

Health Ethics

www.health.nsw.gov.au/public-health/rad/Ethics/ethics_index.html

Issue One

September 2003

This month in health ethics

August has been a busy month for ethics in NSW Health

On August 27 we held our first meeting of Chairs and Executive Officers of NSW Health Human Research Ethics Committees (HRECs). Attendees had the opportunity to discuss and comment on the pilot Shared Scientific Assessment Scheme; Kerry Breen, Chair of AHEC, brought us up to date on their plans for the next triennium; and members of the Health Ethics Branch presented the results of the round of consultations with NSW Health HRECs and how the issues raised have been used to inform the development of the Department's research ethics strategy.

This strategy is aimed at providing support, education and liaison opportunities for NSW Health HRECs.

On August 29, a forum to consult with researchers and industry on the Shared Scientific Assessment Scheme was held. A large number of industry representatives and researchers attended the forum, and they provided valuable comments and feedback on the scheme to date.

Proceedings from the two events will be available shortly on our website www.health.nsw.gov.au/public-health/rad/Ethics/ethics_index.html, or simply go to www.health.nsw.gov.au and search for 'research ethics'.

Also, in late July, the Branch convened a meeting of all the Chairs of existing clinical ethics committees operating in NSW Health. The Department will continue to work to develop liaisons between clinical ethics committees.

Profile: The Children's Hospital at Westmead Human Research Ethics Committee

Each month, Health Ethics will feature a profile of a NSW Health HREC

The first meeting of the Human Research Ethics Committee of The Children's Hospital at Westmead (then known as the Royal Alexandra Hospital for Children, Camperdown) was held on May 29, 1981. The Committee consisted of 4 medical members and was chaired by the hospital's president. In its first year, it established the hospital's first guidelines for conducting research based on the Australian College of Paediatrics Code of Ethics in regard to research in children and considered 15 protocols. From those early days, the Committee has grown to 13 members from a wide variety of backgrounds including medical, surgical, nursing, basic science, behavioural science and linguistics, as well as laypeople. We meet 6 times per year and consider up to 120 new protocols, including:

- sponsored multi-centre clinical trials
- gene therapy trials
- basic research into rare disorders
- epidemiological and public health research
- behavioural and psychological research.

The Committee is advised by its Scientific Advisory Committee, the hospital's Drug Committee and Radiation Safety Committee, so that by the time a protocol reaches the Ethics Committee, the members can concentrate on the ethical aspects of the proposed research.

The core principle, which guides our decision-making, is to protect the rights and welfare of children and adolescents, and their families, involved in research. The Committee acts as an advocate for the interests and needs of children who are generally not in a position to speak for themselves. We are responsible for ensuring:

- the research is justified
- the risks to the child are minimal or at least balanced against the benefit to the child or children generally
- informed consent from parents/guardians or the child themselves is obtained in a manner appropriate to the study
- the conduct of unscientific and unethical research is prevented.

Although we are constantly being challenged to keep up with developments in research and ethics, our Committee takes a certain amount of pride in its expertise in reviewing matters relating to the ethics research involving children and would be happy to provide advice to other HRECs.

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Prof Kevin Gaskin, Chairperson,

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SSAS update

The Shared Scientific Assessment Scheme has now been operating for 6 months, with 13 applications received to date. An interim report, incorporating feedback from users of the scheme, will be made available to the SSAS Reference Group later in the year. This will be used to determine whether any changes should be made for the remainder of the pilot.

Feedback received to date from applicants and ethics committees, has been positive. In particular, many ethics committees have reported that the Final Report produced by the Shared Scientific Assessment Committee (SSAC), has been very useful.

Whilst participation in the scheme remains voluntary, some ethics committees have chosen to modify their terms of reference in order to make application to the scheme by eligible parties mandatory. In addition, some ethics committees have modified their application procedure so that researchers must indicate in their submission, whether or not their application has been reviewed by the SSAC.

Further information is available from our website (search under SSAS): www.health.nsw.gov.au

Quality Improvement and Ethics Review Working Party

The Health Ethics Branch, in collaboration with Quality and Clinical Policy Branch, has commenced a project to assist health professionals to determine when QI activities require independent ethics review. NHMRC advice, released in 2003, provides the basis for identifying 'reviewable' from 'non-reviewable' activities. The NSW Health Quality Improvement and Ethics

Review (QUIER) Working Group, comprised of ethics committee and quality representatives, has used that advice to develop practical guidelines for identifying potential ethical risks for a range of QI activities. The Working Group has also been working towards developing recommendations that streamline review of QI activities where appropriate, in particular, identifying situations where expedited or 'fast track' review would be sufficient. The Working Group was due to complete its deliberations after August 2003.

Contact

Julie Letts, Senior Analyst, Clinical Ethics,
Health Ethics Branch. **Tel.** 9391 9465,
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Training day in research ethics

We are planning a training day in research ethics for members and executive officers of NSW Health HRECs. The proceedings will be based on the training day presented at the Ethics in Human Research Conference, held in Canberra earlier this year, and the facilitator will be Colin Thompson, consultant, NHMRC.

The aim of the training day is to provide an understanding of the principles and values of research ethics as expressed in the NHMRC *National statement on ethical conduct in research involving humans*.

Date Friday November 28, 2003

Time 10.00am – 4.00pm

Venue Harbourview Hotel, North Sydney

Further information, including program and registration form, is on our website at: www.health.nsw.gov.au/public-health/rad/Ethics/ethics_index.html.

Upcoming events and conferences

September 28-October 3 September 28-29	Sydney – (NSW) 28 International Congress on Law and Mental Health <i>Pre-conference</i> – Medicine and Industry: Changing Paradigms in Ethics, Law and the Health Professions – 2003 Plenary
September 30	– Social Justice within Diversity , Australian Institute of Health, Law and Ethics website: www.law.unimelb.edu.au/aihle/eventsdiary.html#jul
October 10 (Sydney) October 31 (Lismore) November 7 (Dubbo) November 12 (Wagga Wagga)	NSW Health workshop on new Human Tissue and Anatomy Legislation . See 'What's New' section and attached program
November 2-7	Mt Buffalo – Centre for Human Bioethics Intensive Bioethics course , website: www.arts.monash.edu.au/bioethics/index.html
November 16-20	Hepburn Springs, Victoria – Centre for the Study of Ethics in Medicine and Society, Monash University, 3rd intensive research ethics course . Contact Deborah.zion@arts.monash.edu.au
November 20-23	Hobart, Tasmania – Australian Institute of Health Law and Ethics' 8th annual conference The Risk Society – Challenges in Health, Law and Ethics , website: www.law.unimelb.edu.au/aihle

What's new

Cloning and research involving human embryos

The NSW Parliament has passed the following legislation:

- *Human Cloning and Other Prohibited Practices Act 2003*
- *Research Involving Human Embryos (NSW) Act 2003*.

These *Acts* apply corresponding Commonwealth laws, which were passed by the Federal Parliament last year. They allow the operation in NSW of the Commonwealth/State regulatory scheme regarding the use of human embryos, which was agreed last April by the Council of Australian Governments.

The *Human Cloning and Other Prohibited Practices Act* bans certain practices in relation to human embryos, including:

- creating a cloned human being
- creating a cloned human embryo (part of the process of so-called 'therapeutic cloning')
- creating human embryos purely for research
- altering the genome of a human embryo in such a way that the alteration is inheritable
- commercial trading of human eggs, sperm and embryos.

The *Act* will be reviewed in 2 years.

The *Research Involving Human Embryos (NSW) Act 2003*, applies a national licensing scheme regulating embryo research.

The *Act* requires a licence to be obtained from the Licensing Committee of the National Health and Medical Research Council, before any research may be undertaken on a human embryo.

The Licensing Committee will only permit such research if:

- the embryo is an excess ART embryo, that is, it was created for the fertility treatment of a woman, but is no longer required by that woman for implantation purposes
- proper consent from the individuals identified in the *Act* has been given for the use of the embryo for research
- the research has been approved by an HREC
- the embryo was created before April 5, 2002 (this condition expires on April 5, 2005 or an earlier date declared by the Council of Australian Governments).

In issuing a licence, the Licensing Committee will consider:

- restricting the number of embryos to those necessary to achieve the research goals
- the likelihood of significant advance in knowledge or improvement in technologies from the research
- any relevant guidelines of the NHMRC
- the HREC's assessment.

Any HREC assessing proposals for embryo research must be familiar with the requirements of the above *Acts*. Detailed advice for HRECs is available in the NHMRC publication *Information for Human Research Ethics Committees considering proposals for the use of excess ART embryos*, which can be found on the NHMRC website.

The legislation does not extend to require a licence for research on existing embryonic stem cell lines (ie where extraction of the stem cells from the embryo has already taken place). The relevant requirements for an HREC to approve such research can be found in the NHMRC's *Interim advice regarding the consideration of research proposals involving the use of stem cells from human embryos*, which was distributed to HRECs in September 2001, and is also available on the NHMRC website.

New human tissue legislation

The NSW Parliament has passed the *Human Tissue and Anatomy Legislation Amendment Act 2003*. **It is anticipated that the *Act* will commence on November 1 this year.** This *Act* provides for certain rules governing the use of human tissue for medical, therapeutic or scientific purposes. Scientific purposes include medical research. In summary, the following requirements are enacted in relation to:

- Research involving any human tissue (including blood, body parts, organs, or other tissue) removed or expelled from the body of a person for the purposes of a medical, dental or surgical procedure whilst the person was alive, requires the written consent of the person or, if the person has since died, the senior available next of kin.
- Research involving any tissue removed from the body of a dead person for the purpose of a post mortem examination requires the authority of the designated officer of the hospital or forensic institution. The designated officer is required to ensure that the relevant consent was given in writing, either by the deceased prior to death, or the senior available next of kin, or the coroner, as applicable.
- Research involving any tissue removed from the body of a dead person (other than tissue removed for the purposes of a post mortem examination) requires the authority of the designated officer of the hospital where the person died. (The designated officer is required to ensure that relevant consents have been obtained before giving this authority, as above).
- These requirements for consent DO NOT APPLY to small samples of human tissue retained in tissue blocks and slides.

When HRECs are assessing any research protocol involving human tissue removed after the commencement of this *Act*, they should ensure that the necessary consents

outlined above have been obtained. However, ethical considerations as to whether or not consent should be obtained should continue to be applied. Reference should be made to Chapters 15 and 16 of the National Statement to determine if consent is required.

How specific does the consent have to be?

The legal requirement is that the person consents to the use of the tissue for ‘scientific purposes’ or ‘research’. However, the person may have chosen to limit the consent, for example, to certain kinds of research, such as breast cancer research. If the consent is limited, it will be unlawful to use the tissue for other purposes.

Further, the ethical principles in the National Statement may result in the HREC requiring more specific consent as part of their approval of the research protocol.

Further details regarding this legislation, including special provisions regarding tissue removed from wards of the state and persons under guardianship, will be included in the forthcoming policy on genetic research involving human tissue. In the interim, any questions regarding this new legislation can be directed to Deborah Frew.

A copy of the legislation can be viewed on the NSW Parliamentary website at www.parliament.nsw.gov.au

Letters to the editor

As Editor of *Health Ethics*, I would like to encourage you to submit any ideas, questions or other issues you would like considered for publication in this newsletter. My contact details are below.

Cheers
Carmel Edwards

Contacts

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Workshop on the NSW Human Tissue and Anatomy Amendment Act 2003

What has changed and the implications for Health organisations

Time	Workshop topic	Speaker
0900	Introduction	Dr Greg Stewart, Chief Health Officer and Deputy Director General, Public Health
0930	History and background	Legal Branch
1000	– Overview of the changes – Human Tissue, <i>Anatomy and Coroners Act</i>	Legal Branch, Clinical Policy
1030	Morning tea	
1100	– What has changed? Implications for Health organisations – Consents – Post-mortem, non-coronial/information – Coronial – Records/Audits/implications for Health research	– Case examples from Health – NZ experience, David Aro
1300	Lunch	
1400	Questions and discussion	Malynda Flarey/Bill Heiler
1430	Panel to answer questions	Coroner/Legal/Clinical Policy
1515	Afternoon tea	
1545	Summary and close	
1600	Adjourn for refreshments	

Registration form

NSW Department of Health workshop on the NSW Human Tissue and Anatomy Amendment Act 2003

What has changed and the implications for Health organisations

To register complete this form and fax it to:
Karen Thrift, Senior Analyst
Quality and Clinical Policy Branch
NSW Department of Health
Fax. (02) 9391 9898 Tel. (02) 9391 9276
Email. kthri@doh.health.nsw.gov.au

- Indicate which workshop you would like to attend:
- Sydney 10 October 2003 – Red Cross House
Level 5, 153 Clarence St City
 - Sydney 26 November 2003 – Mary Mackillop Conference Centre
11 Mount Street, North Sydney
 - Lismore 31 October 2003 – Southern Cross University
 - Dubbo 7 November 2003 – Western Plain Zoo
 - Wagga 12 November 2003 – Charles Sturt University

TitleFamily name.....Given name

Job title

Company name

Address

.....Tel.....

Email

Confirmation of registration and details of the workshops will be forwarded to you prior to the workshop.