

HUMAN RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

INTRODUCTION

Austin Health affirms its commitment to the highest standards of medical research including the strict observance of relevant ethical principles and practices.

To this end, Austin Health shall appoint and maintain a Human Research Ethics Committee, which shall function with autonomy appropriate to its role.

The Human Research Ethics Committee shall report to the Board of Austin Health annually.

The membership, functions, applications of functions and meeting procedures of the Human Research Ethics Committee, shall conform to the requirements of the Commonwealth of Australia's National Statement on Ethical Conduct in Human Research (2007) and its successor.

The Committee shall ensure that any other relevant requirements of the

- National Health and Medical Research Council Act 1992 (Cth)
- Therapeutic Goods Act 1989 (Cth)
- Human Tissue Act 1985 (Vic)
- Human Tissue Act 1983 (Cth)
- Infertility Treatment Act 1995 (Vic)
- Australian Code for the Responsible Conduct of Research (2007)
- Health Records Act 2001 (Vic)
- Privacy Act 1988 (Cth) s 95
- NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (2003)
- Note for Guidance on Good Clinical Practice (**CPMP/ICH/135/95**) Annotated with TGA comments. (July 2000)
- Guardianship & Administration Act 1986 (Vic)
- Medical Treatment Act 1988 (Vic)

their successors and such other statutes that have relevance to ethical considerations, are not offended in the research practices and policies of Austin Health.

In accordance with the above determinations, all research projects carried out in, or under the auspices of Austin Health involving human subjects, must have the prior approval of the Human Research Ethics Committee.

MEMBERSHIP

The membership of the Human Research Ethics Committee shall conform to the requirements of the NHMRC Statement on Ethical Conduct in Human Research and its successors and shall include as far as possible equal numbers of men and women, at least one-third of whom are from outside Austin Health. The committee shall include:

- Chairperson
- At least two members who are lay people one man, one woman, who have no affiliation with Austin Health are not currently involved in medical, or legal work
- At least two members with current research experience, that is relevant to the type of research to be considered at the meetings they attend.
- At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people, a nurse or allied health professional.
- At least one member who performs a pastoral care role in a community, eg a Minister of Religion, Aboriginal elder
- At least one member who is a lawyer, where possible one who is not engaged to advise the institution
- Where possible one or more of the members should be experienced in reflecting on and analysing ethical decision-making.

Additional members at Austin Health include

- Chairs of all Sub-Committees, or nominees

and may also include one or more of :

- Registered Nurse
- Medical Practitioner
- Epidemiologist
- Other persons as considered appropriate for the type/s of research usually being considered

In attendance

- Manager Research Ethics Unit
- Minutes Secretary of Human Research Ethics Committee
- Chief Medical Officer
- Manager of Austin Life Sciences Office of Research

Further persons may be appointed to a maximum of 22.

A quorum shall consist of the seven core positions and sufficient other members to make up half the total number of members of the HREC.

If the seven core members are not present the chairperson must be satisfied that these members have received all the relevant papers and have had the opportunity to contribute their views and that these have been received and considered (as per Section 5.2.30 of the National Statement).

The Chairperson shall be appointed by Austin Health.

Austin Health shall appoint sufficient staff and provide sufficient facilities for a Secretariat (the Research Ethics Unit) to act on behalf of the Committee.

The Committee may seek advice or assistance from other person/s, with relevant expertise related to a particular project.

APPOINTMENT OF MEMBERS

Austin Health shall appoint Committee members in a fair and transparent manner via the Office of the Chief Medical Officer. Members shall be appointed for a term of three years with the option of future terms. However, future terms are not mandated.

Members absent for three consecutive meetings (without prior notification) will be disqualified.

Members are to submit their resignation from the committee, in writing to the chairperson, at least one meeting in advance unless the member is disqualified for non-attendance.

Members are requested to give at least 4 weeks notice prior to non-attendance at a meeting. Should this not be possible, members should expect to receive all the relevant meeting papers and take the opportunity to contribute their

views so that these can be recorded and considered (as per Section 5.2.30 of the National Statement).

CONDITIONS OF APPOINTMENT

Members shall receive a formal notice of appointment and an assurance that Austin Health will provide legal protection (under current VMIA hospital insurance).

Members who are not staff members of Austin Health shall be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined from time to time by Austin Health's Office of the Chief Medical Officer.

Committee members will be required to sign a confidentiality agreement.

FUNCTIONS

The Human Research Ethics Committee shall carry out the functions of an institutional ethics committee consistent with those set out in the NHMRC National Statement on Ethical Conduct in Human Research (2007) and its successor.

PROCEDURES

The Human Research Ethics Committee (through its Secretariat – the Research Ethics Unit) shall establish, implement and document its working procedures concerning

- Frequency of meetings
- Attendance at meetings
- Conduct and structure of meetings and deliberations
- Preparation of agendas and minutes
- Timely distribution of papers prior to meetings
- Presentation of applications for ethical review
- Timely consideration and review of applications
- Managing conflicts of interest
- Communicating with researchers, including face to face, by telephone and in writing (including email)
- Reporting on its activities to the institution
- Methods of decision-making
- Prompt notification of decisions

- Record keeping
- Monitoring of approved research
- Reporting and handling of adverse occurrences
- Appropriate monitoring
- Receiving and handling of complaints
- Advising institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project
- Attendance, as observers, of people other than members or researchers
- Fees, if any, to be charged
- Confidentiality of the content of protocols and of committee proceedings

SUB-COMMITTEES

To assist the Human Research Ethics Committee in its work, the following sub-committees may provide advice, recommendations and/or decisions:

- Drug Trials Sub-Committee (which also has a reporting requirement to the Drug and Therapeutics Committee)
- Non Drug Study Review Sub-Committee
- Executive Review Sub-Committee
- Such other sub-committees as deemed necessary by the HREC

The Human Research Ethics Committee Secretariat (the Research Ethics Unit) shall establish procedures for the workings of these sub-committees and submit their Terms of Reference to the HREC for approval.

REVIEW OF MINIMAL RISK RESEARCH

The Human Research Ethics Committee (through its Secretariat – the Research Ethics Unit) shall establish procedures for the review of Minimal Risk Research.

COMPLIANCE REPORTS TO THE NATIONAL HEALTH AND MEDICAL RESEARCH

The Human Research Ethics Committee shall report at least annually to the NHMRC information relevant to its ethical review processes as required under section 5.7.4 of the National Statement on Ethical Conduct in Human Research.