researchers, and establishing research relationships with Māori and Pacific communities. Maui is the principal investigator on the Health Research Council-funded project Ngā Tohu o te Ora: Traditional Māori Wellness Outcome Measures, and has research interests in the area of ethics and the interface between mātauranga Māori and science. Maui is a member of the Health Research Council Ethics Committee, and has previously been a member of ECART and the Auckland Regional Health and Disability Ethics Committee. He is married and has three children.

Gareth Jones CNZM

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 the University of Otago, in science and bioethics respectively. He was made a 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 publications include: *Speaking for the Dead: The human body in biology and medicine* (2000; second edition, 2009), *Stem Cell Research and Cloning: Contemporary challenges to our humanity* (co-editor, 2004), *Medical Ethics* (co-author, 4th edition, 2005), *Designers of the Future* (2005), *Bioethics: When the challenges of life become too difficult* (2007), and *A Tangled Web: Medicine and theology in dialogue* (co-editor, 2009).

Richard Randerson CNZM

Bishop Richard Randerson was born in Takapuna, and studied at Otago University in arts and theology. He later undertook post-graduate studies in New York City and San Francisco in ethics and socioeconomics.

Ordained as an Anglican priest in Auckland in 1965, and bishop in 1994, Richard Randerson has served in a variety of ministries in New Zealand, the United States, the United Kingdom and Australia. His roles have included industrial chaplaincy, inner city ministry, social justice officer, a bishop in Canberra, and Dean of Auckland's Holy Trinity Cathedral. He has played a prominent role in the media, speaking and writing on issues such as poverty and justice, race relations, peace and inter-faith dialogue, and social ethics. In 2000/01 he was appointed by the New Zealand Government to the four-person Royal Commission on Genetic Modification. In this role he engaged in extensive consultation with the New Zealand public, both at open meetings and with Māori on marae. The interface between science, ethics and the public good was central to the Commission's work. He is the author of three books: *Christian Ethics and the New Zealand Economy* (1987), *Hearts and Minds: a Place for People in a Market Economy* (1992) and *A Word in Season: Reflections on Spirituality, Faith and Ethics* (2008).

Bishop Randerson was appointed a Companion of the New Zealand Order of Merit in 2004.

Now resident in Wellington, he is married to Jackie, whose background is in marriage and high school guidance counselling. They have three adult children and four grandchildren.

Robyn Scott

Robyn Scott's background is in both not-for-profit management and education. She studied at Wellington College of Education (now the Faculty of Education, Victoria University of Wellington) and Victoria University of Wellington before embarking on a career in primary school teaching and the teaching of speech and drama and music. From there she moved to managing a not-for-profit organisation, working particularly in the area of health support and health advocacy.

Robyn is currently executive director of Philanthropy New Zealand, and is charged with leading and developing this key organisation, which works to motivate and inspire philanthropists and grant makers.

Robyn lives in Wellington with her husband and two school-aged children. Outside work she enjoys a range of mostly family activities that tend to centre on children's sport and cultural events, and also enjoys travel and reading. She is an alumna of Leadership New Zealand, having graduated in 2006.

Andrew Shelling

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 disorders, focusing on infertility and reproductive cancers.

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, University of Auckland, and is extensively involved in teaching reproduction, genetics and cancer at the university. Dr Shelling has recently served as president of the New Zealand branch of the Human Genetics Society of Australasia. He is currently an associate editor of the journal *Human Reproduction*, which is one of the leading journals in the area of reproductive research. He is a trustee for the Nurture Foundation for Reproductive Research.

Appendix 2: Terms of Reference for ACART

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 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, to the Director-General of Health, to ECART and to providers
- publish the guidelines on the internet and in any other publications (if any) that the committee thinks appropriate
- 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 timeframes 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 timeframes 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
- 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 publication the committee thinks appropriate that states the time, place, and purpose of any such meeting, and that it 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 eight and not more than 12 members appointed by the Minister of Health.

Lay/non-lay membership

At least half of the total membership of ACART must be lay persons.

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 chairperson 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. The ECART member or chairperson 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 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
- 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 3: Member Attendance

Table 1: Member attendance at ACART meetings, 2008/09

Member	11 July 2008	12 September 2008	14 November 2008	13 March 2009	8 May 2009	Total
Prof Sylvia Rumball (Chairperson)	A	X	X	X	X	4/5
Adjunct Prof Ken Daniels (Deputy Chairperson)	X	A	X	X	X	4/5
Prof Gareth Jones	X	A	X	X	X	4/5
Dr Ian Hassall	X	A	X	X	X	4/5
Christine Rogan	X					1/1**
Bishop Richard Randerson		X	X	X	X	4/4
Cilla Henry	X	X	X	X	X	5/5
Maui Hudson	X	X	X	A	X	4/5
John Forman	X	X	A	X	X	4/5
Robyn Scott	X	A	X	X	X	4/5
Prof Mark Henaghan	X	X	X	X	X	5/5
Assoc Prof Andrew Shelling	X	X	X	X	X	5/5
Dr Richard Fisher	X	X	X	X	X*	5/5
Total members present	**11/12**	**8/12**	**11/12**	**11/12**	**12/12**	

* Half-day attendance

** Christine Rogan's term at the Committee ended after 11 July 2008. Richard Randerson was then appointed to the ACART Committee.

A Apologies

X Present

Note: Members also participated in working group meetings.

Appendix 4: ACART Working Groups

Working group	Responsibilities
Executive Group Sylvia Rumball (Chairperson) Ken Daniels Maui Hudson	Responsible for governance and administrative matters, as delegated by ACART
'Treatment' Working Group Ken Daniels (Chairperson) John Forman Maui Hudson Richard Fisher Robyn Scott Sylvia Rumball	Responsible in 2008/09 for leading work on use of donated sperm with donated eggs, and development of guidelines to cover this procedure
PGD Working Group Gareth Jones (Chairperson) Andrew Shelling John Forman Mark Henaghan Richard Fisher	Responsible in 2008/09 for leading work on finalising guidelines on PGD with HLA tissue typing
Use of Frozen Eggs Working Group Andrew Shelling Christine Rogan Gareth Jones Richard Fisher	Responsible in 2008/09 for leading work on providing advice to the Minister of Health on the use of frozen eggs
IVM Working Group Andrew Shelling Richard Fisher	Responsible in 2008/09 for leading work on: • a scoping project on IVM • commissioning a technical report on the risks and benefits of the collection of immature eggs and the use of eggs that have been matured by IVM • preparing a consultation paper on IVM • considering outcomes of consultation and making recommendations to ACART

Working group	Responsibilities
Import and Export of Gametes and Embryos Working Group Sylvia Rumball Mark Henaghan Gareth Jones	Responsible in 2008/09 for leading work on a scoping project on import and export of gametes and embryos under sections 38 and 39 of the Act
Requirements for Informed Consent in Reproductive Research and Treatment Working Group Mark Henaghan John Forman Sylvia Rumball Richard Randerson	Responsible in 2008/09 for a scoping project on requirements for informed consent in reproductive research and treatment

Appendix 5: Summary of Applications 1997–2009

(submitted to ECART and its predecessor, the National Ethics Committee on Assisted Human Reproduction (NECAHR))

The following tables set out the numbers and outcomes of applications for:

- surrogacy
- donation of eggs or sperm between certain family members
- embryo donation.

ECART has not considered any applications for PGD with HLA tissue typing. Table 1 sets out the numbers and outcomes of surrogacy applications from 1 January 1997 to 30 June 2009.

Table 1: Applications for surrogacy, 1997–2009

Year	Number approved[a, b]	Number declined[a]	Number deferred
1997	1	0	0
1998	2	1[c]	4
1999	4	0	3
2000	5	1	2
2001	6	1	1
2002	1	0	3
2003	5	0	3[d]
2004	5[e]	0	1
2005	15	4	0
2006	16	0	1
Total	**60**	**7**	**18**

Year	Number approved[a, b]	Number declined[a]	Number deferred
July 2006–June 2007	13	1	1
July 2007–June 2008	18	0	0
July 2008–June 2009	18	0	0
Total	**49**	**1**	**1**

Notes

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

b This includes applications approved outright and applications approved subject to conditions.

c In 1999 NECAHR considered a variation to the original 1998 application and approved it.

d One application was subsequently withdrawn.

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

Table 2 sets out the numbers and outcomes of applications for donation of eggs or sperm between certain family members from 1 July 2005 to 30 June 2009.

Table 2: Applications for the donation of eggs or sperm between certain family members, 2005–2009

Year	Number approved[a,b]	Number declined[a]	Number deferred
July 2005–June 2006	2	1	1
July 2006–June 2007	5	0	0
July 2007–June 2008	9	2	0
July 2008–June 2009	9	0	0
Total	**16**	**3**	**1**

Notes

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

b This includes applications approved outright and applications approved subject to conditions.

Table 3 sets out the numbers and outcomes of applications for embryo donation from 1 July 2006 to 30 June 2009.

Table 3: Applications for embryo donation, 2006–2009

Year	Number approved[a,b]	Number declined[a]	Number deferred
July 2006–June 2007	1	0	0
July 2007–June 2008	9	0	0
July 2008–June 2009	2	1	0
Total	**12**	**1**	**0**

Notes

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

b This includes applications approved outright and applications approved subject to conditions.

Table 4 sets out the numbers of applications approved by ECART, by ethnicity, from September 2005 to June 2009.

Table 4: Applications approved by ECART, by ethnicity, September 2005 to June 2009

	Number in ethnic group	Total
Surrogacy		
Intending mother		67
European	61	
Māori	1	
Asian	5	
Intending mother's partner		67
European	66	
Māori	1	
Birth mother		67
European	59	
Māori	6	
Asian	1	
Māori/Pacific	1	
Birth mother's partner		47
European	41	
Māori	5	
Pacific	1	
Within-family gamete donation		
Recipient woman		25
European	20	
Māori	3	
Asian	1	
Other ethnicity	1	
Recipient woman's partner		25
European	20	
Māori	3	
Asian	1	
Other ethnicity	1	
Donor egg		19
European	14	
Māori	3	
Asian	1	
Other ethnicity	1	
Donor sperm		6
European	5	
Māori	1	

	Number in ethnic group	Total
Embryo donation		
Donor woman		13
European	13	
Donor man		13
European	13	
Recipient woman		13
European	12	
Māori/European	1	
Recipient man		13
European	12	
Māori/European	1	
Total		
European	336	375
Māori	23	
Asian	9	
Other ethnicity	3	
Pacific	1	
Māori/Pacific	1	
Māori/European	2	