ecart

Ethics Committee on
Assisted Reproductive Technology

Terms of Reference

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

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

Functions of ECART
ECART has the following functions:

- to consider and determine applications for assisted reproductive procedures[1] or human reproductive research[2]

- to keep under review any approvals previously given, including those applications approved prior to the existence of ECART, and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals

- to liaise with ACART on matters relating to assisted reproductive procedures and human reproductive research and, to forward to the advisory committee reports received under section 19(5) of the HART Act together with any comments or requests for advice that ECART considers appropriate

- to consult with any persons who, in the opinion of the committee, are able to assist it perform its functions

- any other functions that the Minister of Health assigns to the committee by written notice.

Guiding principles

[1] "Assisted reproductive procedure"
(a) means a procedure performed for the purpose of assisting human reproduction that involves –
- the creation of an *in vitro* human embryo; or
- the storage, manipulation, or use of an *in vitro* human gamete or an *in vitro* human embryo; or
- the use of cells derived from an *in vitro* human embryo; or
- the implantation into a human being of human gametes or human embryos; but

(b) does not include an established procedure.

[2] "Human reproductive research" means research that uses or creates a human gamete, a human embryo, or a hybrid embryo.

ECART shall be guided by the following principles:

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

- the human health, safety, and dignity of present and future generations should be preserved and promoted

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

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

- donor offspring should be made aware of their genetic origins and be able to access information about those origins

- the needs, values, and beliefs of Māori should be considered and treated with respect

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

Operation of ECART
ECART must operate:

- in accordance with the HART Act and any other enactment

- in accordance with these Terms of Reference

- in accordance with any guidelines or advice issued by ACART or transitional guidelines gazetted by the Minister of Health under section 79 of the Human Assisted Reproductive Technology Act; and

- in accordance with Chapters 1-4 of the *Operational Standard for Health and Disability Ethics Committees*; and

- expeditiously, having regard, in particular, to the effect that undue delay may have on the reproductive capacity of individuals.

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

Composition and membership

Guiding principle

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

Member numbers

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

Lay/Non-lay membership

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

For the purposes of these Terms of Reference, a lay person is a person who, at no time during the person's membership of ECART or in the 3 years before becoming a member of ECART:

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

Member categories

ECART's lay membership shall include:

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

ECART's non-lay membership shall include:

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

Ex-officio attendance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee meetings

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

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

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

i. open meetings for the discussion of broad issues, particularly if ECART is reviewing human reproductive research
ii. closed meetings when necessary to ensure the privacy and confidentiality of participants

iii. closed meetings when applicants provide good and sufficient reasons for this to occur, and the minutes of the meeting should reflect these reasons.

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

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

Decision-making process

Wherever possible, ECART should determine matters by consensus decision. Where a consensus cannot be reached, a vote shall apply, with a two-thirds majority of those voting required for any decisions. In the event a two-thirds majority cannot be reached, the Committee will defer the application, write to the applicant concerned and invite them to address any specific concerns raised by the Committee; make further submissions and/or provide further information to the Committee for its further consideration with respect to the application. A response must be submitted to the Committee no later than six months of the Committee's request. At the next meeting after receipt of the further information, or after six months of the Committee's initial consideration of the application (whichever is earlier), the Committee will reconsider the application. If at that time a consensus or a two-thirds majority cannot be reached, the application is deemed to be declined.

In relation to specific research or specific treatment involving Māori participants, the Chairperson should ensure that expertise in Māori cultural perspectives be available to ensure that all issues are appropriately considered from a Māori cultural perspective. Where it is not possible for a member with such expertise to attend an ECART meeting or for those members' views to be sought and represented at the meeting, ECART may consider deferring the matter and/or seeking external advice.

On occasion, individual members may wish to abstain from some or all of the decision making process because of strong moral or religious reasons. If a member abstains from voting, it will be treated as if the member was not in attendance for the purposes of achieving a consensus or a two-thirds majority (that is, it does not count as a vote). The reason for the abstention should be recorded.

Advice from ACART

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

ECART actions

ECART may give its written approval:

- for the performance of assisted reproductive procedures by a nominated person; or

- for the conduct of human reproductive research by a nominated person.

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

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

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

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

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

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

Expert advice and consultation

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

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

Advice may be sought from recognised experts with:

i. specialist knowledge in the field of assisted reproductive technology

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

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

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

Training for members

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

Reporting requirements

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

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

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

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

The annual report shall also include:

i. a list of training undertaken by ECART members, and a statement on processes for orientation and training of new ECART members.

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

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

Fees and Allowances

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

The Chairperson shall receive an attendance fee of $498 per day (plus half a day's preparation fee). The attendance fee for members is set at $369 per day (plus half a day's preparation fee). The Chairperson and Deputy Chairperson shall receive an allowance of up to one extra day each per month to cover additional work undertaken under the delegated authority of ECART. The Ministry of Health shall pay actual and reasonable travel and accommodation expenses of ECART members.

Servicing of ECART

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