NATIONAL ETHICS COMMITTEE ON ASSISTED HUMAN REPRODUCTION

ANNUAL REPORT

TO THE

MINISTER OF HEALTH

FOR THE
YEAR ENDING 31 DECEMBER 2000
FOREWORD

Important issues arising from this report include:

- implications of the incremental application of technologies by fertility clinics
- appropriate public consultation by NECAHR
- measures to ensure ongoing scientific credibility of NECAHR
- enforcement of NECAHR's guidelines
- need for flexibility in any proposed legislation relating to assisted human reproduction.

Often NECAHR is asked to review a proposed new application of an established practice that now creates ethical issues. It is difficult, maybe impossible, to predict at the outset where technologies may lead. Embryo and foetal selection provide an example of this complexity. Genetic screening prior to implantation in the uterus to identify and select an embryo free of an hereditary disease rather than, at a later point, aborting a developing foetus that shows evidence of the disease - such foetal selection is already an established practice - may to some people be ethically acceptable. However, genetic screening on the basis of gender to ensure a daughter and sister within an established family may not be considered ethically acceptable. Also, there are always differences in the health conditions and other circumstances of parties involved in the application of technologies, and NECAHR takes account of these. It is this kind of complexity and variability that has led NECAHR to work largely on a case-by-case basis to date. NECAHR establishes criteria for guidelines on the basis of precedent, and avoids an early classification of applications from clinics into categories for some of which they could exercise their discretion without recourse to formal ethical review. Some such classification may be possible in the future once guidelines are in place.

NECAHR acknowledges how important public consultation is in making its decisions: applications for ethical review often challenge what New Zealanders believe are commonly shared values and practices, for example, an application for surrogacy as a means of family formation. At the same time, NECAHR is aware of the pluralistic nature of New Zealand's society. It is aware of how specialised knowledge in the field of assisted human reproduction is and that it is not always fully understood. The Committee is acutely aware, too, of the private and personal aspects of most requests for ethical review. Consequently, public consultation although essential, is not always straightforward. When possible, the Committee uses opportunities that offer good investigative journalism to engender public discussion. It also consults about proposed guidelines. For example, the guidelines for non-commercial altruistic surrogacy using IVF as treatment will be distributed shortly for public consultation. NECAHR also informs itself about public debate by reading relevant reports and submissions in the field that have been called for by groups other than itself, and follows media reports, published correspondence and radio ‘talk-back’ programmes. Arrangements are being put in place to make NECAHR's work public via a website.

From time to time, fertility clinics have been critical of the level of specialised scientific expertise on the Committee to inform its discussions. In response to these
criticisms, meetings are now attended by a clinic’s representative with scientific expertise who has been nominated by the clinics to advise NECAHR on specialised scientific matters. NECAHR also seeks expert advice from time to time.

The point is sometimes made that NECAHR ‘lacks teeth’ to enforce its findings, and that there should be a regulatory frame-work for clinicians and researchers in the assisted human reproduction field. Although the Committee has no legislative powers, fertility clinics currently demonstrate a due regard for and compliance with its ethical review findings. Clinicians are also bound by their own professional codes of practice and the requirements of their accreditation body, the Reproductive Technologies Accreditation Committee (RTAC). This is an Australian body with New Zealand representation. There is merit in working with Australia when the sector in New Zealand is so small. There has been an informal undertaking by RTAC to make compliance with NECAHR's guidelines a requirement of accreditation for New Zealand clinics. This undertaking will be pursued when public consultation on the surrogacy guidelines is completed and the guidelines formalised.

NECAHR is of the view that there is a gap in the law with regard to assisted human reproduction. From time to time, it has felt that it has been forced inappropriately to take an ad hoc role in policy formulation in the vacuum that exists. However, NECAHR urges legislation that allows for flexibility in a rapidly developing technological field.

Rosemary De Luca  
Chairperson  
National Ethics Committee on Assisted Human Reproduction
Purpose of Report

The terms of reference of the National Ethics Committee on Assisted Human Reproduction (NECAHR) require it to provide the Minister of Health with a brief report on the Committee’s activities each year.

This report provides a summary of the NECAHR’s operation during 2000.

Background to the establishment of NECAHR

NECAHR was established as a Ministerial advisory committee under section 46 of the Health and Disability Services Act 1993 to provide ethical review of research and innovative treatment proposals in the field of assisted human reproduction in New Zealand. The current membership of NECAHR and its terms of reference are set out in Appendices 1 and 2 respectively.

Summary of Key Issues and Events

The Committee met four times in 2000, in February, April, July and November. The Committee considered eleven new proposals and five proposals brought forward from 1999. A table providing details of each application considered during 2000 is attached as Appendix 3.

Membership

At the end of 2000 there were two vacancies on the Committee, one for an obstetrician and gynaecologist and the other for a Maori member with medical expertise. Nominations were obtained for the two vacancies. Cabinet noted the appointment of Dr Anne Robertson to fill the vacancy for an obstetrician and gynaecologist and the appointment was referred to the Government caucuses for discussion in early 2001. The preferred nominee for the vacancy of Maori member with medical expertise withdrew and further nominations have been sought.

Representatives from Other Organisations

The following organisations/people attended Committee meetings during 2000 to discuss legal and ethical issues of non-commercial surrogacy.

- Human Rights Commission
- Commissioner for Children
- Dr Joanne Dickson, Geneticist, Wellington Hospital
- Dr Hal Levine, Anthropologist, Victoria University of Wellington

Draft Guidelines for Non-commercial Surrogacy using IVF as Treatment

NECAHR agreed to give ethical approval, in principle, for non-commercial altruistic surrogacy using in vitro fertilisation (IVF) as treatment in July 1997. NECAHR stipulated that for the meantime applications should be reviewed on a case-by-case basis.
As NECHAR has considered each particular application for non-commercial altruistic surrogacy using IVF as treatment, it has developed draft guidelines. The guidelines take the form of criteria which should be met for ethical approval to be given to applications for non-commercial surrogacy using IVF as treatment.

The criteria have been developed progressively as issues arose. They have also evolved within the context of overseas developments in this area. The Committee will continue to consult with interest groups, including the Human Rights Commissioner and the Commissioner for Children.

A copy of the draft guidelines operating in 2000 are attached as appendix 4.

**Guidelines for the Collection, Storage, Use, and Disposal of Sperm from a Deceased Man**

These Guidelines were finalised at the February 2000 meeting of the Committee and have been distributed to fertility clinics.

A copy of the guidelines is included as appendix 5.

**Submissions**

**Submission to the Health Committee**

In December 2000, NECAHR made an oral submission to the Health Committee on the two Assisted Human Reproduction bills currently before the Committee. The main difference between the two Bills is that the Private Member’s Bill, prepared by Dianne Yates MP, establishes a licensing authority for fertility clinics. The Assisted Human Reproduction Bill, the Government’s Bill, proposes to establish NECAHR in its own legislation.

**Submission to the Government Administration Committee**

In February 2000, NECAHR submitted comments and recommendations relating to Section 13 “Surrogacy” of the Law Commission’s discussion paper, *Adoption: Options for Reform*. (The submission was an appendix to NECAHR’s 1999 Annual Report).

In late 2000, the Committee considered the Law Commission’s *Report 65, Adoption and Its Alternatives* and agreed that a subcommittee of NECAHR would prepare a submission to the Government Administration Committee on Chapter 18 (Adoption and the Challenges of Assisted Human Reproduction). The submission was due in February 2001.

**Complaint Against NECAHR from the Human Rights Commission**

In late 1999, NECAHR received formal notification of an investigation of a complaint from the Human Rights Commission relating to alleged discrimination on the basis of age and family status. The complaint arose from an application considered by the Committee on non-commercial altruistic surrogacy using IVF as treatment.
A conciliation meeting was held on 13 February 2000 between the Human Rights Commission, the complainants, the Chairperson of NECAHR, and a Ministry of Health representative. A confidential agreement was signed by all parties in March 2000 resolving the complaint. The agreement clearly stated that there was no admission of liability by NECAHR.

As a result of the complaint, NECAHR invited the Human Rights Commissioner and the Commissioner for Children to its meeting on 4 July 2000 to discuss the Committee’s Draft guidelines on non-commercial altruistic surrogacy using IVF as treatment. Some amendments were recommended as a result of that meeting and NECAHR is in the process of consulting on those amendments. Fertility Clinics continue to be advised of any changes to the Guidelines.

Also as a result of the complaint, the Ministry of Health’s administration processes associated with NECAHR’s functioning were reviewed.

**Issues under consideration**

*Within Family, including Intergenerational, Gamete Donation*

The Committee gave further consideration to within family, including intergenerational, gamete donation. NECAHR sought expert advice from a geneticist and an anthropologist and also the views of the Fertility Clinics on this issue. NECAHR agreed to review all cases of 'within family', including intergenerational, gamete donation and to develop written criteria on the basis of precedent, with a view to producing draft guidelines for public consultation. The Committee will give further consideration to this issue in 2001.

*Preimplantation Genetic Diagnosis*

NECAHR approved an application to extend a study involving the development of pre-implantation genetic diagnostic techniques using donated 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 related to the reliability of the tests and the purposes for which they could be used, for example, detection of serious genetic disease in the embryo.

*Embryo Donation*

NECAHR began considering the issues relating to the donation, storage, and disposal of frozen embryos.

Key questions for the committee include:

- Should the committee approve the donation of frozen embryos to persons other than those whose gametes led to the formation of the embryos, and if so, under what conditions?
- How and when should frozen embryos be disposed of?
What sorts of consents should be obtained in relation to storage from persons who had embryos in storage before the current forms stating persons' wishes were in use?

The Committee wrote to all Fertility Clinics seeking information on their existing policies and practices and their views on the ethical issues relating to embryo donation.

**Attendances at Conferences**

The Chairperson of NECAHR:
- attended the Summer Seminar of the University of Otago's Bioethics Centre, Dunedin, February 2000, and responded to a public lecture, *Reproductive Ethics and the Family*, presented by international guest philosopher, James Lindemann Nelson;
- attended the conference of the Australian Association of Professional and Applied Ethics, University of Queensland, Brisbane, 8-9 July 2000, (private funding) and met with Dr Brenda Almond, Professor of Moral and Social Philosophy at the University of Hull and member of Britain's Human Fertility and Embryology Authority (HFEA);
- participated in a teleconference of national and state ethics, regulatory and data organisations in Australia and New Zealand and presented a report on behalf of NECAHR covering issues for NECAHR, both recurring and new, and regulation and legislation issues;
- presented a paper on ethical issues in biomedical research at the Business Information in Action 2nd Annual Law Conference, held in Wellington, November 2000.

**Media Presentations**

The Chairperson participated in media presentations when the opportunity arose.

**Academic publication**

Appendix 1

Membership of the
National Ethics Committee on Assisted Human Reproduction

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 twelve 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.

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 eighteen years and has published a number of papers on this issue.

Alison Douglass
Alison Douglass is employed as a solicitor with Tripe, Mathews and Feist, specialising in civil litigation (including medico-legal and compensation issues), criminal and family law. She is former chairperson of Wellington Ethics Committee, and a member of the Wellington Women's Lawyers Association and the Wellington District Law Society District Courts Committee.

Dr Alastair Gunn
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
Audrey Jarvis is a microbial geneticist, now retired, who worked as the Principal Scientist, New Zealand Dairy Research Institute, Palmerston North. She has been a lay member and chair of the Manawatu-Wanganui Ethics Committee and has also served on the Executive Committee on the NZ Microbiological Society. She is currently a member of the Executive Committee of the International Committee of Taxonomy of Viruses and the New Zealand Committee for Microbiology.

Dr Arlene Smyth
Dr Smyth is a general practitioner working at the Island Bay Medical Centre, Wellington.

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 Maori member on the Waikato Ethics Committee, and also serves on a number of other local marae and community committees.
Dr Anne Robertson (appointed Feb 2001)
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.

Dr Pat Touhy – Director-General of Health’s Representative (until Feb 2001)
Pat Touhy is the Ministry of Health’s Chief Advisor, Child, Youth and Family.

Dr Barbara Nicholas – Director-General of Health’s Representative (from Feb 2001)
Barbara Nicholas is currently employed as Senior Advisor (Services Research), Health Services Policy and is located in the Christchurch office of the Ministry. Her academic background is in microbiology and theology and she holds a PhD in bioethics. She has extensive experience in the field of bioethics, which includes lecturing at the Otago Medical School in this subject.

Vacancy – Maori member with medical expertise.
Appendix 2

TERMS OF REFERENCE

National Ethics Committee on Assisted Human Reproduction

THE ROLE OF THE COMMITTEE

The National Ethics Committee on Assisted Human Reproduction (“NECAHR”) is a ministerial advisory committee established under section 46 of the Health and Disability Services Act 1993 (“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 Maori, 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 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 (“the Minister”). NECAHR’s membership shall include members with specialist knowledge of and experience in assisted human reproductive procedures. NECAHR shall have at least two Maori 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 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 9 consecutive years. Unless a person sooner vacates their office, 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 ARRANGEMENTS
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
- 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)

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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.
• 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 ASSESSMENT OF DECISION MAKING PROCESS

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, etc. as directed by the committee
• 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:

Minister of Health
## Applications to NECAHR in 2000

**Appendix 3**

Summary of proposals and their ethical issues considered by NECAHR from 1 January 2000 to 31 December 2000

<table>
<thead>
<tr>
<th>CODE</th>
<th>DATE RECEIVED</th>
<th>DISCUSSED AT THE MEETINGS OF</th>
<th>FAST TRACK APPROVAL (DELEGATED AUTHORITY)</th>
<th>FAST TRACK APPROVAL (WHOLE COMMITTEE)</th>
<th>DATE OF LETTER OF DECISION</th>
<th>PROPOSAL</th>
<th>APPLICANT</th>
<th>ETHICAL ISSUES CONSIDERED</th>
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| 98/5 | 01/08/1998    | 11/08/1998 10/11/1998 13/04/1999 08/06/1999 03/08/1999 05/10/1999 07/12/1999 | N/A                                      | N/A                                    | 28/01/2000                | Non-commercial surrogacy using IVF | Artemis North Shore | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
• the donation of gametes between siblings  
• the importance of family counselling  
• the consideration of whakapapa  
• genetic risks  
• the rights of the child to know its genetic and cultural origins  
• the legal status of the birth and commissioning parents. |
| 98/9 | 01/11/1998    | 10/11/1998 09/02/1999 8/6/99 3/8/99 05/10/1999 | N/A                                      | N/A                                    | 22/03/2000                | Non commercial surrogacy using IVF | Otago Fertility Services | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
• the surrogate mother lives in a community where contraception is not used. How can she ensure that she and her partner will not conceive their own child?  
• the age of the surrogate  
• safety concerns regarding the last birth by the surrogate mother, and where the new birth will |
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<th>CODE</th>
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<tr>
<td>99/4</td>
<td>06/05/1999</td>
<td>08/06/1999 03/08/1999 05/10/1999 07/12/1999</td>
<td>At the meeting held 8 June 1999 the Committee agreed that this proposal to implement a pilot study to culture blastocysts could be reviewed using the fast track approach subject to receiving a satisfactory formal application from Fertility Plus. At the 7 December 1999 meeting it was noted that a formal application had still not been received, and that the study was now not proceeding.</td>
<td>N/A</td>
<td>28/01/2000</td>
<td>Application for a pilot study to culture blastocysts</td>
<td>Fertility Plus National Womens Hospital</td>
<td>take place • whether hormones taken by the surrogate mother will interfere with any breastfeeding she does for her own children • whether the potential health benefits of the birth mother breastfeeding outweigh the risk of bonding developing.</td>
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<tr>
<td>99/6</td>
<td>01/06/1999</td>
<td>08/06/1999 03/08/1999 22/02/2000 (Provisional approval given subject to legal and citizenship issues being addressed) 04/07/2000 (final approval given)</td>
<td></td>
<td>N/A</td>
<td></td>
<td>Non-commercial surrogacy using IVF and donated oocytes</td>
<td>Fertility Associates Auckland</td>
<td>Considered in terms of the draft guidelines for non-commercial surrogacy using IVF as treatment.</td>
</tr>
<tr>
<td>99/11</td>
<td>27/07/1999</td>
<td>03/08/1999</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>Non-commercial</td>
<td>Artemis North Shore</td>
<td>Considered in terms of the draft guidelines on</td>
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| 99/12 | 18/08/1999    | 05/10/1999                  | N/A                                      | N/A                                   | 28/01/2000               | Comparison of Various Methods of Storage and Processing of Human Sperm Pre-Freezing and after Thaw | Fertility Associates Hamilton | Issues considered during the review of this proposal include:  
  - cultural aspects relating to the disposal of body tissue  
  - the need for the consent form to clarify how long patients will be given to decide whether they should participate in the research  
  - the need for a principal investigator to be named. |
| 99/13 | 23/08/1999    | 05/10/1999                  | N/A                                      | N/A                                   | 28/01/2000               | Non-commercial surrogacy using IVF | Fertility Associates Auckland | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
  - The social issues of intergenerational surrogacy were important, given that the proposed surrogate is the woman’s mother. |
| 99/14 | 01/12/1999    | 07/12/1999                  | Committee agreed to fast-track application 99/14 once additional information received. | 10/11/2000 | Non-commercial surrogacy using IVF | Fertility Associates Auckland | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
  - ethnicity issues, which will be be important if relevant to the case  
  - whether counselling should include the children of the birth mother, and questions about the extent to which they were involved  
  - whether the participants had been given sufficient information in an appropriate manner, to enable them to make an informed decision. |
  - The need for a consent form in order for Committee to make a decision. |
| 2000/02 | 25/01/2000 | 22/02/2000                  | NECAHR deferred a decision until following information | Non-commercial surrogacy using IVF | Fertility Associates Auckland | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
  - Birth mother should have at least one live birth of her own (or ideally have completed her own... |
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| 2000/03| 01/02/2000 and 18/04/2000 | 23/02/2000 18/04/2000       | She provided:                           |                                       | 10/05/2000                | Research proposal involving human follicular cells ("Picking Good Eggs"). | The New Zealand Centre for Reproductive Medicine (The Fertility Centre) | Issues considered:  
- Noted there might be a toxicology issue with the removal of cells in terms of what would be administered to the eggs.  
- Whether the proposal would make any difference to fertilisation and storage of embryos.  
- Noted that the selection criteria could affect the viability of the study (egg age would have an effect on the physiology of the egg)  
- Clarify wording on consent form and information sheet – participants must be aware that they may gain information on their egg quality and treatment results, but that there will be no benefits otherwise. |
| 2000/04| 14/04/2000    | 04/07/2000                   | At the meeting of 4 July 2000 the meeting agreed that a sub-committee would fast track the application when: |                                       | 15/09/2000                | Non-commercial surrogacy using IVF | The Fertility Centre | Considered in terms of draft guidelines on surrogacy using IVF as treatment, and in particular:  
- Costs (noted housekeeping assistant payments would not be considered payment)  
- Legal status of birth mother’s separation from her husband |
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<td>2000/5</td>
<td>17/04/2000</td>
<td>04/07/2000</td>
<td>legal advice and reports had been received from both parties; clarification of the status of the husband separated from the birth mother; and confirmation that the birth mother’s 6 year old child will be counselled.</td>
<td></td>
<td>28/11/2000</td>
<td>Decision pending counsellor’s report and lawyers report.</td>
<td>Non-commercial surrogacy using IVF</td>
<td>Otago Fertility Services</td>
</tr>
<tr>
<td>2000/6</td>
<td>16/06/2000</td>
<td>04/07/2000</td>
<td>Committee agreed to fast track the application once the following information was considered:</td>
<td></td>
<td>15/09/2000</td>
<td>Non-commercial surrogacy using IVF</td>
<td>Fertility Associates Auckland</td>
<td>Application considered in terms of the criteria set out in the draft guidelines on commercial surrogacy using IVF as treatment.</td>
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| 2000/7 | 12/06/2000 | 04/07/2000 (Deferred pending a completed application form and confirmation on numbers and ages of children involved) | | | | | | Application was withdrawn. | Non-commercial surrogacy using IVF | The Fertility Centre, Christchurch | Considered in terms of the draft guidelines on commercial surrogacy using IVF as treatment, and in particular:  
- Health of commissioning mother and any risk to child born as a result of a surrogacy arrangement.  
  [She had suffered from postpartum psychosis – committee considered the likely reoccurrence without pregnancy and sought further information]. |
| 2000/8 | 18/08/2000 | Considered by round robin in September 2000 and accepted with the following two suggestions made:  
- it would be inappropriate to include in the project any persons whom the applicant was currently counselling about Donor Insemination.  
- the participants | 25/09/2000 | Sharing information with Children/ offspring conceived by donor insemination | Ken Daniels, University of Canterbury | The ethical issues considered were:  
- Parents providing what has traditionally been seen as private/personal information for public use.  
- Need to respect the rights of participants in the project. |
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| 2000/9 | 09/11/2000 | Considered at the 28 November 2000 meeting | At the meeting of 28 November 2000 and gave conditional approval to the proposal. It was agreed that a subcommittee of NECAHR would fast-track the proposal once the applicants had provided the following additional information: 1. change wording in the Application Form to clearly show that only non-viable embryos will be used. 2. provide information to NECAHR on the type of information the researchers would be able to provide to embryo donors and, if appropriate, make reference to this in the information | | 06/12/2000 (conditional approval) | Application for extension of study of preimplantation diagnostic techniques to include non-viable, invitro fertilised embryos. | Fertility Associates, Auckland | Issues considered:  
• Purposes for which the tests could be used.  
• Reliability of the tests. |
sheet for donors;
3. provide information to NECAHR on the proposed mechanism, if any, for providing feedback to embryo donors on any relevant information regarding their embryo, and, if appropriate, make reference to this in the information sheet for donors;
4. ask applicants on the consent form whether they wish to know or discuss any significant outcomes of the research (because people are entitled to receive reports on studies in which they have participated);
5. advise NECAHR on whether there is likely to be any potential value in the study for individual couples and, if so, how will donor couples be advised. The
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<td>2000/10</td>
<td>09/11/2000</td>
<td>Considered at the meeting of 28 November 2000.</td>
<td>consent form should clearly state that this study will not benefit the donors’ current IVF treatment but may improve the outcome for others undertaking IVF in the future; 6. refer to the procedure of taking two cells from the embryo at around the eight cell stage in both the consent form and the information sheet. 7. advise NECAHR on the reliability of information obtained through the study and, who will be performing the FISH procedure, and what controls are in place.</td>
<td></td>
<td>08/02/2001</td>
<td>Variation to draft guidelines for non-commercial surrogacy using IVF as a treatment application from someone wishing</td>
<td>Artemis North Shore Fertility</td>
<td>Issues considered:  • the surrogate would be neither a family member nor a close friend of the commissioning parents.</td>
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  - 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? |
Draft Guidelines

for

Non-commercial Surrogacy

using IVF as Treatment

Prepared by the National Ethics Committee on Assisted Human Reproduction
April 2000
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.
A report on the medical status of the birth mother must be included in the application, ie 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, eg in considering the disposal of gametes, that the gametes would be offered to whanau, in the case of Māori 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 life style 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, eg 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 and
  - 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.
Guidelines
for the
Storage, Use, and Disposal
of Sperm
from a Deceased Man

February 2000

Prepared by the

National Ethics Committee on Assisted Human Reproduction (NECAHR)
c/o Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND
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\textsuperscript{2}, 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 which 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 bi-cultural 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 whanau, hapu and iwi
- the need for a process that is culturally supportive and safe
- the need to protect whakapapa
- the need to protect fertility\(^4\)
- 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. Whanau 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/hapu contact
- all information provided by Māori be safeguarded and protected within the health system or as directed by the donor or whanau\(^5\).
  - (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.)

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\(^3\) Manatu Maori Guidelines for the Use of Assisted Reproductive Technology, Wellington, 1991

\(^4\) NECAHR understands this to mean the need to avoid actions that may lead to infertility.

\(^5\) Smith, R. Draft Guidelines prepared for NECAHR on the Collection, Storage, Use and Disposal of Gametes, Waitaatea, July 1997
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.

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, eg 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, eg the limits of personal autonomy when considering the use of a deceased person’s gametes
- vulnerability of participants, eg individuals undergoing chemotherapy or individuals grieving following the death of a partner
- privacy considerations, eg 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 include⁷:

- 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, eg in relation to marital status, age, and access to services.

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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 whanau. Iwi/hapu/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:

a. that sperm be available for use by a person/couple who have already produced a child/children by donor insemination using that sperm
b. that sperm be disposed of in a culturally appropriate manner, eg in the case of a Māori donor, returned to whanau.

Appropriate counselling is mandatory for men donating sperm.  

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.

2.2 Sperm placed in storage prior to medical intervention, eg 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, eg in the case of a Māori donor, the donor should seek whanau advice on the disposal

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8 Draft Code of Practice for Centres using Assisted Reproductive Technology. Reproductive Technology Accreditation Committee, revised March 1997
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/whanau.

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.