National Ethics Committee on
Assisted Human Reproduction

Annual Report to
the Minister of Health

for the year ending 31 December 2001
Foreword

A particular focus for the National Ethics Committee on Assisted Human Reproduction (NECAHR) in 2001 was early work on the development of guidelines for providers of fertility services in the areas of pre-implantation genetic diagnosis and donation of already-existing embryos for reproductive purposes. This work marks a shift to a more proactive role for the Committee. In the past, a major focus for NECAHR was the development of guidelines for a narrow category of surrogacy, that is, altruistic non-commercial surrogacy using IVF as treatment. Once ethical approval for this category of surrogacy was granted in principle, details of the surrogacy guidelines were developed at the same time as the cases on which they were based were being submitted for ethical review. Neither pre-implantation genetic diagnosis nor donation of embryos for reproductive purposes is currently being offered as a service by fertility clinics. The model of developing guidelines on the basis of cases has, however, been retained in relation to within-family gamete donation. With rapidly developing technologies, keeping up with and ahead of proposed services and, in particular, weighing risks and benefits, present a major challenge for the Committee.

At its December 2001 meeting NECAHR deliberated on its own processes and approaches. As new members join the Committee and others retire there is a need for ongoing work on group dynamics. It is also important for NECAHR to consider from time to time what distinguishes it as an ethics committee. It is useful to articulate the ethical frameworks, perspectives and values that shape both the views of each of its members and the consensus view that it reaches in its decision-making. Continuity, challenge and progress in NECAHR’s work rely on members’ willingness to participate in open debate and make use of literature that informs about new international developments in reproductive technologies and their applications, as well as about theoretical, political and popular stances on these. The Committee’s work also relies on full documentation of precedents through detailed minutes and a work schedule that is updated after each meeting. The Committee’s administrative processes have also now been fully documented.

Accountability and transparency are critical for the work of the Committee. In the past year there were several opportunities to comment in the press, on radio and on television on New Zealand’s situation with regard to developments in the field of assisted human reproduction. Participation live in TV One’s “Face the Nation” programme was probably the most challenging of these. Communications staff at the Ministry of Health were most helpful in preparing background materials and advice about working with the media. NECAHR now has its own website, www.moh.govt.nz/necahr. All media involvement is very carefully balanced against respect for the privacy of individuals whose needs in relation to forming their families comprise the subject matter of the Committee’s work.
NECAHR’s deliberations continued to be informed in a practical way by Dr Peter Benny, who attended meetings as specialist adviser chosen by fertility clinics. Further understandings were developed through participation at the symposium of the New Zealand Infertility Society, at which I was a guest speaker. There was a request from that gathering for someone who had experienced infertility and related services to be appointed to NECAHR, and this was passed on to the Minister of Health. In my capacity as chairperson I accepted an invitation to visit the clinic of Wellington Fertility Associates to explain the Committee’s decision-making and administrative processes to staff. All of these activities contributed significantly to the continuing development of good professional working relations between NECAHR and the sector within which it functions. Early in its existence NECAHR was criticised on occasion for its processes. It is probably fair to say that the ethical review system is currently working well and is generally well accepted by both providers of services and their clients. There is more understanding of NECAHR’s cautiously progressive stance and its thorough approach to its work.

It is important to view developments in assisted human reproduction within the wider international context. Issues that arise in New Zealand are more often than not also being debated elsewhere. New Zealand clinics work closely with their Australian counterparts, and they share a monitoring and accreditation system. NECAHR’s guidelines for New Zealand clinics are recognised within this system. In 2001 I participated again in a meeting of representatives from the various regulatory authorities in Australia. This time the meeting was extended to a symposium at which there were speakers on regulatory approaches in France, South East Asia, Canada, USA and the UK. I was able to explain New Zealand’s proposed legislation, the current approach to regulation, which rests mainly on professional self-regulation and ethical review, and some of the cultural and ethical values, which distinguish New Zealand, for example, an emphasis on openness, information sharing and record keeping. Ashgate publishers in the UK will publish the symposium’s proceedings in 2002.

NECAHR’s effective functioning depends greatly on its members’ generosity in sharing insights, experience and understandings, contributing many hours of their time, and cheerfully tolerating what is often a strict chairing style necessitated by a full agenda and time constraints. It also depends on the support of Ministry of Health staff who service the Committee so ably and professionally.

Rosemary De Luca
Chairperson
National Ethics Committee on Assisted Human Reproduction
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Origins of the National Ethics Committee on Assisted Human Reproduction (NECAHR)

The National Ethics Committee on Assisted Human Reproduction (NECAHR) was initially established under section 46 of the Health and Disability Services Act 1993 and was later reconstituted under section 11 the New Zealand Public Health and Disability Act 2000. Since 1993, applications for ethical approval of assisted human reproduction research and innovative treatment have been assessed at a national level by NECAHR and its predecessor, the Interim National Ethics Committee on Assisted Reproductive Technologies (INECART).

Aims and functions

NECAHR’s functions are to:

- review assisted human reproductive proposals (including health research and innovative treatment) to determine whether they are ethical and, in particular, to determine whether:
  - the rights of the people involved will be protected
  - proper account will be taken of the ethical perspectives of Māori, and other cultural, ethnic, religious, and social groups in New Zealand
- develop for providers protocols and guidelines relating to the ethical issues involved with aspects of assisted human reproduction
- advise the Minister of Health on ethical issues relating to assisted human reproduction
- consider any other matters relating to assisted human reproduction that the Minister of Health from time to time determines.

NECAHR’s full Terms of Reference are set out in Appendix 1.

Membership

The Committee may have up to 10 members. Members may serve no more than nine consecutive years on the Committee. Members, year of appointment of each, and expiry date of current term as at 31 December 2001 were:

- Ms Rosemary De Luca, Chairperson
  Lay member, appointed to INECART in 1993, term expires 30 June 2002
- Mr Ken Daniels
  Health researcher, appointed 1995, term expires 30 June 2002
- Ms Alison Douglass
  Lay member, appointed to INECART 1993, term expires 30 June 2002
• Dr Alastair Gunn
  Lay member, appointed 1998, term expires 30 June 2002

• Dr Audrey Jarvis
  Lay member, appointed to INECART in 1993, term expires 30 June 2002

• Ms Rose Smith
  Health professional, Māori member, appointed to INECART in 1993, term expires 30 June 2002

• Dr Arlene Smyth
  Health professional, appointed 1999, term expires 30 June 2002

• Dr Anne Robertson
  Health professional, appointed 2001, term expires 31 January 2004

The Committee also appoints a specialist to advise, where necessary, on technical matters relating to assisted reproductive technology. This person does not take part in decision-making. The position is rotated annually among fertility clinics. In 2001, the specialist advisor to the Committee was Dr Peter Benny, Director of The Fertility Centre, Christchurch.

The Director-General of Health also appoints a representative to provide information on government policy and ministerial views. In 2001, the Director-General’s representative was Dr Barbara Nicholas.

In 2001, nominations were sought for a Māori member with medical expertise, and also a Māori lay person with cultural and ethics expertise. Cabinet noted the appointment of Dr Beverley Lawton to fill the vacancy for a Māori member with medical expertise, and Ms Helene Leaf as the Māori lay member. These appointments were for terms of two years and took effect from February 2002 when they were gazetted.

NECAHR wrote to the Minister of Health recommending that she appoint a consumer representative in the next round of appointments to the Committee.

See Appendix 2 for further details on Committee members.
Key issues considered in 2001

The Committee met four times in 2001 – in April, June, August and December. The Committee considered 14 new proposals and two proposals brought forward from 2000. A table providing details of all applications considered during 2001 is attached as Appendix 3.

1 Draft guidelines for non-commercial altruistic surrogacy using IVF as treatment

NECAHR agreed in July 1997 to give ethical approval in principle for non-commercial altruistic surrogacy using in vitro fertilisation (IVF) as treatment. NECAHR stipulated that in the interim applications should be reviewed on a case-by-case basis.

NECAHR has incorporated its findings and decisions on these applications into a set of draft guidelines. These take the form of criteria for ethical approval of future applications.

Whenever a fertility services provider wishes to proceed with non-commercial surrogacy using IVF as treatment, the provider must submit the proposal for ethical review and have it assessed in terms of the guidelines. As at 31 December 2001, NECAHR had approved 18 applications for non-commercial surrogacy using IVF as treatment and declined three applications. NECAHR requires that clinics inform it of the outcome of any approved surrogacy arrangement, and that this include details of when the IVF programme began, when pregnancy was confirmed or the programme was discontinued, any adverse events, and the outcome of any pregnancy. NECAHR has been notified of only one birth resulting from a surrogacy arrangement using IVF as treatment.

The Committee has continued to develop the guidelines as issues have arisen. Overseas developments have been taken into account. The Committee sought feedback on the draft guidelines from a number of interested groups and individuals in 2001, and has made some minor changes in response to that feedback. A list of people and organisations who made submissions is attached as Appendix 4. The Committee expects to release the amended draft guidelines in early 2002. These will remain in draft format and applications will continue to be considered on a case-by-case basis until legislation on assisted human reproduction has been enacted. In 2001 the Committee considered seven applications for non-commercial surrogacy using IVF as treatment, including two applications carried over from 2000. Four of those applications were approved, one did not receive ethical approval and two were deferred pending provision of further information to the Committee.

A copy of the draft guidelines as at December 2001 is attached as Appendix 5.
2 Guidelines for posthumous use of sperm using a deceased man's sperm

Guidelines on this issue were finalised at the February 2000 meeting of the Committee and have been distributed to fertility clinics. Ethical approval is required for all proposals that do not meet the guidelines. The Committee received no applications for posthumous use of sperm in 2001.

A copy of these guidelines is attached as Appendix 6.

3 Within-family gamete donation

NECAHR clarified its position on applications for within-family gamete donation. Following correspondence with the clinics about current practice, the Committee has asked to review all proposals for intergenerational (across generations) gamete donation and proposals for intragenerational (within the same generation) gamete donation where the donor gametes and recipient gametes are from related people, either of a blood relationship such as brother and sister or a close social relationship such as adopted siblings.

Within-family gamete donation is a complex and controversial practice that involves ethical, social and cultural factors. The ethical concerns relate to biological and social relationships. The Committee had been advised by a geneticist at its meeting on 28 November 2000 that genetic abnormalities were not a great concern in within-family gamete donation, rather the practice is more of a social issue. The Committee also needs to consider whether any proposal might cross boundaries and establish relationships that may not generally be acceptable because of a perceived analogy with incest.

NECAHR intends to develop guidelines on within-family gamete donation by monitoring ethical issues that arise from the individual proposals that it reviews. The Committee is also monitoring international developments in this area. The Committee received two applications for within-family gamete donation in 2001. One was for sister-to-sister egg donation (see Appendix 3, proposal 2001/13). The Committee considered and approved this application although it has informed clinics that such applications do not require ethical approval. The Committee also received an application for within-family intergenerational gamete donation. The Committee declined this application because of concerns about informed consent (see Appendix 3, proposal 2001/11).
4 Pre-implantation genetic diagnosis

In 2001, NECAHR gave approval to two clinics to develop the technique of embryo biopsy for the purpose of pre-implantation genetic diagnosis (PGD) using donated non-viable embryos. To date, three clinics have received ethical approval to develop the technique of embryo biopsy using non-viable embryos. Any proposal to apply these techniques in infertility treatment would require a separate application to NECAHR for ethical review, and would be considered on its merits. Key issues relate to the reliability and safety of the tests and the purposes for which they could be used, for example, detection of serious genetic disease in the embryo.

Fertility clinics have indicated that there may be an application to apply the technique in late 2002. The Committee will give further consideration to the significant ethical issues associated with PGD in 2002 with a view to developing guidelines for clinics. NECAHR is monitoring international developments in this area.

5 Embryo donation

NECAHR has not received an application for embryo donation. However, some clinics have indicated that they have clients interested in donating their embryos for reproductive purposes and have sought NECAHR’s advice on how it would address the wider ethical issues involved in embryo donation.

NECAHR began developing guidelines for embryo donation by undertaking a literature search of international policy and practice in this area, including an examination of the ethical issues involved in this practice. NECAHR expects to have draft guidelines available for clinics in 2002.

Website

NECAHR launched its website in late 2001. The website is intended to make NECAHR’s processes and decisions more accessible to the public. Public comment on NECAHR’s guidelines and processes can be made via the website at http://www.newhealth.govt.nz/necahr.htm.
Conferences and media presentations

The chairperson represented NECAHR at an international symposium in Melbourne on the regulation of reproductive technologies and presented a paper entitled *The New Zealand Way: ART within an Ethical Framework*. This symposium was a satellite to the 17th World Congress on Fertility and Sterility. Another Committee member also attended in a private capacity.

The chairperson attended and spoke at the New Zealand Infertility Society’s 2001 conference in September.

Dr Anne Robertson represented NECAHR at the New Zealand Bioethics Conference in Dunedin from 8–10 February 2002.

The chairperson participated in media presentations when the opportunity arose.
Appendix 1: Terms of Reference

The role of the committee

The National Ethics Committee on Assisted Human Reproduction (NECAHR) is a ministerial committee established under sections 11 and 16(3) of the New Zealand Public Health and Disability Act 2000 (the Act).

NECAHR’s functions are to:

- review assisted human reproductive proposals (including health research and innovative treatment) to determine whether they are ethical and, in particular, to determine whether:
  - the rights of the people involved will be protected
  - proper account will be taken of the ethical perspectives of Māori, and other cultural, ethnic, religious, and social groups in New Zealand
- develop for providers protocols and guidelines relating to the ethical issues involved with aspects of assisted human reproduction
- advise the Minister of Health on ethical issues relating to assisted human reproduction
- consider any other matters relating to assisted human reproduction as the Minister of Health from time to time determines.

Composition of the committee

Individuals appointed to NECAHR have a range of experience, from first-time appointees with little or no experience as a member of such committees to members with extensive experience. NECAHR draws considerable benefits from having a diverse membership with a range of skills, attributes, and experience.

NECAHR shall consist of not more than 10 members appointed by the Minister of Health. NECAHR’s membership shall include members with specialist knowledge of and experience in assisted human reproductive procedures. NECAHR shall have at least two Māori members. At any time, at least half the members of NECAHR shall be lay members.

For the purposes of appointments to NECAHR, a lay member is defined as anyone who:

- is not a registered health professional engaged in health care delivery or employed in the provision of health or disability services
- is not involved as a researcher in health and disability research in the field of assisted human reproduction
- may not be construed by virtue of current or previous employment to have a potential conflict or professional bias in assessing a majority of applications presented to NECAHR for ethical review.
The Director-General of Health will appoint one person to represent the Ministry of Health. It will be the responsibility of that person to provide NECAHR with information regarding government policy and ministerial views.

**Terms and conditions of appointment**

Members of NECAHR are appointed by the Minister of Health under section 16(3) of the New Zealand Public Health and Disability Act 2000 for a term of office of up to three years. Members may be reappointed from time to time. No member may hold office for more than nine consecutive years. Unless a person vacates their office sooner, every appointed member of NECAHR shall continue in office until their successor comes into office. Any member of NECAHR may at any time resign as a member by advising the Minister in writing.

Any member of NECAHR may at any time be removed from office by the Minister for disability, bankruptcy, neglect of duty, or misconduct, proved to the satisfaction of the Minister.

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

**Chairperson**

The Minister will from time to time appoint a member of NECAHR to be its chairperson. The chairperson will preside at every meeting of NECAHR at which they are present. The chairperson may from time to time appoint a member as deputy-chairperson.

**Duties and responsibilities of a member**

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

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

1. NECAHR members should have a commitment to work for the greater good of the committee.

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

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

**Conflicts of interest**

4. 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 NECAHR and its members and will ensure it retains public confidence.

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

6. When members believe they have a conflict of interest on a subject which 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.

7. A member of NECAHR who has a proposal before the committee or who has an involvement in the proposal such as a supervisory role shall not take part in NECAHR’s assessment of that proposal. The member may be present to answer questions about a proposal but should be asked to leave the meeting while the remaining members consider the proposal. This will allow proposals to be considered in a free and frank manner.

**Confidentiality**

8. The public has a right to be informed about the issues being considered by NECAHR. NECAHR should have procedures in place regarding the release of information and processing requests for information.
9 NECAHR also has a duty to protect the rights of those making applications for ethical review. NECAHR should therefore determine what information can be appropriately released, and to whom and under what circumstances information should be released. The following duties in relation to committee information should be observed by individual members. These provisions ensure that the NECAHR committee as a whole maintains control over the appropriate release of information concerning applications or issues before it.

- Meetings of NECAHR, including agenda material and minutes, are confidential. Members should ensure that the confidentiality of committee business is maintained.
- Members are free to express their own views within the context of committee meetings, or the general business of NECAHR.
- Members should publicly support a course of action decided by NECAHR. If unable to do so, members should not publicly comment on decisions.
- At no time should members individually divulge details of committee matters or decisions of NECAHR to persons who are not committee members. Disclosure of committee business to anyone outside the committee should be on the decision of the committee, or between meetings, at the discretion of the chairperson of NECAHR. In choosing to release or withhold information, the committee must comply with the provisions of the Official Information Act 1982 and the Privacy Act 1993.
- Committee members should ensure that committee 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 the committee.

**Fees and allowances**

Members of NECAHR, and of any sub-committees appointed by NECAHR, 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. Currently the chairperson receives an honorarium of $10,000 per annum, and the attendance fee for members is set at $250 per day (plus half a day’s preparation fee). NECAHR pays for actual and reasonable travel and accommodation expenses.
Meetings of the Committee

Meetings shall be held at such times and places as NECAHR or the chairperson of NECAHR decide.

At any meeting, a quorum shall consist either of half the total number of members when that number is even, or the majority of the members when that number is odd. The quorum must include a balance of lay members and members with specialist knowledge of and experience in assisted human reproductive procedures.

Every question before any meeting shall be determined by consensus decision-making.

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

Working

In carrying out its terms of reference, NECAHR:

- will be serviced by the Ministry of Health
- will be provided with personal indemnity insurance by the Ministry of Health
- may carry out information gathering and research as is reasonably required
- may consult such other expert persons that are considered reasonably necessary to carry out the committee’s functions
- may not disclose any confidential information without the approval of the Minister of Health
- none of the individual members will make media statements without the consent of the committee
- the committee should advise the Minister of Health prior to making any media statements or publishing any reports.

Key ethical principles

When scrutinising proposals, NECAHR should be satisfied that the following key ethical principles have been adequately upheld before giving ethical approval for a proposal to proceed:

- participants’ right to autonomy
- participants’ right to informed consent
- protection of participants from undue harm

1 For the purposes of this document, “participants” refers to the clients of providers of fertility services, and also includes a potential child when appropriate.
• freedom from coercion and inducement
• participants’ right to privacy
• principles and obligations under the Treaty of Waitangi
• cultural equity and partnership
• research and treatment merit.

Principles of natural justice
In undertaking the ethical review of applications, NECAHR should adopt the principles of
natural justice. NECAHR should therefore ensure that:
• it has the appropriate expertise available to adequately review each proposal
• all processes are open, transparent, and fair
• it is unbiased in considering applications for ethical approval
• all relevant parties are:
  – advised of the process to be undertaken
  – given the opportunity to be heard and to comment on issues (a reasonable period of
time should be given for the parties to respond)
  – kept informed of the progress of a review
  – advised of the outcome of the review
• in making decisions, no conflict of interest exists or appears to exist
• reasons are given for any decisions or recommendations made. This is of particular
importance when:
  – ethical approval is not granted to an application
  – a health professional or researcher is directed to suspend a health research project/
innovative practice until a complaint can be resolved
  – ethical approval is subsequently withdrawn.

Review of a decision
NECAHR has an obligation to review any new information which pertains to any previous
decision to grant or decline ethical approval of a proposal. NECAHR should advise applicants
that any decision may be reviewed on the basis of new information in the future.

Any person may, at any time, request that NECAHR review a proposal in the light of new
information. NECAHR should ask those requesting a review of a decision to put their request in
writing and to enclose the relevant new information.
When a request for review is received, NECAHR should review any new information and decide whether there are sufficient grounds for changing its initial decision to grant or decline ethical approval of a proposal.

Any review should be conducted in an open and transparent manner. All relevant parties should be advised that a review of new information is being undertaken and kept informed of a review’s progress.

If NECAHR decides that the new information raises sufficient grounds for changing its decision, NECAHR should advise all parties accordingly. Depending on the nature of the proposal and the information supporting the request for review, it may be appropriate for NECAHR to request that the originator of the proposal cease all activities covered by the proposal until the outcome of the review is known.

NECAHR should advise all parties of the outcome of the review and request that the parties concerned indicate whether they are satisfied with the outcome of the review. If all parties are not satisfied with the outcome of the review, the issue should be referred to either the HRC Ethics Committee (in the case of issues relating to health research) or the Director-General of Health (in all other cases). An independent person or group appointed by the Director-General or HRC Ethics Committee will undertake a review of the decision-making process used by the committee.

**Withdrawal of ethical approval**

It is important to protect patients and research participants from undue harm. Circumstances may arise in which NECAHR should withdraw ethical approval from a proposal in order to protect participants. Circumstances where ethical approval may be withdrawn include:

- when complaints that appear to have some substance have been received from participants
- where a proposal has deviated from approved protocols
- where new information becomes available that indicates that the safety of participants may be at risk
- where an applicant has not reported significant or unexpected adverse outcomes to the committee
- where an applicant has not met one or more conditions placed on them when ethical approval was given. (This may include not meeting reporting requirements specified at the time of ethical approval.)
When ethical approval is given to a proposal, NECAHR should advise health professionals and researchers that, if they fail to meet any conditions upon which approval is contingent or if they deviate from an approved protocol without first obtaining the committee’s consent, the proposal will automatically cease to have ethical approval.

When considering the withdrawal of ethical approval, NECAHR should follow the principles of natural justice. The health professional or researcher should be given an opportunity to comment on any evidence or complaints.

Where ethical approval is withdrawn, the applicant should be notified in writing. NECAHR should request the applicant to cease all activities and advise participants of the removal of ethical approval. It may also be appropriate for a committee to notify:
- the organisation employing or funding the applicant
- the Health and Disability Commissioner
- other health and disability ethics committees
- the Health Research Council Ethics Committee
- the appropriate health professional body
- the Ministry of Health.

**Independent**

A person who submitted a proposal for ethical review to NECAHR may seek a second opinion regarding NECAHR’s decision to withhold ethical approval. Requests for a second opinion should generally be made in writing. Second opinions should be directed to the Director-General of Health.

When a request for a second opinion is received, the Director-General of Health will establish an independent advisory group (consisting of members with the appropriate expertise) to provide a second opinion.

A second opinion will adhere to the principles of natural justice. All relevant parties will be advised of the process that will be undertaken and will be kept informed of the progress of the second opinion process.

A second opinion:
- is concerned with issues related to the ethics of the proposal
- is not regarded as a higher judgement but rather as a review of NECAHR’s decision-making process
• does not overturn NECAHR’s decision; in other words, the conclusions of the advisory group that provides the independent assessment does not bind NECAHR to take any particular action

• should be taken into account by NECAHR when reconsidering the proposal and reaching its final decision.

The final decision regarding the granting or withholding of ethical approval rests with NECAHR.

The advisory group assessing NECAHR’s decision making process will:

• take into account the decision reached by NECAHR after it conducted an initial review of the proposal
• give written reasons supporting its conclusions.

The advisory group that provides the second opinion may comment on whether NECAHR had:

• received adequate information from the applicant
• taken reasonable and appropriate steps to gather and consider all relevant information. Factors that may be considered include:
• the availability of information
• whether additional information could have been sought from the applicant, experts, or from other committees which may have considered related proposals
• been in a position to adequately consider and assess the application through possessing or seconding appropriate expertise
• adhered to the principles of natural justice
• adequately recorded and conveyed to the applicant those factors which were considered critical to the decision.

The advisory group is not restricted to the material that was considered by NECAHR. Other information that was available at the time when the original decision was made or new information that has come to light may be considered in order to determine whether that information is relevant to the decision of the initial review.
Reporting requirements

NECAHR is required to:

- keep minutes of all committee meetings – which outline the issues discussed and include a clear record of any decisions or recommendations made
- prepare a brief annual report to the Minister summarising the work of the committee for the past year.

Performance measurement

The committee will be effectively undertaking its tasks when it:

- provides timely and comprehensive ethical review of proposals involving assisted human reproduction
- provides timely advice to the Minister of Health on issues relating to assisted human reproduction
- develops and drafts protocols to assist fertility clinics in developing proposals for health research and innovative practice relating to assisted human reproduction
- performs these functions within the budget provided.

Servicing of the committee

The Ministry of Health will provide the services of a committee secretary. The duties of the secretary will be to:

- prepare draft minutes
- prepare agenda and meeting notes
- draft correspondence, reports, as directed by the committee and so on
- circulate papers and written material to committee members
- organise meeting venue and catering as required
- make travel and accommodation arrangements
- arrange for the timely and accurate payment of meeting fees and allowances
- administer the committee budget.

Authorised by the Minister of Health
February 2001
Appendix 2: Membership of the National Ethics Committee on Assisted Human Reproduction (2001)

Rosemary De Luca (Chair)
Rosemary De Luca is a Senior Lecturer in the Department of Arts and Language Education at the University of Waikato. She was until recently the Chair of the Waikato Ethics Committee and was also a member of the Working Group revising the National Standard for Health and Disability Ethics Committees. She has 12 years’ experience in health sector ethics, and teaches and has published widely in this field. Her current research interests include the language and procedures associated with informed consent to medical treatment in hospitals.

Associate Professor Ken Daniels
Ken Daniels is an Associate Professor in Social Work at the University of Canterbury. He teaches values and ethics and has taken advanced studies in bioethics. He has been researching and writing in the field of assisted human reproduction for 24 years and has published over a hundred papers, chapters and books on this issue. He is currently involved in research in Sweden, Germany, the United Kingdom, Singapore, Argentina and New Zealand.

Alison Douglass
Alison Douglass is a partner in the law firm Tripe Matthews and Feist, specialising in civil litigation and health law. She is former chairperson of the Wellington Ethics Committee and a member of the medical misadventure advisory panel to ACC. She has a Masters degree in Bioethics.

Associate Professor Alastair Gunn
Dr Alastair Gunn is an Associate Professor in the Department of Philosophy at the University of Waikato. He was a member of the Waikato Ethics Committee for a number of years. He has an interest in health ethics, in particular issues relating to assisted human reproduction.

Dr Audrey Jarvis
Dr Jarvis is a microbial geneticist, having retired from the position of Principal Scientist at the New Zealand Dairy Research Institute, Palmerston North. She has served on national and international scientific committees, and has received New Zealand and international awards in recognition of her scientific achievements. She has been active on health ethics committees and at regional and national level, and is currently chairperson of the Inter-Church Commission on Genetic Engineering.
**Dr Arlene Smyth**

Arlene Smyth is a general practitioner practising at the Island Bay Medical Centre in Wellington. Her main interests are in the area of women’s and children’s health, and she is a practising GPO (General Practitioner Obstetrician). She is involved in undergraduate teaching for the University of Otago, regularly tutoring medical students in her general practice and also in the Department of Obstetrics at Wellington Women’s Hospital. She is also involved in the Wellington Doctors for Sexual Abuse Cases (DSAC) and is on the Quality Assurance Committee for MATPRO (the Wellington Maternity Project).

**Rose Smith**

Rose Smith is a registered general and obstetrics nurse and is currently employed as the senior staff nurse, General Surgical and Urology Unit, Health Waikato. She has been a Māori member on the Waikato Ethics Committee, and also serves on a number of local marae and community committees.

**Dr Anne Robertson**

Anne Robertson is a consultant obstetrician and gynaecologist. She has an extensive background in obstetrics, gynaecology, sexual health and in ethics. As a health professional member of the Manawatu-Whanganui Ethics Committee since 1996 she has developed significant experience in and knowledge of the area of ethical review in the health sector.
## Appendix 3: Summary of proposals considered by NECAHR from 1 January to 31 December 2001

<table>
<thead>
<tr>
<th>Code</th>
<th>Date received</th>
<th>Discussed at the meetings of Fast track approval (delegated authority)</th>
<th>Fast track approval (whole committee)</th>
<th>Proposal</th>
<th>Applicant</th>
<th>Ethical issues considered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000/05</td>
<td>17/04/2000</td>
<td>04/07/2000 (Deferred the application pending further information including: information on the commissioning father’s wider support, and his legal rights; and clarification from the gynaecologist on the meaning of this two year timeframe re commissioning mother’s recovery from cancer). 28/11/2000 Decision pending counsellor’s report and lawyer’s report. 24/4/2001 Received one legal report but agreed to seek further information on some outstanding legal issues. Agreed that two separate counselling reports are required, but should be undertaken closer to the time treatment is anticipated to begin. Agreed to reconsider application when outstanding information provided. 28/08/2001 4/12/2001</td>
<td>Non-commercial surrogacy using IVF</td>
<td>Otago Fertility Services</td>
<td>Considered in terms of draft guidelines on surrogacy using IVF as treatment, and in particular survival of the birth mother – concerns about approving surrogacy when the commissioning mother was potentially terminally ill (and the impact of cancer on her eggs was unknown). 21/12/2001 Approved</td>
<td></td>
</tr>
<tr>
<td>2000/11</td>
<td>01/11/2000</td>
<td>Considered at the 28 November 2000 meeting. Further information requested. 24/04/2001 Received additional information from applicant re commissioning mother’s medical condition. 28/08/2001 4/12/2001</td>
<td>Non-commercial surrogacy using commissioning mother’s gametes.</td>
<td>Fertility Associates, Auckland</td>
<td>Issues considered: can a birth mother reasonably be expected to carry a child with a resultant risk to a child in the future where there is no clear evidence that the replacement of the embryo in the surrogate would have a better chance of conception than replacement into the commissioning mother? 16/05/2001 Approval was withheld because the application did not meet the conditions set out in NECAHR’s draft Guidelines (require the existence of a medical condition that precludes pregnancy or makes pregnancy damaging to the commissioning mother or the child).</td>
<td></td>
</tr>
<tr>
<td>2001/01</td>
<td>9/02/2001</td>
<td>Agreed to fast track once assurances provided regarding joint counselling. 24/04/2001</td>
<td>Non-commercial surrogacy using IVF as treatment</td>
<td>Fertility Associates Auckland</td>
<td>Considered in terms of the Draft Guidelines for Surrogacy Using IVF as Treatment. 25/06/2001 Approved</td>
<td></td>
</tr>
<tr>
<td>2001/02</td>
<td>25/01/2002</td>
<td>24/04/2001 Advised to submit formal application if wished to proceed. (Have not received an application.)</td>
<td>Non-commercial surrogacy using IVF as treatment</td>
<td>Gynaecology Clinic, Tokoroa Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2001/03</td>
<td>9/04/2001</td>
<td>24/04/2001</td>
<td>Non-commercial surrogacy using IVF as treatment</td>
<td>Fertility Associates, Wellington</td>
<td>Considered in terms of the Draft Guidelines for Surrogacy Using IVF as Treatment. Particular issues considered: health of birth mother 16/05/2001 Approved, conditional on IVF treatment being delayed at least until after the six month follow-up smear for CIN111 has been taken</td>
<td></td>
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<tr>
<td>Code</td>
<td>Date received</td>
<td>Discussed at the meetings of</td>
<td>Fast track approval (delegated authority)</td>
<td>Fast track approval (whole committee)</td>
<td>Proposal</td>
<td>Applicant</td>
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<tr>
<td>2001/04</td>
<td>11/03/2001</td>
<td>24/04/2001, 19/06/2001</td>
<td>Agreed to fast track once additional information provided (still awaiting additional information)</td>
<td>Cryopreservation of mature oocytes for medical reasons</td>
<td>Fertility Associates, Auckland</td>
<td>Issues considered: informed consent (ensuring information relating to success of treatment was accurate and clear to patients considering the treatment)</td>
</tr>
<tr>
<td>2001/05</td>
<td>9/04/2001</td>
<td>24/04/2001</td>
<td>Establishment of embryo biopsy and blastomere transportation service for pre-implantation genetic diagnosis (using donated non-viable embryos)</td>
<td>The Fertility Centre, Christchurch</td>
<td>Issues considered: NECAHR’s jurisdiction over gametes and embryos that are sent overseas for diagnostic tests. Whether a distinction can be made between diagnosis for social vs medical reasons and to what extent NECAHR will be consulted. Cultural perspectives – how would applicant inform embryo donors about the procedure in a culturally appropriate way.</td>
<td>16/05/2001</td>
</tr>
<tr>
<td>2001/06</td>
<td>9/04/2001</td>
<td>24/04/2001</td>
<td>Cryopreservation of Ovarian Tissue</td>
<td>The Fertility Centre</td>
<td>Issues considered: Experimental nature of some of the procedures involved in cryopreservation and use of thawed tissue. The need to include the risk of carcinoma transmission on the patient consent form. Whether an age restriction should be put on the procedure (in line with its decision on an earlier proposal for cryopreservation of ovarian tissue where it set a limit of 16 years based on the definition of a ‘consenting adult’).</td>
<td>16/05/2001</td>
</tr>
<tr>
<td>2001/08</td>
<td>9/04/2001</td>
<td>Considered at the 19 June 2001 meeting</td>
<td>Non-commercial surrogacy using IVF as treatment</td>
<td>Fertility Associates, Wellington</td>
<td>Considered in terms of the Draft Guidelines for Surrogacy Using IVF as Treatment. Particular issues considered: Ensuring legal issues adequately addressed Ensuring that parties are aware that the use of PGD in treatment has not been ethically approved in New Zealand.</td>
<td>13/07/2001</td>
</tr>
<tr>
<td>2001/09</td>
<td>25/05/2001</td>
<td>19/06/2001, 28/08/2001, 4/12/2001</td>
<td>Agreed to reconsider once additional information provided</td>
<td>Development of an efficient and safe technique for the biopsy of human embryos</td>
<td>Fertility Plus, Auckland</td>
<td>Issues considered: Criteria for determining an embryo is non-viable. Information given to embryo donors about the research Confidentiality and anonymity – needs to be made clear to donors that there will be no genetic analysis of the cells taken.</td>
</tr>
<tr>
<td>Code</td>
<td>Date received</td>
<td>Discussed at the meetings of</td>
<td>Fast track approval (delegated authority)</td>
<td>Fast track approval (whole committee)</td>
<td>Proposal</td>
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<tr>
<td>2001/10</td>
<td>9/05/2001</td>
<td>Considered at the 19 June 2001 meeting</td>
<td>Agreed to fast track once additional information provided</td>
<td>Non-commercial surrogacy using IVF as treatment</td>
<td>The Fertility Centre, Christchurch</td>
<td>Considered in terms of the Draft Guidelines for Surrogacy Using IVF as Treatment</td>
</tr>
<tr>
<td>2001/11</td>
<td></td>
<td>Considered at 28 August 2001 meeting.</td>
<td>Within-family (inter-generational) sperm donation</td>
<td>Fertility Associates, Auckland</td>
<td>Issues considered related to informed consent and, in particular: the proposed donor's vulnerability and the potential for coercion an indication from the counsellor about the donor's unwillingness to take part in the proposal that the proposed mother and her stepson will be living in close proximity while he would also be the biological father of a child. This could create what is seen as a potentially problematic situation. There were also concerns about the apparent lack of independent support for the proposed donor, concern about what appeared to be planned deception about the nature of conception by the parties involved in the proposal and therefore about the welfare of a child where he or she did not know about the nature of conception.</td>
<td>12/09/2001 Declined</td>
</tr>
<tr>
<td>2001/12</td>
<td>8/08/2001</td>
<td>28/08/2001</td>
<td>Non-commercial surrogacy using IVF as treatment subsequent to Proposal 99/5 – freezing of embryos in anticipation of future surrogacy.</td>
<td>Fertility Associates, Wellington</td>
<td>Considered in terms of the Draft Guidelines for Surrogacy Using IVF as Treatment</td>
<td>Specific issues considered: the Committee noted that this proposal is a variation to the Draft Guidelines for Non-commercial surrogacy using IVF as Treatment in that the proposed birth mother (surrogate) does not have a close relationship with the commissioning parents and this would be simply an altruistic arrangement. NCEAHR considered a number of issues in its deliberations on this proposal including: the perceived pressures on the birth mother’s psychological health, in the short term, including: the recent death of her partner; and her potential vulnerability to postnatal depression the welfare of the birth mother’s existing child, and what information about the arrangement would be given in the future to that child.</td>
</tr>
<tr>
<td>2001/13</td>
<td>8/08/2001</td>
<td>Considered at the 28 August 2001 meeting</td>
<td>Within-family (intra-generational) gamete donation</td>
<td>Fertility Associates, Wellington</td>
<td>Relationship between the donor and recipient</td>
<td>21/09/2001 Approved</td>
</tr>
<tr>
<td>Code</td>
<td>Date received</td>
<td>Discussed at the meetings of</td>
<td>Fast track approval (delegated authority)</td>
<td>Fast track approval (whole committee)</td>
<td>Proposal</td>
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<tr>
<td>2001/14</td>
<td>14/11/2001</td>
<td>Considered at the 4 December 2001 meeting</td>
<td></td>
<td></td>
<td>Fertility Associates, Auckland</td>
<td>Issues relating to informed consent and the type of information made available to participants</td>
</tr>
</tbody>
</table>
Appendix 4: Individuals or organisations who made submissions on surrogacy to NECAHR in 2001

Commissioner for Children
Family Planning Association of New Zealand
Fertility Associates, Auckland
Human Rights Commission
National Council of Women
New Zealand Infertility Society
New Zealand Law Society (Biological and Medical Issues Committee)
New Zealand Medical Association
The Nathaniel Centre (New Zealand Catholic Bioethics Centre)
Professor John Hutton
Right to Life, New Zealand
Appendix 5: Draft guidelines for non-commercial altruistic surrogacy using IVF as treatment

Prepared by the National Ethics Committee on Assisted Human Reproduction
Last revised May 2001
c/o Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND

Introduction

The National Ethics Committee on Assisted Human Reproduction (NECAHR) agreed to give ethical approval to a general application for non-commercial surrogacy using in vitro fertilisation (IVF) as treatment in July 1997 and to review applications on a case-by-case basis. The draft guidelines have been developed progressively as cases are reviewed. NECAHR will continue to notify clinics of amendments to the guidelines.

Each and every instance of this practice with which any infertility services provider wishes to proceed must be submitted individually for ethical review and will be assessed on a case-by-case basis and in relation to these guidelines.

The following issues and/or reporting requirements must be addressed for ethical approval of non-commercial surrogacy using IVF as treatment.

Provider

A report on the medical status of the birth mother must be included in the application, i.e. age of the mother, number and ages of children, existing medical conditions. Information on the birth mother’s age is necessary as the risks to the mother’s health and likelihood of a less successful outcome increase with age. Information on the number and ages of children is necessary in order to know whether the birth mother is likely to be capable of having a normal pregnancy. A surrogate who already has children of her own is likely to be more aware of the medical and psychological risks to herself.

The application should be explicit about conditions that may impact on the safety of the birth mother when undertaking treatment and pregnancy and should include documentation from medical advisors.

The treatment must be in accordance with the RTAC guidelines.
If the birth mother has a partner, the provider must discuss with the birth mother and her partner how they will ensure that they do not conceive their own child during the IVF treatment.

Screening of birth mother’s partner. NECAHR considers that screening of the birth mother’s partner should be the standard screening carried out for partners of women undergoing IVF treatment, i.e. for HIV and Hepatitis A and C.

The provider is to report to NECAHR on each non-commercial altruistic surrogacy using IVF as treatment which has been approved:
• when the IVF programme begins
• when pregnancy is confirmed or the programme is discontinued
• any adverse events
• the outcome of pregnancy, and
• the outcome of the adoption and guardianship process.

NECAHR requires that the clinic’s policy takes account of different cultures, e.g. in considering the disposal of gametes, that the gametes would be offered to whānau, in the case of donors.

**Commissioning parents**

The commissioning parents’ use of their own gametes. One or both of the commissioning parents should be the potential child’s genetic parents.

The existence of a medical condition that precludes pregnancy or makes pregnancy damaging to the commissioning mother or the child. There should be medical reasons for the commissioning mother not undertaking a pregnancy.

The relationship between the birth mother and the commissioning parents. NECAHR prefers that the birth mother be either a family member or close friend of the commissioning parents.

Expenses related to pregnancy and childbirth. Such recompense may be made, but no payment should be made in lieu of employment.

**Birth mother and her partner**

The family status of the birth mother. The birth mother and her partner should have completed their family as this reduces the likelihood that they will want to keep the child. Problems could arise if they had not completed their family or begun it, including in relation to medical complications due to surrogacy which then prevented further pregnancy.
If the birth mother has a partner, the birth mother and her partner should take measures to ensure that they do not conceive their own child during the IVF treatment.

**Legal advisers**

The purpose of legal advice is to ensure the legal implications of surrogacy are addressed to enable the respective parties to give informed consent. There must be different lawyers for the commissioning couple and for the birth mother (and her partner if she has one).

Reports from two different legal advisers indicating that the participants clearly understand the legal issues and the current environment in which surrogacy agreements are legally unenforceable.

NECAHR does not require a formal agreement. This does not preclude a statement of intent between the parties allowing them to work through the issues, and enabling both parties to clearly state their intentions and expectations.

Dispute resolution. NECAHR advises that participants discuss possible disputes. For example, about the custody of the child, termination of pregnancy, and lifestyle issues during pregnancy with counsellors and legal advisers, before the proposal is finalised. It should be noted that disputes may ultimately be resolved by a court.

Legal advisers must ensure that participants understand that the child will legally be the child of the birth mother (and her partner if there is agreement) to the surrogacy arrangement, unless adopted by the commissioning parents.

Legal advisers must ensure that participants clearly understand procedures relating to guardianship, custody and adoption and the requirements that adoptive parents have to meet, if they wish to adopt the child.

**Counsellors**

Counselling must be undertaken by qualified counsellors and be culturally appropriate.

Counselling must include discussion of the following:

- the possibility of a breakdown in the arrangement such that the birth mother wishes to keep the child, or the commissioning parents do not wish to adopt the child
- the position of both parties in the event of a multiple birth
- the risk of rejection of a child for any reason, e.g. if the child is born with a disability or abnormality
• discussions about the possibility of legal termination of a pregnancy if fetal abnormality is diagnosed before birth (we still need to ensure this is consistent with the Contraception, Sterilisation and Abortion Act 1977)
• the possibility of the birth mother deciding against a termination in the above situation and discussions about the subsequent care of the child
• amount of control that genetic parents have over the birth mother’s conduct of her pregnancy
• the availability of a permanent, accurate record of conception and gestation for the child
• any issues covered in a written agreement

Appropriate counselling. NECAHR expects that clients be counselled as two separate family groups, together as a group and individually. Existing children should be included in counselling in an age appropriate manner.

The Committee prefers that two counsellors be involved, one for each family group. NECAHR prefers that there be a month free of counselling after the initial counselling period and then further counselling to allow clients to think through the issues without counselling intervention.

A counselling report which confirms that the issues raised by NECAHR have been discussed and in the professional judgement of the counsellor they have been adequately understood. NECAHR wishes to receive a report on the outcome of the counselling process when the proposal is forwarded for final approval.

NECAHR expects counsellors to follow the usual counselling practice of recording the family histories of those involved in the surrogacy arrangement. If there are life experiences, e.g. psychiatric problems, substance/physical/sexual abuse which may predispose any of the applicants to risk when moving into a new situation, or which may pose a risk to the potential child, these must be referred to in the counsellors’ report.

Dispute resolution. A process should be set up for the resolution of disputes for example, about the custody of the child or any other issues following discussion with counsellors and legal advisers, before the proposal is finalised.
Further considerations

The Committee is prepared to consider an application deviating from the proposed guidelines. If any applicant wishes to deviate from any of the proposed guidelines, they should indicate this and give their reasons, at the time of the application.

Please note that these guidelines which NECAHR wishes to see addressed in applications for non-commercial altruistic surrogacy using IVF as treatment are provisional only. NECAHR cannot at this time guarantee that the guidelines include all the issues it might wish to have addressed by applicants in proposals for non-commercial altruistic surrogacy using IVF as treatment. Where new issues do come to its attention, NECAHR undertakes to inform potential providers of this in as timely a fashion as possible.

The Committee welcomes comment on the proposed guidelines, to assist in the ongoing development of the guidelines. The Committee requests that previous draft guidelines be destroyed.
Appendix 6: Guidelines for the storage, use and disposal of sperm from a deceased man

Prepared by the
National Ethics Committee on Assisted Human Reproduction (NECAHR)
c/o Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND
February 2000

Background

On several occasions since its establishment, the National Ethics Committee on Assisted Human Reproduction (NECAHR) has received requests from providers for advice about the storage, use and disposal of sperm which they hold on behalf of a man who dies some time after the sperm has been retrieved. It is also technically possible to retrieve sperm from a comatose man or within 24 hours of death, although advice on this aspect has not yet been requested.

The Committee also acknowledges that technological advances may in the future allow the efficient freezing and thawing of ova and grafting of ovarian tissues, so that ultimately pregnancies may be achieved. This may extend the options for posthumous reproduction to include use of cryopreserved ova. It is beyond the scope of these initial guidelines to address these possibilities. The Committee endeavours to regularly review these Guidelines to reflect the likely advances in treatment and technology.

The Committee has considered these requests within the broader framework of the collection, storage, use and disposal of human gametes, and has identified a number of issues that are grouped here according to their main focus. Some of these issues apply to living as well as deceased persons.

1.0 Cultural focus

NECAHR acknowledges that a bicultural approach to addressing issues such as the possible use of gametes can accommodate diversity of opinion within and between cultures. The Committee considers these issues to be important:

- the values and tikanga inherent in whānau, hapū and iwi
- the need for a process that is culturally supportive and safe

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• the need to protect whakapapa
• the need to protect fertility
• the need to protect individual and informed choice.

It is important that the partnership principles of the Treaty of Waitangi be encompassed within the guidelines. NECAHR emphasises the importance of the following:

• protection of whakapapa Māori, confidentiality and privacy
• respect for tikanga Māori and kaumatua counselling. Whānau assistance at the initial interview. Recognition that the donor has the right to refuse or accept this support
• a record of Māori donors be maintained with the following:
  – name
  – address
  – date and place of birth
  – name of marae to which donor is affiliated, if applicable, and tribal affiliations
  – the names and aliases of an individual’s parents and tribal affiliations
  – birthplace (if known), tribal/hapū contact
• all information provided by Māori be safeguarded and protected within the health system or as directed by the donor or whānau.

The Assisted Human Reproduction Bill (currently before Parliament) will legally require providers to record information about donors and children born using assisted human reproductive technology.

1.1 Ethical focus

The Committee acknowledges that there are wide social implications if children are conceived from donated gametes. Some of the implications and issues relate to:

• the concept of family and relatedness of family members, including issues surrounding intergenerational donation
• the special status of gametes once they have been collected and stored, because of their potential to become a human being
• issues of consumerism, commodification and technology in relation to reproduction.

Particularly in relation to deceased persons there is the issue of the acknowledgement of finiteness and mortality in relation to human life and reproduction.

4 NECAHR understands this to mean the need to avoid actions that may lead to infertility.
The Committee considers key ethical principles, including:

- the balancing of benefits and risks for all parties, and prioritising of needs
- the benefits and risks for children specifically, e.g. if they know they have been conceived using gametes from a person deceased at the time of conception
- issues of consent in relation to information, non-coercion and autonomy, e.g. the limits of personal autonomy when considering the use of a deceased person’s gametes
- vulnerability of participants, e.g. individuals undergoing chemotherapy or individuals grieving following the death of a partner
- privacy considerations, e.g. confidentiality of the collection of information, sensitivity of the information and how it is safeguarded, balanced against the resulting child’s right to know his/her origins
- cultural appropriateness.

1.2 Legal focus

Issues considered by NECAHR include:

- the potential child’s interests should be considered in any decision made about the use of gametes
- whether gametes can be “owned” and what form of property they might constitute
- inheritance rights for children conceived posthumously
- the significance of consent or direction given before death in relation to the posthumous use of gametes
- the lawfulness of decisions to retrieve gametes for posthumous use without the prior consent of the deceased person
- the application of overseas common law cases to New Zealand, and in particular: R v Human Fertilisation and Embryology Authority ex parte Blood (1997) 2 All ER 687
- the human rights legislation in New Zealand, e.g. in relation to marital status, age, and access to services.
2.0 Guidelines

Against the background outlined in the previous section, the Committee proposes the following guidelines for the use of sperm.

Consent forms must include specifications as to what is to happen should the sperm donor die leaving sperm in storage at a clinic/service. All donors should be expected to discuss related issues with partners and family. For Māori, there should be the opportunity to discuss the use or disposal of sperm with partner and whānau. Iwi/hapū/kaumatua may provide support counselling and whakaritenga.

2.1 Sperm provided for use by a non-specified person/couple (donor insemination)

Options for what should happen on the death of a sperm provider must be:

• that sperm be available for use by a person/couple who have already produced a child/children by donor insemination using that sperm, or

• that sperm be disposed of in a culturally appropriate manner, e.g. in the case of a Māori donor, returned to whānau.

Appropriate counselling is mandatory for men donating sperm.5

Donors should be encouraged to designate two or more people who will inform the clinic/service in the event of the donor’s death.

In relation to donors who were recruited prior to these guidelines, clinics/services are required to consult with NECAHR if there is potential or actual conflict over the decision-making.

In situations where further ethical guidance is necessary, NECAHR should be consulted.

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5 Reproductive Technology Accreditation Committee, 1997, Draft Code of Practice for Centres using Assisted Reproductive Technology, revised March.
2.2 Sperm placed in storage prior to medical intervention, e.g. chemotherapy, IVF

Options on the consent form for what should happen on the death of a sperm provider:

(a) that sperm should be disposed of in a culturally appropriate and respectful manner as specified, e.g. in the case of a Māori donor, the donor should seek whānau advice on the disposal, or

(b) that sperm be available for use only by a specified person within a specified timeframe; if that person dies, (a) applies. All donors or partners of the deceased should be encouraged to inform the wider family/whānau.

If the option selected in the consent form leads to a request for insemination by the partner of the deceased, then clinics/services must provide appropriate implications counselling which would include, for example, the advisability of a suitable time lapse before making use of the sperm, to allow for considered decision-making.

When consent has not been and cannot be obtained, or when there is a request for a variation to these requirements, an application for ethical review must be submitted to NECAHR. A counselling report should be included, as part of this application.

Clinics/services should undertake an annual review of the storage arrangements, either with the person whose sperm is being stored or, in the event of his death, a designated person. When renewing the consent for storage, the clinic should also ask the person to renew consent for the use and disposal of the sperm. It is expected that sperm collected in these circumstances would be stored for a maximum period specified by the clinics.

2.3 Sperm collection from a comatose person or recently deceased person without his prior consent

The Committee considers that collection of sperm from a comatose or recently deceased person without that person’s prior written consent is ethically unacceptable.