

# Health Ethics

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

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## This month in health ethics

### *Welcome to the last edition of Health Ethics News for 2004!*

The past few months have seen some changes to the Health Ethics Branch. We welcomed our newest member, Doukessa Lerias, in September. Doukessa is on secondment from St George Hospital where she provided executive support to the South Eastern Sydney, Southern Section HREC. Doukessa is the project officer responsible for the Shared Scientific Assessment Scheme and the Department of Health Ethics Committee.

### **Profile: NSW Department of Health Ethics Committee**

The NSW Department of Health Ethics Committee (DoHEC) was first established in November 1993 and was formerly known as the *State-wide Health and Confidentiality Ethics Committee*. In February 2000, the committee changed its name to the *NSW Department of Health Ethics Committee*. To date there are 14 members on the Committee, including a number of professional care and research experts, especially in the disciplines of epidemiology, population health, genetic counselling, rehabilitation and the legal profession. At least five members of the committee are direct employees of NSW Health. Nine of the committee are non-institutional members, and include lay people and other professionals not employed by NSW Health. Dr Garry Pearce was appointed as the Chairperson in February 2004. Dr Pearce is the Director of Occupational Health & Safety Centre, Concord Repatriation Hospital and is also the Chairperson of the Central Sydney Area Human Research Ethics Committee (Concord Zone).

The NSW Department of Health Ethics Committee (DoHEC) meets every six weeks for a total of seven meetings per year. The Committee reviews an average of 15 applications per year. The function of DoHEC is to assess proposals involving access to personal health information for research or other purposes that is owned, or held by the NSW Health Department and/or the NSW Ambulance Service. Research proposals reviewed by the Committee usually involve access to identifiable or potentially identifiable data held in data registers by NSW Health or, require the linkage of data obtained from the NSW Health or the NSW Ambulance Service data collections, with data from an external collection source. DoHEC accepts proposals from both internal

We also said farewell, temporarily, to Deborah Frew, Manager Health Ethics Branch. Deborah is on secondment for a period of 6 months to the Ministry for Science and Medical Research. During this time Julie Letts will be Acting Manager for the Branch.

The Branch has also been busy preparing for our Annual Meeting of HREC Chairs and Executive Officers, which was held last month. This meeting is reported on elsewhere in this newsletter. As this is the last edition of *Health Ethics News* for the year 2004, Health Ethics Branch would like to wish all a happy and safe Christmas and holiday period.

investigators (i.e. from departments within NSW Health) and external investigators (e.g. universities, interstate and commonwealth agencies). The most pressing issues that DoHEC works with in its assessment of such proposals is that of privacy, confidentiality and data storage.

For further information, contact:

Doukessa Lerias  
Project Officer  
Ph: 9391 9861  
Email: [dleri@doh.health.nsw.gov.au](mailto:dleri@doh.health.nsw.gov.au)

### **The future of the NSW Health Pilot Shared Scientific Assessment Scheme – final evaluation**

The results of the final evaluation of the Shared Scientific Assessment Scheme (SSAS) have now been finalised. The purpose of the evaluation was to determine whether the SSAS met its objectives and to make recommendations on whether the SSAS should continue beyond the term of the pilot.

The evaluation consisted of a retrospective study of the review of multi-centre clinical trials by eight NSW Health HRECs between July and December 2002, conducted by Professor Colin Thomson (of Houston Thomson Pty Ltd) and a prospective study of the operations of the pilot conducted by Ms Davina Gherzi (of the National Health and Medical Research Council's Clinical Trials Centre).

The results indicated that the SSAS was generally successful in meeting its objectives. The majority of HRECs and applicants who participated in the prospective study thought that the SSAS should continue. The SSAS was effective in reducing the workload of HRECs where the final report produced by the SSAC replaced the HRECs' own scientific review. Some

improvement could be made to the timeliness of the SSAS, particularly if HREC meeting times could be aligned with SSAS meeting times.

The cost of operating the SSAS was sustainable during the course of the pilot although the workload of the SSAC members and expert reviewers requires monitoring to determine whether the workload would remain at acceptable levels. The SSAS was under-utilised during the term of the pilot. The number of trials submitted did not reach the target number of trials expected. Further promotion of the SSAS with industry and researchers is required to encourage its use and criteria, which determine the types of trials eligible for the SSAS, should be amended to further enhance utilisation.

Recommendations from the final evaluation include expanding the type of trials eligible to those clinical drug trials yet to be reviewed by 2 or more NSW Health HRECs, improving timeliness and undertaking further promotion to enhance utilisation. The final evaluation also notes that SSAS must be integrated with further efforts to streamline the review of multi-centre research and that work commence on a co-ordinated national approach.

Health Ethics Branch will discuss changes to the scheme with HRECs at our planned site visits, in early 2005. The report on the final evaluation of the Scheme will be distributed to HRECs shortly, however the recommendations from this report will not commence until 2005. An Industry Forum will be held on the 15<sup>th</sup> December 2004, inviting all researchers and members of the pharmaceutical industry to discuss the planned changes that will be made to the scheme.

For further information, contact:

Doukessa Lerias  
Project Officer  
Ph: 9391 9861  
Email: [dleri@doh.health.nsw.gov.au](mailto:dleri@doh.health.nsw.gov.au)

### **Standard compensation clause for Patient Information Sheets**

Many of you have expressed concern regarding a trend to include inadequate or misleading statements in Patient Information Sheets pertaining to compensation for injury as a result of participating in a clinical trial. Health Ethics Branch has therefore developed a model compensation clause, which may be used by HRECs as a basis on which to examine similar clauses, and to provide guidance for those developing Patient Information Sheets. An Information Bulletin containing this clause will be circulated by the end of the year.

For further information, contact:

Ainsley Martlew  
A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

### **National forum on multi-centre research**

NSW Health (in cooperation with the Ministry for Science and Medical Research and the NHMRC) has initiated a meeting with representatives from all state and territory health departments,

and AHEC, to discuss the issue of the review of multi-centre research. This meeting will be held in February 2005.

The objective of this inaugural meeting is to provide a forum for discussion on a nationally consistent means of streamlining the review of multi-centre research. It is anticipated that a standing committee will be established to co-ordinate approaches between jurisdictions and to discuss common issues in research ethics.

For further information, contact:

Ainsley Martlew  
A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

### **Quality assurance/accreditation model**

The need for a mechanism to measure the quality of HREC review is widely recognised and is part of AHEC's agenda for this triennium. NSW Health is developing a pilot model of quality improvement for HRECs. This will, for the first time, enable HRECs to possess a quality tool by which they are able to assess their own performance. If successful, it is anticipated that this tool will be used as a basis on which to develop a model of quality accreditation for HRECs.

Health Ethics Branch anticipates that a quality assurance model will be developed early next year, for piloting with a small number of HRECs. Watch this space for further developments.

For further information, contact:

Ainsley Martlew  
A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

### **Standard operations manual**

The Branch is developing a standard operational procedures manual for HRECs and Executive Officers. The objective of this manual is to contribute to the effective functioning of HRECs by standardising administrative procedures and therefore ensuring a consistency of practice. It will also help minimise duplication of effort for HRECs, Executive Officers, and for those making applications to HRECs.

The existence of acceptable written working practices and procedures goes a considerable way to evidencing that an HREC has acted reasonably in evaluating and reaching an opinion upon an application for ethical approval. It is intended that HRECs will use the manual as a basis upon which to develop their own specific written procedures.

The standard operations manual will be available by the end of the year.

For further information, contact:

Ainsley Martlew  
A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

### **Annual Meeting report**

Health Ethics Branch held its 2<sup>nd</sup> Annual Meeting of HREC Chairs and Executive Officers on 29 October at the Harbourview

Hotel, North Sydney. There were 51 attendees in total with most HRECs sending at least one representative. Representation also included members from the university sector.

The meeting provided an overview of the year that was for research ethics, and informed HRECs of the projects on our agenda for the coming 12 months. These projects include work on standard documentation and clinical trial agreements, a model of quality assurance for HRECs, interstate consultation on multi-centre research, expansion of the Shared Scientific Assessment Scheme, and policy work on issues such as fees, conflicts of interest and insurance and indemnity.

Deborah Frew ran an instructive session on insurance and indemnity. Francine Kelly, Assistant Director, Health Ethics Section, NHMRC, also advised on the progress of the National Application Form. A feature of the afternoon was the evaluation of the Shared Scientific Assessment Scheme and its future, and attendees were able to engage in open discussions with Health Ethics Branch about this initiative. The Scheme is mentioned in detail elsewhere in this newsletter.

The meeting also afforded HREC Chairs and Executive Officers the opportunity to provide feedback to the Branch on their training and education needs for the coming year. Training and development needs identified included:

- Adverse events – monitoring of, and reporting.
- Privacy – additional training.
- Monitoring.
- Communication across HRECs.
- Access to drugs post trial.
- The extent to which HREC deliberations should be available to the public.
- Co-ordination with the university sector.
- Application of Human Tissue legislation.
- Education and training of HREC members.
- Review of student projects.
- Periodic training day of National Statement
- Training specifically for Chairs and Executive Officers

The Branch will keep these topics in mind when developing our training schedule for 2005.

The meeting also gave HRECs and Executive Officers the opportunity to provide feedback to the Branch on our performance. On average, attendees rated the provision of advice and support, and the overall performance of the Health Ethics Branch as 9 out of 10. Respondents were very satisfied with our training and education program, and our policy development.

Some particular comments included:

*“Site visits would be great”*

*“FAQs on web page”*

*“You are doing a great job so just keep doing more of the same”*

*“Very large emphasis on clinical ethics – not enough on behavioural, epidemiological or public health research”*

*“The provision of workshops/annual meetings has been an excellent opportunity for networking”*

*“Have been a visitor to several committees – great idea”*

*“Meeting face-to-face with other Executive Officers makes me feel less isolated, good to know that others are grappling with similar issues”*

*“Good attempts, but ethics committees are ethics committees”*

*“Excellent innovation – please continue”*

*“Thanks to Greg Stewart for his vision”*

*“HREC members found the training and the networking beneficial”*

*“The Health Ethics Branch is wonderful – the best thing that’s happened to HRECs ever!”*

The Branch is grateful for the feedback provided. We are especially pleased to hear that HRECs have found our initiatives to be worthwhile.

Copies of presentations from the meeting are available by contacting:

Ainsley Martlew  
A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

### **Suggested reading**

The following editorial is recommended to HREC members:

**Clinical trial registration: A statement from the international committee of medical journal editors.** *The New England Journal of Medicine* 2004; 351: 12.

This editorial focuses on the issue of clinical trial registration, and identifies a number of possible reasons for registering all clinical trials, including:

- Improved transparency on the reporting and performance of clinical trials.
- Enhanced public confidence.
- The importance of having access to all clinical information necessary to inform health care decisions.

The International Committee of Medical Journal Editors (ICMJE) has indicated that all eleven-member journals will require, as a condition of consideration for publication, registration of clinical trials in a public trials registry. This policy will apply to any clinical trial starting enrolment after July 1 2005.

Health Ethics Branch is unaware of the existence of a comprehensive public clinical trials registry in Australia. Nevertheless, HRECs may wish to forward this article to researchers for their information. The Branch is watching this issue closely and will advise on any updates as they arise.

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A/Senior Analyst, Research Ethics  
Ph: 9391 9292  
Email: [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)

**New policy for living kidney donation in NSW**

NSW Health has released a new policy that for the first time formalises requirements and considerations for living kidney donation in NSW. In NSW, a living donation of a kidney has until now, only been permitted where it is "directed", that is the donor agrees to donate their kidney for transplantation to an identified recipient, usually a spouse or partner, family member or close friend - a common and long established practice in NSW.

In particular, the policy addresses what provisions should be made for assessing the suitability of living donors. This includes the need for adequate assessment of donors to ensure that their decision is voluntary, free of undue influence and fully informed. The policy reaffirms that the Human Tissue Act prohibits the sale of organs, or payment of money in return for organ donation.

Since March this year, NSW Health has sought community views and the opinion of health professionals on whether "non-directed" kidney donation should be practised in this State. Non-directed donation kidney donation refers to where a living donor wishes to donate a kidney to any suitable stranger on the waiting list. This is already practised in some other Australian States and overseas.

The consultation process and resulting policy support non-directed kidney donation. Special procedures apply to those wishing to become non-directed kidney donors.

A discussion paper outlining some of the ethical and clinical issues involved in living kidney donation is available on the NSW Health website at:

[http://www.health.nsw.gov.au/pubs/2004/living\\_kidney.html](http://www.health.nsw.gov.au/pubs/2004/living_kidney.html)

The policy is available as circular 2004/70 on the NSW health intranet at:

<http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/2004/cir2004-70.pdf>

For further information, contact:

Julie Letts  
Acting Manager, Health Ethics Branch  
Ph: 9391 9751  
Email: [jlett@doh.health.nsw.gov.au](mailto:jlett@doh.health.nsw.gov.au)

**A reminder about important dates**

Below are dates of events, seminars and conferences in 2004-2005.

<b>Saturday 5 December 2004 to Thursday 9 December</b>	Intensive Research Ethics Course. Centre for the Study of Ethics in Medicine and Society (Monash Medical School, Alfred Hospital)	Portsea, Victoria. For more information, email <a href="mailto:ethics.centre@med.monash.edu.au">ethics.centre@med.monash.edu.au</a>
<b>Wed 15 December 2004</b>	SSAS Industry Forum	North Sydney. For more information, please contact Doukessa Lerias, Project Officer, Health Ethics Branch <a href="mailto:dleri@doh.health.nsw.gov.au">dleri@doh.health.nsw.gov.au</a>
<b>Thursday 12 May 2005 to Friday 13 May</b>	NHMRC Ethics in Human Research Conference 2005	Canberra. For more information, visit the website at <a href="http://www.communicationlink.com.au/ethics/main.aspx">http://www.communicationlink.com.au/ethics/main.aspx</a>

**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**

**Julie Letts** Acting Manager, Health Ethics  
Tel (02) 9391 9751 email [jlett@doh.health.nsw.gov.au](mailto:jlett@doh.health.nsw.gov.au)  
**Ainsley Martlew** A/Senior Analyst, Research Ethics  
Tel (02) 9391 9292 email [amart@doh.health.nsw.gov.au](mailto:amart@doh.health.nsw.gov.au)  
**Doukessa Lerias**, Project Officer  
Tel (02) 9391 9861 email [dleri@doh.health.nsw.gov.au](mailto:dleri@doh.health.nsw.gov.au)