

Alfred Ethics Committee Newsletter

April 2010

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Welcome to this special edition of the Alfred Ethics Committee Newsletter. We are often asked about the workings of the General Ethical Issues Sub-Committee (GEI S-C). In this issue we attempt to provide an overview of the GEI S-C and answer your questions.

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What is the GEI S-C?

Purpose

The purpose of the GEI is to identify and consider ethical matters relevant to Alfred Health and the wider community, and provide information and/or guidance on key issues. Monthly meetings are held to keep abreast of issues that are constantly arising with the emergence of new diseases, medical and scientific technologies and changes in community attitudes.

The GEI S-C also provides a forum for discussion of ethical matters relating to patient care from the points of view of both the patient and those providing care. The main Ethics Committee is focussed primarily on reviewing the ethical aspects of specific research applications, while the GEI S-C's brief is broader than this. The GEI S-C considers matters of human research ethics policy or guidance and research-related issues on behalf of the main Ethics Committee.

Reporting and dissemination of information

The GEI S-C reports to the main Ethics Committee (of which it is a sub-committee) and to the Alfred Health executive as part of the Ethics Committee report. GEI S-C activities are also reported to the Alfred Health Board and the AMREP Council.

Decisions and information resulting from GEI S-C meetings are disseminated via various means, such as reports and submissions, the Research and Ethics website, the Ethics Newsletter and the Weekly Information Pack.

What does the GEI S-C aim to achieve?

The key aims of the GEI S-C are to:

- provide a forum for consideration of ethical issues related to all facets of The Alfred's functions
- consider the ethical issues brought to the Ethics Committee from various sources within Alfred Health

- keep abreast of ethical debate in all areas relevant to The Alfred's activities
- assist the Ethics Committee in raising awareness of ethical issues within Alfred Health.

How do items come to the attention of the GEI S-C?

The GEI S-C becomes aware of issues requiring ethical consideration in various ways, for example:

- The main Ethics Committee might identify particular issues within a research project, that require further exploration (ie. using social media for health research)
- Alfred Health staff approach the GEI S-C with specific concerns or proposals, or after recognising a need for guidelines to cover a new area (eg. guidelines for telephone consent, guidelines about concurrent enrolment in clinical trials, input on the Clinical Photography Guidelines)
- Ethics Committee members and researchers identifying areas for improvement in participant documentation (ie. standard wording for risky procedures, patient privacy brochure)
- Issues receiving attention in the media, about which the GEI S-C can provide a forum for discussion (eg. the controversy in 2009 about diagnosis of brain death)
- Clinicians seeking ethical consideration of novel procedures (ie. protocol for using donor lungs from non-heart-beating donors).
- Calls for public consultation and feedback on policies, guidelines and resources developed by bodies such as the National Health and Medical Research Council, the Australian Law Reform Commission, etc.

The GEI S-C often seeks the involvement of experts from Alfred Health and AMREP for these discussions and when preparing submissions.

Some recent activities

Compensation wording

The standard compensation statement used in Participant Information Forms for sponsored clinical drug/device trials was revised by the GEI S-C to more accurately reflect a participant's options in accessing compensation in the event of injury as a result of participation. The new clause has been adopted by the Victorian Department of Health and the Consultative Council for Human Research Ethics' streamlining of ethical review program and is now in use throughout Victoria.

Publicity of research in progress

Media stories about research are an important means of publicity, recruitment and funding. However, misleading publicity can create false hope and damage the informed consent process. The GEI S-C published information for researchers in the [June 2009 newsletter](#), reiterating the requirement of the [Australian Code for the Responsible Conduct of Research](#) that research findings (at whatever stage of the research) be peer reviewed before they are publicised. Researchers should seek guidance in how to determine what is "fair comment" and in dealing with the media.

Guidelines currently under development

Research in private practice settings

Ethical guidelines are being drafted to highlight the issues that ethics committees and researchers need to consider and address when research is being conducted in various settings outside the hospital such as private specialist clinics, GPs, and other community settings.

Student research and data ownership

There is some uncertainty about the ownership of data collected by PhD students conducting research in the hospital. Data involving Alfred Health patients is the property of Alfred Health and will remain so if the student leaves the project. Existing guidelines relating to intellectual property do not specifically address data ownership. The GEI S-C is looking into this and is developing some basic guidelines for researchers and supervisors.

Use of social media for research

The use of social networking internet sites for research is an emerging area of research which raises new ethical issues. The Ethics Committee is beginning to see applications for research employing this technology.

Traditional ethical safeguards are difficult to apply in social media settings characterised by the free flow of information and multiple simultaneous interactions. Challenges include the lack of control over information flow, lack of privacy, communicating potential risk, ensuring informed consent, verifying the genuineness of participants and information, and the potential for deception and coercion.

As yet, there is minimal ethical guidance for researchers and ethics committees. A Working Group has been established to monitor and identify issues, and recommend suitable research approaches and resources.

Other issues considered include:

- Safety monitoring and reporting
- Establishing registers of 'healthy control' blood donors
- Archiving of research records
- Research involving illegal activities

Do you have an issue for the GEI S-C?

Alfred Health and AMREP staff members who have any relevant issues that they would like considered by the General Ethical Issues Sub-Committee may direct enquiries to:

Ms Kordula Dunscombe

Secretary GEI S-C

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k.dunscombe@alfred.org.au

- Clinical registries and opt-out consent
- Genetic testing in research and implications for life insurance
- Retaining data when participants withdraw from clinical trials
- Interaction of the Health Records Act and the Guardianship & Administration Act
- Managing hospital./industry conflicts of interest
- When to inform GPs of their patients' involvement in research.

Membership

Prof John J McNeil (Chair)

Epidemiologist, Monash University (also Chair of main Ethics Committee)

Prof Paul Komesaroff (Deputy Chair)

Endocrinologist, Head of the Clinical Ethics Service

Dr Susannah Ahern Medical Admin

Ms Marta Ago Lawyer

Dr Tracey Caulfield Lay woman

Mr Simon Cohen Lawyer

Mr Peter Gallagher Lay man

Rev Marilyn Hope Chaplaincy

A/Prof Peter Hunter Director, Sub Acute & Medical Services, A/Prof Aged Care, Director Rehab, Aged & Community Care Alfred Health

Dr Roderick McRae Anaesthetist

Dr Phoebe Mainland Anaesthetist

Dr Annett Miller Expertise in regulatory affairs

Ms Elizabeth Mullaly Psychology, Caulfield Hospital

Ms Janine Roney Infectious Diseases

Prof Alison Street Haematology

Dr Tim Sutton Gynaecologist (retired)

Prof John Wilson Head Cystic Fibrosis

Ms Michelle Wright Lawyer

Ms Rowan Frew Ethics Manager

Ms Kordula Dunscombe Secretary GEI S-C

Submissions to government bodies 2008-2010

- Ethical Issues Involved in Transitions to Palliation and End of Life Care for People with Chronic Conditions: A Discussion Paper for Patients, Carers, and Health Professionals
- Draft National Protocol for Donation after Cardiac Death
- Proposed Accreditation Scheme for the National Approach to Single Ethical Review
- Harmonisation of Multi-Centre Ethical Review (HoMER) Enabling System
- NHMRC Draft Issues Paper: The Commercialisation of Human Tissue
- NHMRC Draft Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State, and draft "A guide for families and carers of people with profound brain damage".
- Australian Law Reform Commission on Discussion Paper 72 Review of Privacy.