

Health Ethics

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

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This month in health ethics

Welcome to a new edition of Health Ethics News

It has been some time since our last newsletter, but having overcome a rather busy 2005/06, we hope to produce Health Ethics News again on a regular quarterly basis.

This edition includes a profile of the Justice Health HREC that was submitted to us some time ago. We thank Justice Health HREC for their patience in finally seeing their profile published! The Justice Health HREC has expertise in a number of specialised areas, and is particularly familiar with reviewing research that may expose criminal activity – which can be a vexed issue, especially for HRECs that are not familiar with the law in this area. As an adjunct to this profile, an article appears later in the newsletter about the provisions of the NSW Crimes Act and protection for researchers who may learn about the commission of crimes in the course of undertaking their research.

In research ethics, the major focus since the last newsletter has been on streamlining ethical and scientific review of multi-centre research.

The Branch has also been carefully following the incident in the UK where several healthy volunteers in a Phase I clinical trial were admitted to intensive care after suffering a serious and unexpected adverse event. We are working on ways to ensure that clinical trials undertaken in NSW Health remain safe for participants and, to this end, strengthening our mechanisms of scientific review. Articles on these projects appear in this edition.

In relation to clinical ethics, The Department has recently released Policy Directive PH 2006_027 "Clinical Ethics Processes in NSW Health". A short summary of that policy appears in this edition.

If you would like any further information about any of the items in this edition of Health Ethics News, please contact the officer from the Health Research and Ethics Branch mentioned at the end of the article.

Deborah Frew
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Profile: Justice Health Human Research and Ethics Committee

The Justice Health¹ 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.

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:

¹ Corrections Health Service became Justice Health on 1 July 2004.

- 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.

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Researcher's responsibility regarding committal of serious offences

Fundamental to ethical conduct of research is the confidentiality of information obtained in the course of such research. However, where researchers acquire knowledge that a serious offence has been committed, a real or perceived conflict may result between this principle of confidentiality and reporting obligations under the criminal law.

Section 316 of the Crimes Act 1900 (NSW) requires that, if a person has committed a serious indictable offence and another person knows or believes that the offence has been committed that person should bring that information to the attention of the police or another appropriate authority. Failure to do so is itself an offence. A "serious" indictable offence means one which is punishable by imprisonment for life or for a term of 5 years or more. Questions often arise regarding research where the investigator may inadvertently discover that a participant has committed such an offence.

These are two important points to remember when considering this issue. First, the section only applies to serious indictable offences, not to any illegal activity. Second, researchers are given some protection from this provision through Section 316(4) of the Act, which prevents a prosecution for an offence being commenced against a person without the approval of the Attorney-General if the knowledge or belief that an offence has been committed was formed in the course of practising or following specific

professions, which include 'researcher for professional or academic purposes'. This protection is not absolute; the possibility of prosecution of researchers still exists where the Attorney approves such a prosecution. However, the requirement for the Attorney's approval for any such prosecution is designed to ensure that proceedings against these persons not be commenced without proper consideration of all issues.

Review of the NHMRC National Statement on Ethical Conduct in Research Involving Humans (1999)

The NHMRC, the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC) are conducting a joint review of the National Statement. The revised document, titled the National Statement on Ethical Conduct in Human Research, has now undergone two rounds of public consultation, the second round concluding on 31 March 2006. The first consultation generated 178 submissions, while the second round generated 183 submissions. Of the 183 submitters, 148 have given permission for their submissions to be placed on the NHMRC website.

Health Research and Ethics Branch's submission on the review relates to the following main points:

- The need for enhanced regulation of Phase I clinical trials and for specific guidance surrounding their scientific review.
- Issues surrounding a new provision which stipulates that where an HREC waives the requirement for consent, the institution should make the details of the decision publicly available.
- Clarification surrounding the chapter on databanks, including the ethical issues associated with their establishment and access.
- Issues associated with the chapter on research involving children and young people. In particular, the provision in the draft which allows for "standing parental consent" to override a child's objection to participate in research.

The full text of this submission is available on the NHMRC website. It is expected that the revised National Statement will be issued in December 2006.

The second consultation draft is available on the NHMRC's website at <http://www.nhmrc.gov.au/consult/index.htm>

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Review of the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997)

The NHMRC, together with the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC) are conducting a joint review of the NHMRC/AVCC Statement and Guidelines on Research Practice. The second stage of public consultation on this document, known as the Australian Code for Conducting Research, has now closed. The consultation draft establishes a number of general principles of responsible research conduct, while providing detailed guidance on such matters as records management, authorship, publication and dissemination of research findings, conflicts of interest and peer review. The draft also establishes specific procedures for handling allegations of research misconduct and outlines the relative roles and responsibilities of researchers, institutions and their staff.

Health Research and Ethics Branch has made a submission to this review. The main points raised in the submission relate to the following issues:

- The need for the proper financial management of research funds to be included as a principle of responsible research conduct.
- The need for guidance surrounding relationships involving researchers and institutions with the commercial sector.
- Issues surrounding the proposed procedure for institutional handling of allegations of research misconduct.

A copy of the Branch's submission is available on request by contacting Varnu Tata, Project Support Officer, Health Research and Ethics Branch on (02) 9391 9427 or vtata@doh.health.nsw.gov.au. More information on this review is available from the NHMRC website: <http://www.nhmrc.gov.au/funding/policy/code.htm>

The Royal Australasian College of Physicians Guidelines for ethical relationships between physicians and industry, third edition (2006)

Relationships between clinicians and industry have become progressively more complex, particularly within the research environment. In recognition of this growing complexity and of the need for clinicians and institutions to be able to recognise and appropriately manage potential dualities of interest, the Royal Australasian College of Physicians has released its Guidelines for ethical relationships between physicians and industry, third edition 2006. The guidelines acknowledge that while health care professionals are increasingly required to work closely with industry in a variety of situations, such as when conducting research, when providing health care and in education and training, they need to be aware of how to manage these relationships in an ethical manner.

The guidelines, while advisory in nature, provide a number of recommendations for individual clinicians and

organisations in relation to the various clinical and medical research settings. Particular guidance is provided on topics such as: payments to investigators, institutions and research participants; the publication of research findings; dualities of interest involving researchers with a pecuniary interest in the conduct of research; considerations specific to industry sponsored clinical trials; responsibilities of clinicians as members of ethics committees; and clinicians involved in the recruitment of their own patients.

The full text of the guidelines is available at:

http://www.racp.edu.au/public/Ethical_guide_industry.pdf

Australian Health Ministers' Advisory Council Working Group on A Streamlined National Approach to Ethical and Scientific Review of Multi-centre Research

In response to the well-recognised need for reform of Australia's current system of ethical review of multi-centre research, the Australian Health Ministers' Advisory Council (AHMAC) has convened a working group to examine this issue. The remit of the Working Group is to assess the current arrangements for the review of multi-centre research, to develop options for a nationally co-ordinated system for single ethical and scientific review of health and medical research, and to present a proposal to AHMAC identifying ways forward for achieving this. The Working Group is chaired by NSW Health and includes representation from all states and territories.

The Working Group has engaged a consultant to undertake the substantive work involved in preparing the report. Specifically, the consultant will be required to:

- Identify options for developing a streamlined national system of single ethical and scientific review.
- Consider the feasibility, advantages and disadvantages of each option/model based upon considerations of effectiveness, cost, practicality and speed with which the model can be achieved.
- Recommend the most appropriate option/model.
- Make recommendations regarding the system requirements and potential barriers to the successful functioning of such a model.
- Make recommendations regarding the issues which would require future attention, including the integration of research in fields other than health and medicine.

The Working Group is to be cognisant of the initiatives currently being progressed by individual jurisdictions to streamline the review of multi-centre research. However, options should be canvassed for ways of co-ordinating these so that each research project is scientifically and ethically reviewed only once within Australia.

It is expected that the full report will be presented to AHMAC by the end of 2006. For more information on the progress of the Working Group, please contact the Secretariat, Ms Ainsley Martlew, Senior Analyst, Health

Research and Ethics Branch on (02) 9391 9292 or amart@doh.health.nsw.gov.au.

NSW Health Model for Single Ethical Review of Multi-centre Research

Readers will be aware that Research and Ethics Branch has been steadily working on its major project, the single review of multi-centre research, for quite some time. This project aims to allow for every research project being conducted within the NSW public health system, to be ethically and scientifically reviewed once only.

In the twelve months since the NSW Health Reference Group on Ethical Review of Multi-centre Research first met, much has been achieved behind the scenes. Here's a quick look at what has occurred so far:

- May through April 2005: NSW Health Reference Group meets on three occasions to advise on the issues associated with implementing a model of single ethical and scientific review.
- July 2005: Issues Paper circulated, outlining the proposed model and seeking feedback on a number of key issues.
- August through December 2005: Model is refined based on feedback received. Further consultation with stakeholders. A retrospective study of research projects submitted to NSW Health HRECs is conducted.
- January through February 2006: NSW Health, in conjunction with the NSW Ministry for Science and Medical Research and the Cancer Institute NSW, hosts a series of consultation forums. The forums were attended by 230 attendees and videoconferenced to rural sites.
- April 2006: NSW Health Reference Group meets and endorses the model for implementation.

Research and Ethics Branch is now finalising the details of model to be implemented in 2007. Watch the Health Research and Ethics Branch Website for details:

www.health.nsw.gov.au/healthethics

NHMRC National Ethics Application Form (NEAF)

The National Health and Medical Research Council (NHMRC) has recently released its on-line HREC application form, known as the National Ethics Application Form or "NEAF". NEAF is a web-based tool which enables researchers from all disciplines to submit applications for research proposals to HRECs, using the one application form. The form contains links to relevant guidelines, legislation, reference material and help in answering the questions. Once completed, NEAF can be saved in either PDF, CSV or XML formats, thereby allowing HRECs the opportunity to directly import the data into their research management system.

The series of questions contained in NEAF have been designed to provide HRECs with the information necessary to allow them to make a decision on the ethical acceptability of any given research proposal. The form facilitates the single ethical review of multi-centre research by encouraging a consistent approach towards the information HRECs regularly require researchers to provide in their submissions.

In June 2006, the NHMRC hosted a workshop for NSW Health HREC Chairs and Executive Officers, which allowed participants to experience first-hand the wide-ranging functionality of NEAF. Overwhelmingly, participants expressed their support for NEAF and Research and Ethics Branch is encouraging all NSW Health HRECs to accept research proposals which are submitted using NEAF.

NEAF is now available on-line at:

www.neaf.gov.au

New policy: Clinical Ethics Processes in NSW Health

Research and Ethics Branch has developed policy that provides new guidance to Public Health Organisations (PHOs) in relation to mechanisms by which clinical ethics issues can be addressed in the NSW health system. One of these mechanisms is through referral of issues to the NSW Health Clinical Ethics Advisory Panel. This panel, comprising experts in ethics, law, clinical practice, health administration, consumer and community interests, is well positioned to consider significant ethical issues arising in clinical practice. The policy discusses when, and how referral of issues by PHOs can be done.

Another mechanism by which Area Health Services may address clinical ethics issues is through clinical ethics committees. The policy provides advice as to how such committees should be established and managed, including membership and reporting requirements, and detailed advice about provision of clinical ethics consultation in individual patient cases. The latter has been informed by the results of stakeholder responses to a discussion paper released by Research and Ethics Branch in 2003 titled Improving Clinical Ethics Support: A discussion paper for NSW.

Release of this policy is an initial step forward in providing appropriate support for health professionals and others in dealing with the host of ethical issues that arise in clinical practice. Research and Ethics Branch will be meeting with Area representatives in the near future to discuss this policy and related matters.

Clinical Ethics Processes in NSW Health was released in May 2006 and can be found on the NSW Health website at http://www.health.nsw.gov.au/policies/pd/2006/pdf/PD2006_027.pdf

Any queries should be directed to Julie Letts, Principal Policy Analyst (Clinical Ethics) on 9391 9465 or jlett@doh.health.nsw.gov.au

Standard Clinical Trial Agreement Update

The Health Research and Ethics Branch, in collaboration with Medicines Australia, are developing a standard clinical trial agreement for commercially sponsored clinical trials. Once this standard has been released, those clinical trial agreements that use the pro forma will not need to undergo additional review by research offices or risk managers. There has been close liaison with other States and Territories, and it is anticipated that the standard agreement will be implemented at a national level.

A roundtable was convened between some of the States (including NSW), their lawyers, and Medicines Australia on 30 June 2006 to resolve outstanding issues on the draft agreement.

It is expected that the standard clinical trial agreement will be released later this year.

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Standards for Scientific Review

The widely publicised adverse reactions of six Parexel clinical trial participants in the United Kingdom has highlighted the need for robust processes for the scientific review of research proposals. NSW Health is considering ways to improve the current systems of scientific review for both clinical and non-clinical research projects. Under consideration is the development of standards for scientific review, to be met by all NSW Health HRECs.

The role of the Shared Scientific Assessment Scheme is also under review, in anticipation of the introduction of single ethical review for multi-centre research projects. Health Research and Ethics Branch is considering mechanisms to help HRECs that have difficulty sourcing scientific expertise to undertake appropriate scientific reviews, especially in relation to clinical trials.

Draft standards for scientific review and more details on the review of SSAS will be released shortly.

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RECOMMENDED READING

The Health Report on ABC Radio National, presented by Dr Norman Swan – Monday 10 July 2006

The topic of a recent Health Report is one which Human Research Ethics Committees have become all too familiar with: the use of personal health information for research purposes. The Report examines a number of complex issues confronting HRECs, including the balance between upholding a participant's right to privacy versus the public interest in the research, as well as the role of an ethics committee in balancing the protection of research participants' rights versus the protection of institutional interests. The Report also questions the adequacy of ethics committee procedures for handling complaints from research participants.

The transcript of the report is available at:

<http://www.abc.net.au/rn/healthreport/stories/2006/1680645.htm#transcript>

Lay Concepts In Informed Consent To Biomedical Research: The Capacity To Understand And Appreciate Risk. A. Iltis. Bioethics 2006, 20: 180-190.

This article examines the notion of valid informed consent in the context of biomedical research and discusses the requirement to disclose information regarding potential risks in light of a participant's capacity to understand those risks. The author argues that the capacity to understand and interpret the concept of risk is limited and that this may depend, in part, upon the way in which those risks are explained. The author concludes that there may be some circumstances under which an ethics committee should require potential participants to possess a greater than typical capacity to understand risk.

Don't Blame The 'Bio' – Blame The 'Ethics': Varieties Of (Bio)ethics And The Challenge Of Pluralism. M. Charlesworth. Journal of Bioethical Inquiry, 2: 10-17.

This article seeks to examine ethical reasoning in the context of a pluralist society. An overview of divergent ethical theories is provided, from 'virtue ethics' to 'Kantian ethics', followed by discussion of the challenge of ethical pluralism in liberal societies.

Editorial: Preventing And Processing Research Misconduct: A New Australian Code For Responsible Research. M B. Van Der Weyden. Medical Journal of Australia, 184 (9): 430-431.

In this editorial, the newly released second consultation draft of the National Health and Medical Research Council's Australian Code for the Responsible Conduct of Research is scrutinised. While welcoming many of the Code's requirements, the editorial calls for the accreditation of research institutions and the establishment of a national oversighting body for managing research misconduct. This, it is argued, may go some way towards ensuring research

institutions comply with the Code and engage in responsible and ethical research conduct.

IMPORTANT DATES

Friday 22 September 2006 – NSW Health Training Day: “Especially for new HREC 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. Contact Varnu Tata for more details

Wednesday 18 October 2006 – HREC Annual Meeting for Chairs and Executive Officers to be held at the Royal Australasian College of Physicians, 145 Macquarie Street Sydney.

Sunday 3 December to Thursday 7 December 2006 – Monash Centre for Ethics in Medicine and Society Intensive Research Ethics Course, Bellinzona. For further information, contact:

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Online registration and payment are available from this website:

<http://workshops.med.monash.edu.au/>

Course programs, venue, location and travel directions are available on this website:

<http://conferences.grangecc.com.au/1122>

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