

Health Ethics

<http://www.health.nsw.gov.au/public-health/rad/ethics/index.html>

Issue 4

SHPN (HEB) 030312

May 2004

This month in health ethics

The Health Ethics Branch (HEB) continues activity in both research and clinical ethics fields. The review of the Shared Scientific Assessment Scheme is nearing completion, and development of several clinical ethics policies is in progress. The education seminar on privacy in the research setting was a successful event held in March, with strong attendance by more than 100 participants.

Health Ethics Branch Seminar – Making sense of privacy and confidentiality in the research setting, 26 March 2004

This seminar brought together expertise in the fields of law and law reform, genetic counselling, and privacy regulation to address the complex issues in applying privacy legislation in the research setting. The attendance of more than 100 registrants from Human Research Ethics Committees (HRECs) and the research sector was testament to the interest associated with this changing area. Presentations from the invited speakers and case scenario discussions provided a most useful insight into when, and how to apply the various privacy principles. In particular, attendees valued the opportunity to engage in lively discussion with those from both the research and research review perspectives.

Other privacy issues

As those who attended the privacy seminar will be aware, the new *Health Records and Information Privacy Act* imposes reporting obligations on HRECs. The HEB will shortly be forwarding to HREC executive officers for comment:

- the draft reporting form developed by Privacy NSW
- a draft addition to HREC application forms, which will enable applicants and HRECs to address issues in the Act and to streamline reporting.

HREC Executive Officers will be asked whether they consider a workshop on the new reporting requirements would be useful.

Review of the Shared Scientific Assessment Scheme

The final evaluation of the pilot Shared Scientific Assessment Scheme (SSAS) has now commenced. Thank you to all those HRECs who participated in the evaluation. Both the retrospective and prospective evaluations have now been completed and we expect the final evaluation to be finalised in the coming months. Until the final evaluation has been completed, the SSAS will continue to operate in its current format. HEB would appreciate it if HRECs could inform their researchers that the scheme will

The beginning of 2004 sadly saw the departure from HEB of Carmel Edwards, Senior Analyst, Research Ethics and editor of Health Ethics newsletter. We wish her good luck in her new position and thank her for the enthusiasm and expertise in research ethics that she brought to NSW Health.

continue to operate until the recommendations from the final evaluation have been considered by the SSAS Reference Group.

For queries on SSAS, contact:
Ainsley Martlew
Project Officer
Tel. (02)9391 9292
amart@doh.health.nsw.gov.au

Research Ethics listserv

The IEC listserv was established by the NSW Department of Health in order to provide a national forum for members and executive officers of HRECs to informally share their experiences and expertise. It is a closed list, and we currently have approximately 190 subscribers, spanning across all states and territories. The listserv promotes the discussion and exchange of information pertaining to human research ethics, HREC administrative procedures, and related legislation and guidelines.

To join the listserv:

1. Send an email to majordomo@lists.health.nsw.gov.au
2. In the message box, type 'subscribe doh-iec'.

You will receive a message asking for your contact details and the name of the ethics committee with which you are associated.

To send a message to the listserv, address your email to doh-iec@lists.health.nsw.gov.au

If you are new to the list, or there is something that you would like comment on, post a message. All questions are important. Legislation and guidelines change, and opinion frequently changes. If you reply to a question, please send your reply to all members so that they can participate in the discussion.

Clinical ethics policy consultations

HEB is developing policy and/or undertaking consultation on several clinical ethics issues. They include:

- **Clinical ethics support for health professionals**
A discussion paper *Improving Clinical Ethics Support* was disseminated to a range of stakeholder groups early this year. This paper sought feedback on a range of issues associated with improving the level of support for health

professionals in addressing clinical ethics issues in their practice. Responses have shown that this issue is of significant interest to health professionals and a spectrum of views exist about appropriate mechanisms for achieving this across NSW. An opportunity to discuss the issues raised by the paper in open forum is proposed for the second half of 2004. The closing date for submissions has lapsed, but a copy of the paper can still be found on the Health Intranet at http://internal.health.nsw.gov.au/public-health/research/clinical_ethics/support.html

- **Quality improvement activities and ethics review**
The QI and Ethics Review Working Group have developed draft advice entitled *Quality improvement and ethics review: a practice guide for NSW*. This expands on the 2003 NHMRC advice on this issue and includes a checklist to assist in identifying when quality improvement activities require either expedited or full review by an HREC. This draft advice has been disseminated to HRECs, quality executives and others for comment. Electronic copies can be obtained from Julie Letts. Closing date is 7 May 2004.
- **Living, non-directed kidney donation**
NSW Health's Clinical Ethics Advisory Panel (CEAP), in consultation with the Transplantation Advisory Committee, has developed a draft policy and discussion paper on the practice of living, non-directed kidney donation. This refers to donation by an individual to any suitable stranger on the waiting list, rather than to someone with whom they have close relationship. CEAP is now consulting with key professional and lay groups affected by the draft policy. Closing date for comments is Friday 28 May 2004.

For more information on clinical ethics policy, contact:
Julie Letts, Senior Analyst Clinical Ethics
Tel: (02) 9391 9465
Email: jlett@doh.health.nsw.gov.au

Xenotransplantation

In February, NHMRC concluded the second round of consultation on xenotransplantation. This included release of a comprehensive and informative response paper comprising both the responses received in the first consultation round, and the Xenotransplantation Working Party's subsequent deliberations. In addition, the Working Party undertook a series of public forums in each capital city. The response paper proposed that a stringent process for scrutinising and managing both pre-clinical and (potential) clinical trials be developed, even if no animal-to-human trials are ultimately approved in this country. One of the central dilemmas remains how to weigh compelling individual need against the potentially grave, but unknown risk of public infection. Further information can be obtained by visiting the NHMRC website at <http://www.nhmrc.gov.au/issues/xenotran.htm>

NHMRC – Release of information paper on post-coma unresponsiveness (vegetative state): a clinical framework for diagnosis

NHMRC has recently released this information paper focussing on the assessment and diagnosis of patients with 'post-coma

unresponsiveness', otherwise known as a 'vegetative state'. The challenges in differential diagnosis and provision of prognosis with this relatively uncommon, but devastating condition are clearly discussed.

Copies of the document can be obtained by sending an email to nhmrc.publications@nhmrc.gov.au or visiting the NHMRC website at <http://www.nhmrc.gov.au/publications/synopses/hpr23syn.htm>

Indemnity and insurance issues

As previously noted, the HEB is developing a policy on indemnity and insurance issues for NSW Health HRECs. This is being undertaken in conjunction with the Department's Legal and Finance Branch and the NSW Treasury Managed Fund. There has been a great deal of interest in the development of this policy, and many questions have been raised by executive officers, HREC members and researchers. This has resulted in the development of the policy taking longer than expected. However, it is anticipated that a draft policy will be distributed to Health HRECs for comment in June. To allow sufficient time for feedback, the training day on indemnity and insurance issues and the Annual Meeting of HREC Chairs and Executive Officers, which was scheduled for Friday 30 July 2004, has been postponed. We will advise you of the new date for this seminar in the next newsletter.

Suggested reading

The following article is recommended to HREC members:

Spriggs M, Canaries in the mines: children, risk, non-therapeutic research, and justice. *Journal of Medical Ethics* 2004; 30: 176-181.

Abstract

The Kennedy Kreiger lead paint study received a lot of attention after a US Court of Appeals ruled that a parent cannot consent to the participation of a child in non-therapeutic research. The ruling has raised fears that, if it goes unchallenged, valuable research might not proceed and ultimately all children would be harmed. The author discusses significant aspects of the study that have been neglected, and argues that the study was unethical because it involved injustice and its design meant that the study lacked importance and value. Issues of benefit, risk, and consent are vital, but it is sometimes a mistake to consider these issues before settling questions about justice and the importance and value of the research project. The author concludes by offering a strategy for researchers and reviewers of research to appreciate, in a vivid way, the implications of research participation.

Visiting Program for NSW Health HRECs

The HEB recently called for interested HRECs wanting to participate in the Visiting Program by either visiting, or hosting visits from, other NSW HRECs. About 12 committees are now involved, and Executive Officers should have recently received correspondence detailing allocated sites. The purpose of the Visiting Program is for HRECs to share their experience in the way they "do business" and to identify common challenges and possible solutions.

A reminder about important dates

Below are dates of events, seminars and conferences in 2004.

Postponed. Date to be confirmed.	Seminar on Insurance and Indemnity Issues and Annual Meeting of HREC Chairs and Executive Officers	Sydney.
Friday, 28 May 2004	Centre for Values, Ethics and Law in Medicine 7th Annual Seminar. Theme: Policing virtue?	University of Sydney For more information, visit the Centre for Values, Ethics and Law in Medicine website at www.ehlc.net
Monday, 7 to 9 June 2004	ARCS Annual Scientific Conference	Darling Harbour, Sydney More information, visit the ARCS Australia website at www.arcs.com.au
Friday, 30 July to 1 August 2004	Australian Institute of Health Law and Ethics 9th Annual Conference Theme: Who Needs to Know, Who Wants to Know, Who Cares? <i>"Information in Health: Privacy, E-health, Control and Access"</i>	Macquarie University, Sydney For more information, visit The Australian Institute of Health, Law & Ethics website at www.aihle.org
Saturday, 5 to 9 December 2004	Intensive Research Ethics Course Centre for the Study of Ethics in Medicine and Society (Monash Medical School, Alfred Hospital)	Portsea, Victoria For more information, send an email to ethicscentre@med.monash.edu.au

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.

Contacts

Deborah Frew Manager, Health Ethics Branch
Tel (02) 9391 9751 email dfrew@doh.health.nsw.gov.au

Julie Letts Senior Analyst, Clinical Ethics
Tel (02) 9391 9465 email jlett@doh.health.nsw.gov.au

Ainsley Martlew A/Senior Analyst, Research Ethics
Tel (02) 9391 9292 email amart@doh.health.nsw.gov.au

Rachel Clarke Administrative Officer
Tel (02) 9391 9861 email rclar@doh.health.nsw.gov.au