

1.3.1 Position description lawyer

Alfred Health Research & Ethics Unit

Position Description

Position Title: **Lawyer – Alfred Hospital Ethics Committee**
Status: Honorary
Appointment: Annual

Role of the Committee

The Alfred is a teaching hospital with a strong emphasis on research and innovation. The role of The Alfred Hospital Ethics Committee, as a Human Research Ethics Committee (HREC), is to provide ethical and scientific review of all research involving humans at The Alfred, in accordance with The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007)¹. Members of the Alfred Hospital Ethics Committee are accountable to the Chief Executive, Alfred Health, through the Committee and the Chairperson.

The Alfred Hospital Ethics Committee reviews research activities involving human participants associated with Alfred Health (which includes The Alfred, Caulfield Hospital, Sandringham Hospital and Melbourne Sexual Health Centre), as well as partner organisations (the Baker IDI Heart and Diabetes Institute, Burnet Institute, some Monash University departments, and Nucleus Network).

Role of the Position

Lawyers provide a legal perspective on proposed research and cannot be associated with Alfred Health in any professional capacity. As such, lawyers are not expected to have any pre-existing expertise or involvement in research activities, and are not expected to comment on scientific aspects of research.

Research proposals include plain language summaries that can be understood by all Committee members. Proposals also generally include a Participant Information and Consent Form (PICF) which contains plain language information for research participants to read and consider before agreeing to take part in research. This information also assists Committee members who do not have a medical, scientific or research background to understand and evaluate the ethical implications of the research.

Lawyer members are required to review research proposals and consider ethical issues from a legal perspective. They may at times be called upon to provide a broad lay explanation to the Ethics Committee of relevant legislation relating to health, privacy and research. They will not be asked to provide specific legal advice.

All Committee members are encouraged to offer any concerns or suggestions and actively contribute in discussions.

Ethics Committee

The Alfred Hospital Ethics Committee is constituted according to NHMRC guidelines and reports annually to the Australian Health Ethics Committee (AHEC). It meets once a month to review research applications and address any ethical issues that have been brought to its notice.

¹ The National Statement is available online at <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>, and a hard copy is provided to all Committee members.

1.3.1 Position description lawyer

The Committee has a minimum membership comprising:

- A chairperson
- At least two lay people: one man and one woman
- At least one person with knowledge of, and current experience in, professional care, counselling or treatment of people
- At least one person who performs a pastoral care role in a community, for example a minister of religion
- At least one lawyer
- At least two people with current research experience that is relevant to research proposals to be considered by the Committee

The Committee works in large part on a consensus model, although it may revert to a vote if absolutely necessary. As such, all members seek to raise any issues or concerns they have directly and to respectfully canvas the issues in a collective forum.

To expedite the review process, applications are received about three weeks in advance of the Ethics Committee meeting and divided into research involving Drugs/Devices and Interventions (D&I) and Health and Social Science (H&SS) research. D&I applications are sent to the Research Review Committee, which meets before the Ethics Committee, undertakes a scientific assessment of the research, and makes recommendations regarding acceptance or further review. H&SS applications are assigned to two Ethics Committee members (referred to as the 'primary reviewers') as determined by the Ethics secretariat. Primary reviewers are asked to provide written reviews of projects allocated to them within one week of receipt. However, all members are expected to peruse (and are welcome to provide written comment on) all projects sent to them.

Research Review Committee

The Research Review Committee is a sub-committee of the Ethics Committee. It reviews all drugs and interventional research projects for scientific validity. Membership includes a clinical pharmacologist who reviews all CTN (drug/device) applications. Meetings are held two weeks before the main Ethics Committee meeting. The Research Review Committee makes recommendations regarding approval or interviews to the Ethics Committee. The Ethics Committee may then interview researchers when there are points of clarification or ethical issues best discussed in person. Occasionally, lawyer members of the Ethics Committee are coopted onto the Research Review Committee.

General Ethical Issues Committee

The General Ethical Issues Sub-committee is a sub-committee of the Ethics Committee which meets monthly to keep abreast of issues that are constantly arising with the emergence of new diseases, new medical and scientific technologies and changes in community attitudes. This committee provides a forum for discussion of ethical matters relating to patient care from the points of view of both the patient and those providing patient care. It is also a forum for the consideration of policy matters relating to the ethical conduct and review of research involving Alfred Health. Lawyer members of the Ethics Committee are welcome to join the General Ethical Issues Sub-committee.

Ethical conduct in research

Ethics and ethical principles extend to all spheres of human activity. They apply to our dealings with each other, with animals and with the environment. They also govern our interaction in conducting research. Ethics serve to identify good, desirable or acceptable conduct and provide reasons for those conclusions.

Ethical review of research

The primary purpose of ethical review is to protect the welfare and the rights of human participants in research. There is also an important secondary purpose, which is to facilitate research that is or may be of benefit to the community or to humankind.

The review process requires individual and collective consideration and judgement of scientific and ethical aspects of each research proposal in accordance with key principles of integrity, respect for persons, beneficence and justice, consent, and research merit and safety.

Specific Tasks

1. Read thoroughly and review in detail approximately 1-3 research applications per month to which you will be assigned as primary reviewer, and offer written comments on these projects within a week of receiving the applications.
2. Read approximately 10-20 research applications per month and offer written comments on any issues of concern on any of the projects within a week of receiving the applications.
3. Actively participate in as many of the 12 Ethics Committee meetings as possible during the year.
4. Review and provide timely written comments on post-approval amendments to those research applications for which you are a primary reviewer.
5. If possible, participate in the General Ethical Issues Sub-committee regularly or in response to specific issues.
6. Provide a legal perspective in considering all ethical issues in relation to devices, treatments, practices, or research issues brought before either the Ethics Committee or the General Ethical Issues Sub-committee.
7. All Committee members are expected to consider projects in confidence, and are not authorised to make public comments on behalf of Alfred Health.

Selection Criteria

1. Lawyer members must be independent of Alfred Health and partner organizations (Baker IDI Heart and Diabetes Institute, Burnet Institute, some Monash University departments, and Nucleus Network). A past or current patient of any Alfred Health hospital is not necessarily excluded, provided they can demonstrate that they have no bias in relation to the research enterprise, or the institution.
2. An ability to provide a legal perspective on specific research proposals, with reference to the relevant law in medicine and other areas of research.
3. An ability to listen to, and appreciate the views of others, and to formulate and express a considered opinion in order to help ensure that the Committee can collectively balance the benefits and risks of research and protect participants.
4. An interest in ethics, and a capacity to understand important ethical issues. Formal training in ethics is not required.
5. The capacity to commit time to read and review applications and to attend monthly, evening meetings.
6. The capacity to voice concerns in relation to proposed research put to the Ethics Committee, or practices or issues put to the General Ethical Issues Sub-committee.
7. An ability to appreciate the perspective of prospective research participants, or patients and their next of kin. This includes some appreciation for those with chronic or severe medical conditions (highly dependent on medical care), children or young people, people with intellectual or mental impairment, people in dependent or unequal relationships with health care professionals, and those from particular cultural or minority groups.

1.3.1 Position description lawyer

Applications & Selection

1. Applicants may contact s 47F, Ethics Manager, Research & Ethics Unit, on telephone s 47F or by email to research@alfred.org.au to discuss the position further.
2. Applications should be submitted with a resume and a cover letter addressing the selection criteria, forwarded to s 47F, Ethics Manager, Research & Ethics Unit, The Alfred, Commercial Road, Melbourne 3004, or by email to research@alfred.org.au
3. The closing date is **Thursday 17 December 2009**.
4. Applications will be short-listed for interview based on the selection criteria.
5. Prospective Committee member/s are asked to complete a trial period, involving participation in three Committee meetings, if they are successfully selected at interview and interested in continuing in the selection process.
6. The Committee will consider full Committee membership of new applicants after three months/meetings.
7. Membership of the Ethics Committee is made annually by the Alfred Health Board through the Chief Executive.

Training & Development:

1. The National Statement requires members to undertake appropriate induction and continuing education.
2. New members are asked to attend an induction session with the Ethics Office at a mutually convenient time.
3. New members are generally not assigned as primary reviewers of projects until some time after membership.
4. Opportunities for ongoing training and development are provided by the Australian Health Ethics Committee (AHEC) of the NHMRC, and other organizations.

Remuneration:

This is an honorary position, but there is a payment of \$150 per Ethics Committee meeting attended for those not employed by Alfred Health or associated institutions. This is not paid for attendance at General Ethical Issues Sub-committee meetings.

Liability Insurance:

Professional indemnity insurance is provided annually by Alfred Health for all Committee members.

Car Parking:

Free car parking is available on site for Committee members for attendance at scheduled meetings.