

Health Ethics

<http://www.health.nsw.gov.au/healthethics/>

Issue 7

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This month in health ethics

Welcome the April edition of Health Ethics News!

This is the first edition for 2005 and we are looking forward to a busy and productive year for research and clinical ethics in NSW Health.

In line with national developments, one of our major priorities for this year is to streamline processes for dealing with multi-centre research, including clinical trials and epidemiological research. In February 2005, NSW Health co-sponsored a governmental forum attended by State and Territory governments and the Commonwealth to discuss a national approach to streamlining ethical review of multi-centre research. An article on this inter-jurisdictional forum appears in this edition.

We are also working to further standardise processes amongst our HRECs. We have recently released our Operations Manual for NSW Health HRECs, which we hope will provide useful guidance, particularly for new HRECs or those currently operating without standard procedures. Established HRECs are also encouraged to examine the Operations Manual, as it provides useful tips on matters such as ensuring your HREC has appropriate Terms of Reference, especially given the recent re-organisation of the Area Health Services.

In clinical ethics, an important priority for this year is the implementation of the various guidelines relating to care at the end of life. Articles on these initiatives appear in this newsletter.

Concord Hospital Human Research Ethics Committee profile

The Concord Hospital Human Research Ethics Committee meets once a month to provide ethical oversight of the approximately 120 new research proposals that it receives every year.

About half of these research submissions are clinical trials of new drugs, the majority of which are industry-sponsored multi-centre trials. The areas of highest clinical trial activity include Oncology, Endocrinology, Neurology, Cardiology and Respiratory Medicine.

Other types of research include trials of new devices and diagnostic tests; human tissue research (including genetic testing); medical records research; and a small amount of research using qualitative methods.

Concord Repatriation General Hospital retains strong links with its veteran community. This is reflected in its focus of multi-disciplinary research into ageing. The Ethics Committee has therefore developed particular expertise in reviewing research into the diseases and conditions of ageing, including osteoporosis, neurodegenerative diseases, chronic obstructive pulmonary disease, stroke and prostate disease. In addition, it has been necessary to develop clear policies for considering the issue of consent for research participants who may be cognitively impaired or critically ill.

The Concord Human Research Ethics Committee has 22 members, including four lay people, two lawyers, a Minister of Religion and a group of professionals with a diverse range of expertise in research and clinical care. The committee is chaired by Dr Garry Pearce, staff specialist in rehabilitation medicine.

The Concord Hospital Drug Committee provides separate scientific review of clinical trials of new drugs, and reports to the Ethics Committee.

In 2001 the Ethics Committee agreed to a process of expedited review for minimal risk research, protocol amendments, serious adverse events and some of the more administrative aspects of the ethical review process. The Expedited Ethical Review Panel was set up to meet monthly and is composed of six members of the Ethics Committee, including the Chairman, Deputy Chairman and Clinical Trials Pharmacist. The decisions of the Expedited Ethical Review Panel are to be ratified by the full Ethics Committee at its next meeting.

As research activity at Concord continues to increase in 2005, the Ethics Committee is looking forward to the new challenges of research ethics in the year ahead.

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Inter-jurisdictional Forum: Towards timely, efficient and effective review of multi-centre clinical trials

This government inter-jurisdictional forum was held in Sydney in February 2005. It was co-sponsored by NSW Health Ethics Branch, the National Health and Medical Research Council and the NSW Ministry for Science and Medical Research. The forum brought together representatives of State and Territory

Governments, the Commonwealth Government, the NHMRC, the Australian Institute of Health and Welfare and the New Zealand Government. The forum consisted of:

- presentations on various aspects of multi-centre research
- presentations on initiatives in reviewing multi-centre research by NSW, Victoria, Queensland and New Zealand
- a working session to determine ways forward for Australia.

The delegates to the forum developed nine principles that should characterise any system of ethical review of multi-centre research in Australia.

As a result of this forum, the co-sponsors are seeking to have the issue of ethical review of multi-centre research placed on the national agenda so that a national approach may be facilitated.

The forum papers, including all the papers presented, summaries of discussion, and the nine principles developed can be found at the Health Ethics Branch website at www.health.nsw.gov.au/healthethics/policies.html

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2005 HREC Training Program

This year, the Health Ethics Branch has devised what we hope will be an interesting and informative training and education program for our HRECs.

The first in our series will be a full day devoted to the issues that continue to make life interesting for HRECs, those “hoary old chestnuts: known as privacy, indemnity and insurance, and multi-centre research. A seminar specifically for lay members will be held in August. Topics currently being considered include basic principles of bioethics; clinical trials—everything you ever wanted to know but were too scared to ask—and research risks for vulnerable subjects—balancing benefits and risks. Later in the year, we will be travelling to a rural location to discuss issues confronting our rural HRECs. In November, we will again host our Annual Meeting of Chairs and Executive Officers. See the dates on page 3 of this newsletter.

HREC Standard Operations Manual

HRECs will be aware from the November 2004 edition of the Health Ethics Newsletter that Health Ethics Branch has been developing an Operations Manual for HREC members and Executive Officers. Quality, consistent and timely ethical review of research relies on the existence of effective written terms of reference and operational practices. As such, the Manual is designed to facilitate Area Health Services and their HRECs in developing their own specific terms of reference and operating procedures. This Manual has been issued as a NSW Health Guideline and is available at www.health.nsw.gov.au/policies/gl/2005/GL2005_059.html

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Release of the Guidelines for end-of-life care and decision-making

The *Dying with Dignity: interim guidelines on management* have now been replaced with *Guidelines for end-of-life care and decision-making*. The Guidelines focus on the process of reaching decisions about the withholding and withdrawal of life sustaining treatment in dying patients. The Guidelines discuss the responsibilities of health professionals and emphasise the importance of working with patients and their families. These Guidelines aim to:

- provide practical advice applicable across a range of care settings
- reduce variation in the practice of end of life care, in particular avoiding the extremes of both inappropriate under- and over-treatment
- provide the basis of, and encouragement for, hospitals and units to create their own policies
- provide information on a range of specific issues, including:
 - making decisions about end of life care where the patients cannot do so themselves, including for children
 - resolving disagreements with substitute decision makers, such as family, about limitation of life sustaining treatment
 - appropriate documentation of treatment limitation decisions and subsequent care
 - no cardiopulmonary resuscitation orders
 - use of artificial hydration and nutrition
 - appropriate use of analgesia and sedation.

Health Ethics Branch will hold education seminars during the second half of 2005 and in 2006, and will involve regional areas. The first seminar will be *Decisions at the end-of-life: working together to improve practice* at Sydney Convention & Exhibition Centre on Friday, 29 July 2005. Seminar and registration details forthcoming.

The Guidelines are available at www.health.nsw.gov.au/pubs/2005/endlifecare.html or by contacting the Better Health Centre on 9816 0452 for a hardcopy.

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Advance care planning seminar

Health Ethics Branch conducted a successful half-day seminar on advance care planning for end-of-life care on 9 February 2005. This seminar complemented the release of best practice advice last year titled *Using Advance Care Directives (NSW)*. This

advice had been developed in response to a need identified during consultation on the revised Dying with Dignity guidelines, and with the input of an expert working group. The seminar clearly demonstrated the level of interest in end-of-life issues and was attended by 150 registrants at Westmead Children's Hospital and, by videoconference link, to another 120 people at three regional centres in Port Macquarie, Queanbeyan and Maitland.

The program was moderated by Dr Norman Swan from ABC radio and included a range of interesting speakers including those with medical and nursing backgrounds in palliative care, intensive care, the law, and consumers. A case scenario with panel discussion and audience participation successfully highlighted the challenges in planning for end-of-life care in advance and the issues involved in use of advance care directives.

A CD-ROM is being developed from footage of this seminar and will be available by contacting Health Ethics Branch.

Using *Advance Care Directives (NSW)* are available at www.health.nsw.gov.au/pubs/2004/adcare_directives.html or from the Better Health Centre on 9816 0452 for a hardcopy.

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Over the next few months the Health Ethics Branch will be visiting HREC Chairs and Executive Officers around NSW. At

the top of the list for discussion is administrative procedures for the Shared Scientific Assessment Scheme, the development of the Health Ethics Branch website, the implementation of Standard Operating Procedures and, of course, any issues you would like to discuss with us.

A member of the Branch will be in contact with you to arrange a convenient time and date.

NHMRC Current Projects

As many of you are aware, the NHMRC has invited comment on the *National Application Form (NAF) Consultation Draft 2005 v1.0*. Health Ethics Branch strongly supports the development of a single national application form, the aims of which are to minimise duplications of effort for HRECs and researchers and to improve operational consistencies.

The NHMRC has also invited submissions regarding its *Review of the National Statement on Ethical Conduct in Research Involving Humans* first consultation draft and its *Revision of the Joint NHMRC/AVCC Statement and Guidelines on Research Practice Consultation Draft #1*.

Health Ethics Branch has submitted comments on the above documents, a copy of which can be obtained by contacting Ainsley Martlew, A/Senior Analyst, Research Ethics.

A reminder about important dates

Below are dates of events, seminars and conferences in 2005.

12-13 May 2005	NHMRC 2005 National Ethics in Human Research Conference	Australian Institute of Sport, ACT.
Tue 21 June 2005	2005 HREC Training Program "Hoary Old Chestnuts" <i>Privacy, indemnity, conflicts of interest</i> .	Sydney venue to be confirmed.
Thur 30 June 2005	Clinical Ethics Workshop <i>Centre for Values, Ethics and the Law in Medicine</i>	Macquarie University. Ph. 02 9351 7794 or go to website www.comet-velim.org for details.
Fri 29 July 2005	<i>Decisions at the end-of-life: working together to improve practice</i> Seminar.	Sydney Convention & Exhibition Centre. Registration details to be confirmed.
Mon 22 August 2005	"Especially for Lay Members" <i>Other HREC members welcome but priority given to lay members.</i>	Sydney venue to be confirmed.
Thur 13 October 2005	"A Day in the Bush" <i>Issues confronting HRECs.</i>	Venue to be confirmed.
Fri 18 November 2005	Annual Meeting of Chairs and Executive Officers	Sydney venue to be confirmed.

Recommended reading

"Trust and confidence: towards mutual acceptance of ethics committee approval of multicentre studies". M. Sarson-Lawrence, C. Alt, M.T. Mok, M. Dodds, M.A. Resenthal. *IMJ* 2004, 34: 598-603. This article discusses attempts to study the issues raised by HRECs during the ethical review process and to determine the length of time taken to gain HREC approval for multicentre studies. Trust and confidence between HRECs is a key theme discussed by the authors and is regarded as one of the main barriers to HRECs accepting the ethical review of another HREC.

Our website

Our website has been re-vamped. Please see it at www.health.nsw.gov.au/healthethics/

Letters to the editor

The HEB would like to encourage you to submit any ideas, questions or other issues you would like considered for publication.

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