



HUMAN RESEARCH ETHICS COMMITTEE

Professor John McNeil AM
Chair, The Alfred Ethics Committee

Ethics Committee

Applications

The Ethics Committee received 400 research projects for review in 2010. Of these, 98 were health and social sciences applications, 115 drugs and interventions applications and 187 'low risk' applications, which pose such little risk to participants that they do not need to be reviewed by the full Ethics Committee.

Streamlined Review

Eighteen applications were submitted to the Ethics Committee for review under the new Victorian Government Streamlined Ethical Review Program (SERP). Nineteen SERP projects to be conducted at Alfred Health and reviewed by another certified human research ethics committee (HREC) were authorised for commencement at The Alfred. SERP was developed with the expectation that the time for ethics approval will be reduced and research will commence more quickly than under the previous system where applications were reviewed by the HREC of each study site.

HoMER

The committee also took part in a trust building pilot for the NHMRC's national initiative to streamline the ethical review of multicentre research – HoMER (Harmonisation of Multicentre Ethical Review). The pilot was designed to demonstrate the potential for a single review process, and to encourage confidence in the review of other HRECs. This HREC participated both as a 'reviewing' and an 'accepting' site. HRECs wanting to be part of HoMER will undergo certification to provide a single ethical review for research that may be conducted in different states of Australia.

First-time-in-human Applications

Eight first-time-in-human applications were reviewed and included:

- a new drug to stimulate neutrophil production, which may shorten the duration and reduce the severity of neutropenia after chemotherapy
- a new drug to treat secondary hyperparathyroidism (excessive secretion of parathyroid hormone) in patients who have chronic kidney failure
- an experimental compound being investigated for its potential to regulate airway smooth muscle, which may help in the treatment of patients with asthma
- a new protein developed to treat sensitivity to cat allergens

General Ethical Issues Sub-committee

The General Ethical Issues Sub-Committee (GEI S-C) provides a forum within Alfred Health for the discussion of a wide range of ethical issues: internal matters relating to human research and health care more generally, as well as externally initiated enquiries such as government reviews. The sub-committee met ten times in 2010.

Ethical Issues in Human Research

Research that potentially involves legal risks for participants and researchers

Research that intends, or is likely, to collect information about someone's involvement in illegal activities needs to be designed and conducted with the associated risks in mind. Guidelines were developed in consultation with a range of stakeholders including ethics committee members, researchers from Alfred Health and the Burnet Institute, and Alfred Health legal counsel.

www.alfredresearch.org/ethics/ecguidelines.htm

Accurate information for research participants

A cornerstone of ethical research is informed consent, and participants need clear and accurate information to make an informed decision. The wording in the standard Participant Information and Consent Form templates is periodically reviewed and updated, in step with changing community standards, institutional requirements, laws, etc. In 2010, the sub-committee focused on the clauses describing: (a) compensation for injury sustained through research participation (b) limitations to the confidentiality of participants' information. Both relevant clauses have been revised, trialled and implemented.

Other research-related issues included:

- Research conducted in private practice settings
- Witnessing a person's consent to participate in research – what is required?
- Informing GPs about their patients' participation in research
- Evaluating research projects involving complementary and alternative medicines
- Intellectual property and student researchers

Wider Institutional Ethical Issues

- Educational/promotional activities conducted by pharmaceutical companies which involve the collection of hospital information
- Clinical ethics services and the service at Alfred Health

Public Consultations

Victorian Law Reform Commission's Enquiry into the Guardianship and Administration Act 1986

The Guardianship and Administration Act provides for medical research to be undertaken with adult participants who are unable to give informed consent because of a temporary or long term impairment. However, the Act's research provisions can make certain kinds of research difficult to undertake. The GEI S-C made a submission to the VLRC Enquiry in 2010 and has been closely involved in the subsequent consultation process.

Other public enquiries included:

- NHMRC/AHEC – development of a draft Process Chart to identify quality assurance activities requiring ethical review (submission made)
- Department of Health review of the Mental Health Act 1988 (no submission made)

HREC MEMBERSHIP

Ethics Committee

Professor John McNeil (Chair)
Professor Colin Johnston (Deputy Chair, Drugs and Interventions Group; member with knowledge of relevant research areas)
Roy Olliff (Chair, Health and Social Science Group)
Professor Mari Botti (Deputy Chair, Health and Social Science Group; nursing representative)
Dr Sharon Avery (member with knowledge of professional care and treatment – from February 2011)
Emily Bingle (laywoman – to December 2010)
Elizabeth Burns (laywoman)
Dr Catherine Cherry (member with knowledge of professional care and treatment)
Simon Cohen (lawyer)
Brad Crammond (member with knowledge of relevant research areas – to December 2010)
Dr Peter Douglas (layman; member with experience in analysing ethical decision-making – from January 2011)
Dr Judith Frayne (member with knowledge of professional care and treatment)
Peter Gallagher (layman)
Samantha Gault (laywoman)
A/Professor Richard Gerraty (member with knowledge of relevant research areas)
Reverend Sam Goodes (minister of religion)
Linton Harriss (member with knowledge of relevant research areas)
Reverend Marilyn Hope (minister of religion)
Linda Hornsey (laywoman)
A/Professor David Hunt (member with knowledge of relevant research areas)
A/Professor Peter Hunter (member with knowledge of relevant research areas – from August 2010)
Dr Michael Hurley (member with knowledge of professional care and treatment)
Professor Henry Krum (member with knowledge of relevant research areas)
Jim Mahoney (lawyer)
Maria McKenzie (member with knowledge of relevant research areas)
Stephen Moloney (lawyer)
Fr Ian Morrison (minister of religion)
Linda Murdoch (lawyer – from February 2011)
Shefton Parker (member with knowledge of relevant research areas)
Dr James Shaw (member with knowledge of relevant research areas)
Dr Michael Ward (member with knowledge of professional care and treatment – from November 2010)
Michael Wildenauer (layman)
Dr Fran Wise (Caulfield Hospital representative; member with knowledge of professional care and treatment – to May 2010)
David Zarfaty (layman)
Paul Zawa (lawyer – to December 2010)
Rowan Frew (Secretary)
Dr Angela Henjak (Assistant to Secretary – Drugs and Interventions Group)
Nicole Rosenow (Assistant to Secretary – Drugs and Interventions Group)
Kordula Dunscombe (Secretary – Health and Social Science Group)
Anna Parker (Secretary – Health and Social Science Group)
Tracey Scheller (Ethics Officer – Low Risk applications, Progress Reporting)

General Ethical Issues Sub-committee

Professor John McNeil (Chair)
Professor Paul Komesaroff (Deputy Chair)
Dr Susannah Ahern (Medical Administration representative – to November 2010)
Marta Ago
Dr Tracey Caulfield (to September 2010)
Simon Cohen
Brad Crammond (to December 2010)
Reverend Marilyn Hope
A/Professor Peter Hunter (Caulfield Hospital representative – from April 2010)
Peter Gallagher
Dr Cate Kelly (Medical Administration representative – from February 2011)
Dr Phoebe Mainland
Dr Roderick McRae
Elizabeth Mullaly (Caulfield Hospital representative)
Janine Roney
Professor Alison Street (to February 2011)
Dr Tim Sutton (to July 2010)
Professor John Wilson
Michelle Wright
Kordula Dunscombe (Secretary)
Rowan Frew (Ethics Manager)

Research Review Committee

Professor Colin Johnston (Chair)
Dr Sharon Avery
Dr Catherine Cherry
Dr Andrew Davies
Dr Amanda Davis
Dr Judith Frayne
A/Professor Richard Gerraty
Dr Andrew Haydon
Dr William Kemp
Professor Henry Krum
Anne Mak
Professor John McNeil
Dr James Shaw
Dr Alan Young (to August 2010)
Rowan Frew (Secretary)
Dr Angela Henjak (Assistant to Secretary)
Nicole Rosenow (Assistant to Secretary)

Low Risk Sub-committee

Maria McKenzie (Chair)
The low risk process was changed at the start of 2010 to an out-of-session process involving review by individual Ethics Committee members overseen by the Chair and without meetings or a sub-committee.

