



UPDATE ON STANDARDS FOR ETHICS COMMITTEES

It was a dark and stormy night (I have waited 50 odd years to use that opening) , the worst of our miserable winter but for Wendy Brandon, who made a bumpy flight from Wellington and those enthusiastic branch members who negotiated motorway gridlock, Wendy's presentation on new standards for ethics committees was a highlight of our 2002 Branch seminar series.

There is not space to bring you the cut and thrust of the questions and answers that punctuated the session, but for those who missed the session, here is an abstract of Wendy's presentation.

Health and Disability Ethics Committees ("HDECs") review all research and innovative practice in the health and disability sector. HDECs followed the 1996 National Standard of Ethics Committees. However, the Ministry of Health reviewed these standards, particularly in light of the Gisborne Cervical Smear Inquiry. The result is the new Operational Standard



The Operational Standard is a guideline for ethics committees, designed to:

- protect participants in research and innovative practice and health and disability consumers;
- ensure consistent ethical review;
- guide researchers and research participants;
- promote awareness of the Code of Health and Disability Service Consumers' Rights 1996;
- promote awareness of the Health Information Privacy Code 1994;
- respect the principles of the Treaty of Waitangi by including Maori ethical practices.

The Operational Standard also outlines the minimum requirements that ethics committees must meet for the purposes of s32 of the Injury Prevention, Rehabilitation and Compensation Act 2001, s25(1)(c) of the Health Research Council Act 1990 and the Health Information Privacy Code 1994.

Of the Treaty principles, partnership, participation and protecting Maori values are particularly relevant. Under the Operational Standard, the Human Rights Act 1993 and the New Zealand Bill of Rights Act 1990 are also relevant to ethics committees, as are international ethical guidelines.

Principles of ethical review

The Operational Standard provides several guiding principles. The application of these and weight given to them will depend on the nature of the research or innovative practice in question. They are:

- respect for persons;
- informed consent;
- privacy and confidentiality;
- validity of the research proposal;
- minimisation of harm;
- justice;

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- cultural and social responsibility; and
- compensation for research participants.

Matters requiring ethical review

All proposed health and disability research must be reviewed by an ethics committee where the investigation involves humans and:

- compares established procedure with other procedures, which are not as recognised or established;
- involves access to personal information;
- seeks to further scientific or professional knowledge by questionnaires, interviews or other information-gathering techniques or laboratory analysis of human blood or tissue;
- is research conducted by government departments, unless they have statutory exclusion;
- is observational clinical research or a physiological study;
- is a clinical trial;
- is research involving irradiation, organ imaging or surgical techniques;
- involves innovative practice in health and disability services; or
- is a new treatment or intervention which uses pain or deprivation of basic food or drink as a means to change behaviours.

Matters for which ethical advice may be sought

Generally, questionnaires, surveys or observational studies not involving confidential personal information do not require ethical approval. Neither do audits or internal clinical audits unless additional information is sought.

In some situations people may choose to seek advice from an ethics committee. Ethics committees may be of assistance in making ethical clinical decisions within resource constraints or on other issues, such as withdrawal of life support. Health professionals may wish to seek advice on ethical principles in relation to aspects of service delivery or policies, procedures and staff guidelines, such as:

- the collection, storage, use and disposal of human tissue and bodily substances;
- tagging consumer records;
- policies in sensitive areas (for example sexual abuse reporting);
- issues relating to personal qualifications, privacy and confidentiality in the monitoring and evaluation of services.

Ethics committees are under no obligation to provide advice; however, if the committee has the appropriate expertise it may consent to provide guidance.

Decisions of ethics committees may be subject to judicial review or investigation, for example under the Human Rights Act 1993 or the New Zealand Bill of Rights Act 1990.

Committees must keep records of details, such as reasons for decisions and conditions on approval and also must keep accurate minutes of each meeting.

Appendices

There are several appendices to the operational standard, and these concern:

- guidelines for health research with children;
- research involving people with intellectual disabilities, issues of informed consent and participation;
- research involving unconscious participants;
- clinical evaluation of established therapeutic practices;
- research involving consumers with a terminal illness;
- research involving older persons;
- research involving healthy participants;
- research involving Maori;
- the history of health and disability ethics in New Zealand;
- the relevant New Zealand legislation and codes;
- the terms of reference for the National Advisory Committee on Health and Disability Support Services Ethics;
- the terms of reference for the national ethics committee on assisted human reproduction;
- the health and disability ethics committees (a list of);
- other committees.

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Differences between the National Standard for Ethics Committees, July 1996 and the Operational Standard for Ethics Committees, March 2002

There are many similarities between the 1996 and 2002 Standards and they serve essentially the same purposes. However, there are several fundamental differences.

Since the 1996 Standard the structure of the health sector has changed. The 2002 Standard has, therefore, had to accommodate new committees. Some detail about the new committees and their roles is provided in the 2002 Standard.

The 2002 Standard also provides principles of ethical review. These principles were present to a certain extent in the 1996 Standard; however, they were less prominent and less comprehensive. The emphasis placed on these principles reflects the greater level of guidance provided by the 2002 Standard.

The other major difference between the 1996 and 2002 Standards is that the 2002 Standard is far more comprehensive. The detail provided serves to give further and more specific guidance to ethics committees. It also clarifies certain aspects, which were unclear from the 1996 Standard.

The 2002 Standard is more explicit about matters requiring ethical review and matters about which a person may simply wish to have guidance from an ethics committee. There is also more specific information about what constitutes "innovative practice" and how to deal with multi-centre research proposals.

To contact Wendy, or to read Minter Ellison's Health Law publications go to www.minterellison.co.nz

Bruce Parkes



National Conference 2002

Technology - Adding Value to Health was the theme of the Institute's 2002 Conference, held at the Auckland Exhibition Centre on the 3rd and 4th of July. The 100 people who attended were able to visit the "Health - Institution - Medical Supply & Services Expo being held at the same time.

Conference delegates enjoyed presentations on a diverse range of subjects from Woolworths' on line shopping to Dr Global's Patient Centric Management System. Speaker after speaker emphasised that technology is a tool and not the solution.

For those unable to attend, conference presentations will be available on the ACHSE website in the near future. However, without attending, they might not understand that "vanilla implementations" was part of a presentation "Using technology to Generate Benefits for the Health Sector" and not part of the Woolworths' on-line shopping.



**New Zealand
Institute of Health
Management**
A Branch of the
Australian College of
Health Service
Executives

For all inquiries re Branch activities or membership contact nzihm@xtra.co.nz or (09) 577 5477 Phone/Fax



**Up coming
Seminars**

At Minter Ellison Offices, Level 24, BNZ Tower Building, 125 Queen St
5.30 p.m.

**July 25th
New Health Legislation
Update**

Presented by Wendy Brandon
Head of Minter Ellison Rudd
Watts Health Sector Group

**August 15th
Risk Management in the
Health Sector**

Presented by Karen Price
Head of Minter Ellison Rudd
Watts Risk Sector Group

Light refreshments supplied

Non Members Welcome

Cost:
Members \$20
Non Members \$30

AGM elects new Branch Committee

A new Branch Committee was elected at our Branch AGM held in June. Your 2002— 2003 committee is:

- Denise Tyrrell (chair)
- Ian Wolstencroft (secretary)
- Alan Johns (treasurer)
- Sue Frost
- Bruce Parkes
- David Rees
- Fiona Ritsma
- Trisha Ross
- Jo Wallis

David, Denise, Fiona, Ian and Trisha also serve as National Councillors.

Retiring committee member Ann Robertson continues to serve the Institute as National Treasurer.

Branch Chair

Chairperson of the Auckland Branch is Denise Tyrrell. Denise has been on the Auckland branch since 1998 and on the National Council as secretary since 2001.

Denise has been committed to health throughout her career. She has been involved in a variety of operational and strategic health management roles in both the public and private sector for the last 10 years.

Being a life long learner is important to Denise and this is supported through her involvement in NZIHM. Denise is Clinical Business Manager for Southern Cross Health Trust.



Guest Comment

Welcome to the NZIHM Auckland Branch newsletter.

In June we held the AGM of the Auckland branch and elected 9 committee members. I want to thank all those whom over the last 2 years contributed so much to the Auckland Branch Committee and now have resigned: Felix Pintado, Gary Henry, Sandra Budd, Feisal Keshavjee, Joanne Weninger and Ann Robertson.

I am looking forward to a very active year from the Auckland Branch with a great mix of existing and new committee members willing to bring their energy and enthusiasm.

The committee have met for the first time and started outlining a plan to add value to you over the next year. This includes continuing our evening seminars, networking opportunities, this newsletter, and increasing membership. We will also be contributing ideas to National Council to add further value. I will provide a further update in our next newsletter.

I look forward to your continued support and meeting you at the seminar evenings.

Denise Tyrrell