

# Health Ethics

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

Issue 1

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## This month in health ethics

*Welcome the August edition of Health Ethics News*

The Health Ethics Branch has a new name! We are now known as the Health Research and Ethics Branch, to emphasise our role in enhancing and supporting research in NSW. We retain all our core functions in relation to both research ethics and clinical ethics.

This issue emphasizes our major priorities for the coming financial year. We are continuing with our project of streamlining ethical and scientific review of multi-centre research and further information about this initiative is provided below. We would like to thank those of you who have provided data about the activities of your HRECs to enable us to make evidence-based decisions about how a new streamlined system might work.

The training session for this quarter is specifically targeted at lay members of our HRECs, and will be held on 22 August at the Department of Health. Education sessions for rural health professionals on the Department's Guidelines for end of life care and decision-making are outlined in this issue.

This issue also includes information about important developments at the Departmental and National level which affect HRECs, including: the new Australian Clinical Trials Register; the new ARPANSA Code of Practice on Exposure of Humans to Ionising Radiation for Research Purposes; and a new General Retention and Disposal Authority affecting the retention of HREC records.

## Profile: Justice Health Human Research and Ethics Committee

The Justice Health<sup>1</sup> Human Research Ethics Committee was established as the Institutional Ethics Committee of the Corrections Health Service in 1995. The Committee is bound by the NHMRC National Statement on Research Involving Humans. The Committee consists of 12 members with a wide variety of backgrounds and expertise, including law, medicine, social science and religion. The committee is chaired by Associate Professor Sandra Egger, who is Professor of Law at the University of New South Wales.

Our committee has developed specialist expertise in the area of health and human rights and research on people deprived of their liberty.

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<sup>1</sup> Corrections Health Service became Justice Health on 1 July 2004.

The Committee's major roles are to:

- Consider the methodological and ethical implications of all proposed research projects.
- Advise applicants of approval, rejection or recommendations for changes to research submissions.
- Maintain surveillance of approved research.
- Maintain a register of projects.

Where a research project places demands on Justice Health staff or requires significant resources from Justice Health, advice must be sought from the CEO regarding the ability of Justice Health to provide these resources. In carrying out its functions the Committee will have regard to the risks and benefits to subjects of the research and perceived benefits of the research.

The Committee meets six times a year and also considers projects out of session. The number of protocols considered each year has been between 12 and 15. The types of

protocols being reviewed by the committee include:

- public health research
- behavioural and psychological research
- clinical trials.

The committee has received applications for large population based studies, clinical trials (multi-centered community based trials with a prison component), PhD and Masters proposals. The committee does not usually consider students' proposals unless there are ethical concerns.

The Ethics Committee provides cover for Corrections Health Centres and Juvenile Health Centres statewide. The committee provides advisory support to the newly established Centre for Health Research in Criminal Justice.

For issues which will affect the security and order of Correctional Centres, the Commissioner is advised by the Department of Corrective Services Ethics Committee, which is unrelated to the Justice Health HREC.

For further information, contact:

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## **The Australian Clinical Trials Register.**

From the 1 July 2005, the International Committee of Medical Journal Editors (ICMJE) will not publish the result of any clinical trial that has not been registered with an authorised clinical trial registry.

The National Medical Health and Research Council have spent \$1.5 million to establish a register that will be compliant with the ICMJE requirements. The Australian Clinical Trials Register (the Registry) will be a national, on-line registry that holds

information on clinical trials conducted in Australia. The Registry will be established by the Clinical Trials Centre, which is located in Sydney.

The Registry will be phased in over the next three years with it being fully operational by 2008. Future plans will enable the Registry to link with the World Health Organisation registry to provide access to information on clinical trials worldwide. Although the functionality of the site will be limited in the first instance, trials will be able to be registered from the 1 July. Initially, registration will be by fax or online data entry. Further development of the Registry will be in consultation with stakeholders such as researchers and industry.

The Registry will make important information available to researchers, current clinical trial participants and potential participants. The Registry can reduce the duplication of research, provide a more complete record of research activity in Australia and provide reassurance to the public and research community that all clinical trials are registered and reported, including those with adverse outcomes.

The role of HRECs within the reporting requirements of the Registry is not yet clear. We will keep you updated with any further developments or opportunities for consultation.

Further information on the registry can be found at:

<http://www.nhmrc.gov.au/research/general/clincreg.htm>

## **Responsibilities of HRECs under the new Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes.**

The Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes has been published by the Australian Radiation Protection and Nuclear Safety Agency. The Code of Practice

ensures that participants who are exposed to ionising radiation for research purposes are given sufficient information to ensure informed consent. The Code of Practice also describes information that the HREC must have to adequately consider protocols involving ionising radiation.

As a result of the introduction of the Code of Practice, HRECs may have to amend their application forms to ensure compliance. The Health Ethics Branch will shortly be issuing advice on the implementation of the Code of Practice by HRECs.

The Code of Practice may be found at [www.arpana.gov.au/rps8.htm](http://www.arpana.gov.au/rps8.htm)

## **Health Research and Ethics Branch Project: Streamlining the Ethical and Scientific Review of Multi-centre Research**

The aim of the Research and Ethics Branch's project for streamlining the ethical and scientific review process is to establish a system of review which is effective, efficient and timely for all multi-centre research projects. The key principle underpinning the project is single ethical and scientific review. This means that each project will be scientifically and ethically reviewed only once within NSW Health, with that review being accepted by all other institutions where the research is to be conducted.

A Reference Group, convened by the Director-General and comprised of representations from HREC Chairs and Executive Officers, researchers, industry, government, Area Health Service officers and consumers, has met to consider the issues surrounding this project. In light of these discussions, Research and Ethics Branch has developed an Issues Paper titled "*Streamlining the Ethical Review of Multi-centre Research for NSW Health*" for information and comment.

This Paper outlines some of the main issues surrounding single ethical and scientific review, including research governance, quality of ethical and scientific review and indemnity and insurance. A copy of this Paper is available by contacting Ainsley Martlew, Senior Analyst or from our website: [www.health.nsw.gov.au/healthethics](http://www.health.nsw.gov.au/healthethics)

Following consultation on this Issues Paper, a detailed implementation strategy will be developed and presented at a series of targeted consultation forums to be held later in the year.

## **General Retention & Disposal Authority – Public Health Services: Administrative Records – GDA 21.**

This authority applies to administrative records relating to the provision of health care services currently maintained by public health organisations. The authority permits the destruction of certain records after appropriate minimum retention periods have been met, and identifies which records are required as State archives. HRECs should pay particular attention to Section 5.3.3 which covers records relating to the establishment and meetings of HRECs, and Sections 15.3.1, 15.3.2 and 15.3.3 which covers records relating to applications for the approval of clinical and non-clinical research.

This authority should be used in conjunction with other General Retention and Disposal Authorities issued by State Records including the General Retention and Disposal Authority – Public Health Services: Patient/Client records (GDA 17). It is located at:

[http://www.health.nsw.gov.au/policies/ib/2005/IB2005\\_027.html](http://www.health.nsw.gov.au/policies/ib/2005/IB2005_027.html)

## Standard clinical trial agreement

NSW Health is developing a standard clinical trial agreement with Medicines Australia. The idea behind the standard agreement is to develop one pro forma clinical trial agreement for use by industry, instead of every pharmaceutical company using its own form of agreement. This will save the Research Office from having to check clinical trial agreements where the standard is used, as they will know that the standard has been approved by the Department.

Other States and Territories are also part of this project, so it is hoped that the standard agreement will be implemented nationally. It is expected that the standard agreement will be available for comment by the end of this year. Time is required to achieve agreement by industry, the Department, and other States and Territories.

Enquiries: Lisa Eckstein, Ph: 9391 9861

## Registering your HREC with the National Health and Medical Research Council (NHMRC).

HRECs who have recently changed their name as a result of the Area Health Service amalgamations are reminded that this should be notified to the NHMRC. Likewise, new HRECs which result of a merger are also required to register their details with the NHMRC. Details on how to register can be found at:

<http://www.nhmrc.gov.au/ethics/human/hrecs/register.htm>

## Guidelines for end-of-life care and decision-making: rural seminar series.

NSW Health, in conjunction with the Mid-North Coast Division of General Practice, is holding the first of a series of rural seminars on end of life decision-making. This is to

complement the recent release of the Guidelines for end-of-life care & decision-making. This will be held on Wednesday 14 September at Southern Cross University, Coffs Harbour.

You may register by contacting Mid North Coast Division of General Practice on 6651 5774. For further information on this and future seminars may be obtained by contacting Research and Ethics Branch on 9391 9427. Closing date for registrations for Coffs Harbour is Wednesday 7th September 2005. Registration is free.

NSW Health will also hold this seminar in Wagga Wagga on 23 November 2005 and Bathurst on 3 March 2006.

### Important dates:

22 August 2004 – NSW Health Training Day: “Especially for Lay Members” (other HREC members welcome). Sessions on clinical trials, the history of research ethics, introduction to bioethics and dealing with bereaved relatives. Contact Lisa Eckstein for further details.

Friday 18 November 2005 - Annual Meeting of Chairs and Executive Officers, 2pm, Harbourside Hotel, North Sydney.

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