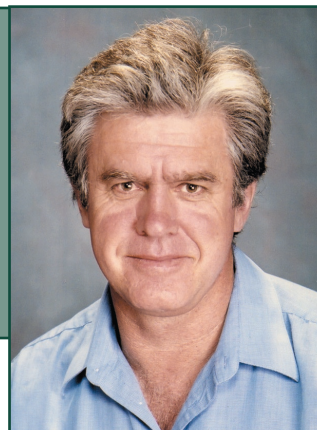


## EDITORIAL

### Martin Tolich Chairperson Multi-region Ethics Committee



The Multi-region Ethics Committee (MEC) was established in December 2004, along with the six other regional ethics committees. The MEC reviews studies that take place in more than one region, or nationally. The MEC is also responsible for any multi-region studies that were taking place before the new system of ethical review was established.

The current 12 member MEC represents a broad range of expertise and life experience. A third of the committee were members of the previous ethical review system. Along with a lawyer, various medical disciplines are represented including psychiatry, pharmacology, oncology, and general practice. Those with research backgrounds include a family violence researcher and a biostatistician. Community members from Māori, Pacific and advocacy groups provide

spirited representation. As the chair of this committee, I have seven years' experience with ethics committees. This committee's collective knowledge base is phenomenal.

The MEC meets in Wellington each third Tuesday of the month. On average, half the applicants meet the Committee in person or via teleconference. The in-person meetings enhance the ethical review process as applicants have an opportunity to answer questions and ask questions of their own.

In September and October there was a large increase in the number of applications received, which placed considerable pressure on the committee. Previously the number of new applications averaged 14 per month. We are working with the Ministry of Health to develop options for managing the workload of the MEC.

A second administrator was appointed in October to assist with the administration of the Committee. Unfortunately our administrator from the outset, Sheryl Kirikiri, left early in November and I would like to thank Sheryl for her work in setting up the committee administration and providing an excellent service to the committee. I welcome our new joint administrators Sue Fish and Michelle Judge.

I'd like to take this opportunity to wish everyone a very merry Christmas and I look forward to working with the ethics and research sectors in 2006.

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# Hui of Māori members of health and disability ethics committees

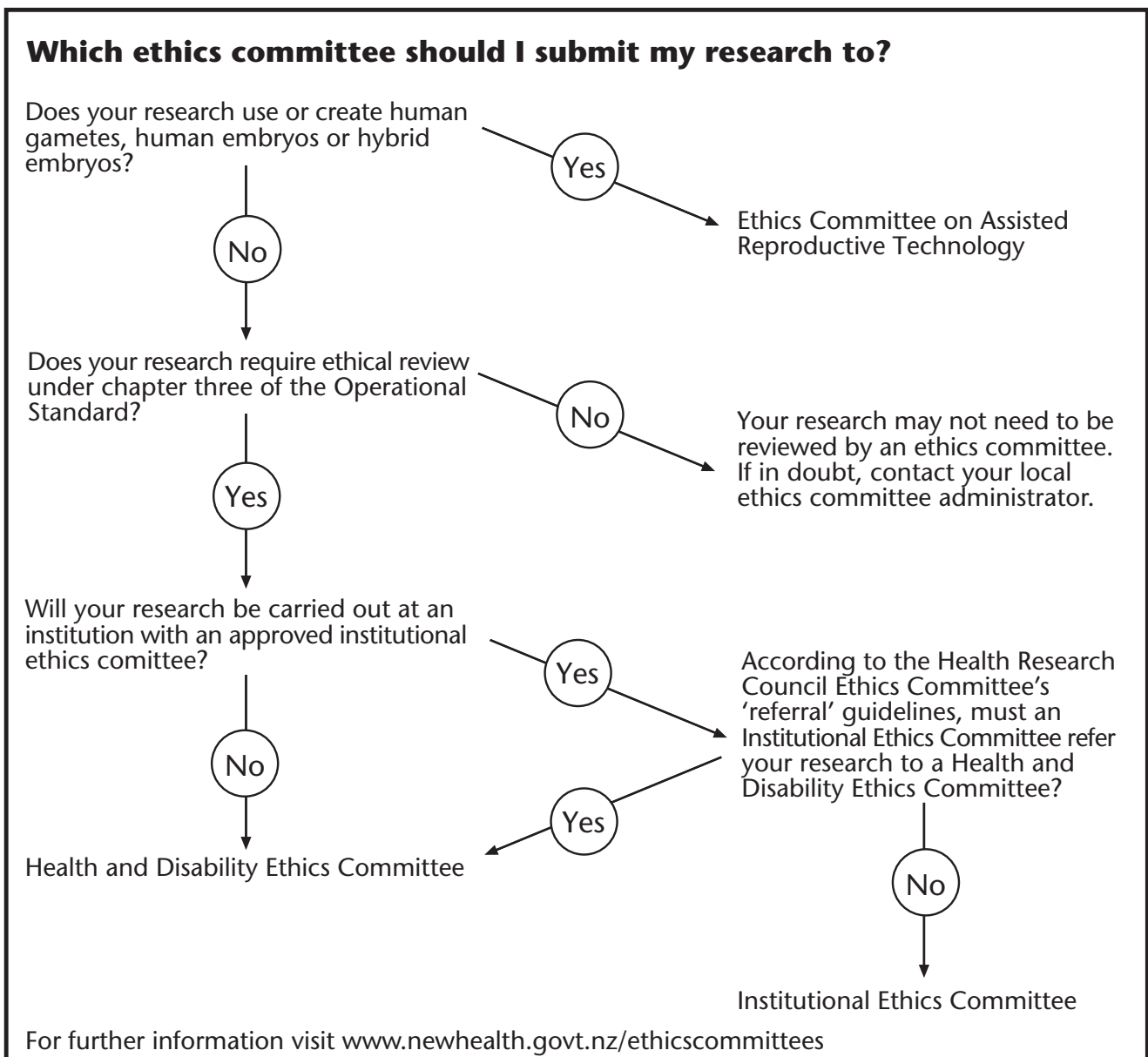
On Tuesday 28 June 2005, some of the Māori members of health and disability ethics committees met to discuss common issues.

Kay Worrall, previous Chair of Auckland X Ethics Committee, facilitated a discussion on the role of Māori members of ethics committees. Judi Strid, Director of Advocacy at the Health and Disability

Commissioner's Office attended and facilitated a discussion on consent and Right 7(10). Andrew Moore, Chair of the National Ethics Advisory Committee (NEAC), gave a talk on the work of NEAC and outlined NEAC's work on a Māori framework for ethical review. The day concluded with a general discussion and an agreement among attendees that they should continue discussions electronically on common issues.

## What committee should I send my application to?

A list of approved institutional ethics committees and the guidelines for when institutional ethics committees should refer applications to health and disability ethics committees are available on the Health Research Council's website <http://www.hrc.govt.nz>



# Meeting of legal members and Chairs of health and disability ethics committees

**On Thursday 23 June 2005, the legal members and Chairs of health and disability ethics committees met to discuss various legal and compensation issues that had arisen within the committees.**

Wendy Brandon, previous Chair of Auckland X Ethics Committee, facilitated a discussion on the role of a legal member on the committee. Matthew McClelland, Barrister Sole, led a discussion on indemnity of ethics committees and members. Judi Strid, Director of Advocacy at the Health and Disability Commissioner's

Office, and Helen Davidson, Legal Advisor at the Health and Disability Commissioner's Office led a discussion on consent and Right 7(10). Alison Douglass, previous Chair of Wellington Ethics Committee and previous member of the National Ethics Committee on Assisted Human Reproduction, gave a short talk on the history of the accident compensation scheme and this led to a discussion on the scope and effect of the new changes to medical misadventure under the Injury Prevention, Compensation and Rehabilitation Act 2001. As a result the following statement was agreed:

## **Compensation for injuries caused as a result of participation in clinical trial**

Participants who are injured as a result of participation in a clinical trial judged by an approved ethics committee to be principally for the benefit of the manufacturer or distributor of the medicine or item being trialled are ineligible for compensation under New Zealand's accident compensation legislation. Manufacturers and distributors typically undertake to provide alternative compensation, guided by the Research Medicine Industry Guidelines.

In the view of the Regional and Multi-Region Ethics Committees, however, common readings of those guidelines have led manufacturers and distributors to offer minimal alternative compensation. Furthermore, the disparity between compensation available to participants in clinical trials and those injured in other circumstances has been highlighted by recent changes that have effectively increased the compensation available under the accident compensation legislation.

In our view, participants should not be disadvantaged with respect to compensation by their participation in a clinical trial, and we believe that it was always within the spirit of the RMI guidelines that such disadvantage should be avoided. Hence the Committees believe that there is an ethical obligation upon manufacturers and distributors to provide

alternative compensation to research participants to a level and on terms broadly similar to that which would otherwise be available under the accident compensation scheme.

We point out in particular that persons injured otherwise than in a clinical trial could normally expect compensation for such things as loss of earnings, travel, accommodation or childcare costs. They would not face a possible exclusion from compensation because they had consented to the risk, or because of the negligence of those in the position of a researcher. (In this latter case, we believe the onus is on the manufacturer and the distributor to ensure that compensation is available to injured participants. We do not believe it is ethically reasonable to force participants to pursue negligent researchers through other legal channels).

We remind manufacturers or distributors of the very low number of claims from clinical trial participants in New Zealand, and of the relatively low levels of compensation available under the accident compensation scheme, as compared to that potentially payable in other comparable research centres.

At a minimum, manufacturers or distributors who are not able or prepared to offer compensation on these terms will be required to explicitly inform participants of the limits of compensation for which they are ineligible, pointing out the differences between the compensation available under the trial and that which would be available were they injured in other circumstances.

## New Appointments

The following appointments were made in 2005. The appointments are all for a three year term.

### Multi-region Ethics Committee

Georgina Johnson, community representative

Simon Jones, researcher

### Northern X Regional Ethics Committee

Joanna Stewart, biostatistician

Wayne Miles, health practitioner

### Northern Y Regional Ethics Committee

John Fitzgerald, researcher

### Central Regional Ethics Committee

Jacqueline Renouf, consumer representative

### Upper South A Regional Ethics Committee

Elizabeth Richards, consumer representative

Ellen McCrae, pharmacist/pharmacologist

### Lower South Regional Ethics Committee

Rosemary Beresford, pharmacist/pharmacologist

### New Multi-region Ethics Committee Administrators

Sue Fish and Michelle Judge have commenced as joint administrators of the Multi-region Ethics Committee. Jacob White is also assisting short-term.

Contact details:

**Sue Fish** Email: sue\_fish@moh.govt.nz

Phone: (04) 470 0646

**Michelle Judge**

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Phone: (04) 470 0655

## Assisted Reproductive Procedures and Human Reproductive Research

**The Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research (the Advisory Committee on Assisted Reproductive Technology or ACART) is established under section 32 of the Human Assisted Reproductive Technology Act 2004 (the HART Act).**

ACART currently has 10 members appointed by the Minister of Health. The Chairperson of ACART is Professor Sylvia Rumball.

Under the HART Act, ACART has several statutory duties and functions, including:

- issuing guidelines and advice to the Ethics Committee on Assisted Reproductive Technology on assisted reproductive procedure or human reproductive research
- providing the Minister of Health with advice on aspects of, or issues arising out of, kinds of assisted reproductive procedure or human reproductive research.

**The Ethics Committee on Assisted Reproductive Technology (ECART) is established and designated under section 27 of the HART Act. Its role is to consider and determine applications for assisted reproductive procedures or human reproductive research.**

ECART currently has eight members appointed by the Minister of Health. The Chairperson of ACART is Ms Philippa Cunningham.

'Assisted reproductive procedure' means a procedure performed for the purpose of assisting human reproduction that involves:

- the creation of an in vitro human embryo
- the storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo
- the use of cells derived from an in vitro human embryo
- the implantation into a human being of human gametes or human embryos; but does not include an established procedure.

'Human reproductive research' means research that uses or creates a human gamete, a human embryo, or hybrid embryo.

The committees replace the previous National Ethics Committee on Assisted Human Reproduction. Both committees met for the first time in September 2005. The Secretariat for ACART and ECART are:

ian\_hicks@moh.govt.nz (04) 470 0666

willow\_mckay@moh.govt.nz (04) 496 2021

# Locality assessment in the system of ethical review

**In December 2004, New Zealand's system of ethical review underwent significant change. Seven new ethics committees were established under the New Zealand Public Health and Disability Act 2000. These seven committees replaced 15 regional committees, and now have larger regions of authority.**

One aspect of the changes to New Zealand's system of ethical review was the introduction of locality assessment. Locality assessment is intended to ensure that any issues in relation to the local population and resources of the host organisation have been taken into account. Investigators are responsible for ensuring that any location they propose for study conduct is appropriate, and that they have made the relevant local arrangements. Each locality organisation in or through which there is to be substantial recruitment or in which the study will be conducted is then responsible for checking that the investigator has met this second responsibility. If the study is not to be conducted in or through any locality organisation, this check is instead an ethics committee responsibility.

In December 2004, the Minister of Health agreed that the Ministry of Health would convene a meeting of stakeholders from ethics committees, locality organisations, and researcher communities. The purpose of the meeting would be to assist the parties to ensure that all responsibilities are recognised and met, and duplication is minimised, by bringing to bear their practical experience of 'field testing' the locality assessment arrangements. To shape

the focus of the meeting agenda and discussion at this meeting, the Ministry is writing to all bodies and individuals that deal with locality assessment. The meeting is likely to be held in early-mid 2006.

In the first instance, the Ministry of Health is seeking your feedback to the following questions on locality assessment:

- What are the strengths of locality assessment processes?
- In what areas can the operation of locality assessment processes be improved?
- Do you have any other comments about locality assessment processes?

Please indicate in your response your level of interest in participating in a further meeting of stakeholders to discuss locality assessment. Your feedback on the above questions will be summarised and circulated to participants prior to the meeting to inform the meeting discussion.

We look forward to receiving your feedback on locality assessment by 27 February 2006. Please send your feedback or direct any queries on this to:

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