

PURPOSE

The Human Research Ethics Committee (HREC) 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. Its role includes establishing procedures to assist in the examination and review of protocols for new forms of treatment and therapy.

The HREC will provide leadership, governance and coordination to ensure human research is conducted according to the highest scientific and ethical principles at Bendigo Health and other health service agencies according to agreements.

The scope of the committee's work is in ensuring that strategies are developed, implemented and maintained for the effective:

- review of human research
- governance of human research
- monitoring of human research

OBJECTIVES

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

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

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 (Cwlth)*;
- *Therapeutic Goods Act 1989 (Cwlth)*;
- *Human Tissue Act 1985 (Vic)*;
- *Human Tissue Act 1983 (Cwlth)*;
- *Infertility Treatment Act 1995 (Vic)*;
- Australian Code for the Responsible Conduct of Research 2007;
- *Health Records Act 2001 (Vic)*;
- *Privacy Act 1988 (Cwlth) s95*;
- 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)*;

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

The Committee shall also comply with Standard 1, Governance for Safety and Quality in Health Services Organisations, Standard 2, Partnering with Consumers and Standard 4, Medication Safety of the National Safety and Quality Health Service Standards (national standards).

In accordance with the above determinations, all research projects carried out in, or under the auspices of Bendigo Health involving human subjects, must have the prior approval either of Bendigo Health's HREC or of an accredited reviewing HREC in the streamlined ethical review system for public health organisations.

KEY PERFORMANCE INDICATORS

1. The HREC (through its Secretariat) shall establish, implement and document its working procedures.
2. The HREC (through its Secretariat) shall establish and maintain procedures for the review of Low/Negligible Risk Research.
3. The HREC shall report to the Board of Bendigo Health annually.
4. The HREC 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* (2007).
5. The Human Research Ethics Committee shall report annually to the Health Services Commissioner of Victoria studies involving reliance on Privacy Principles.

MEMBERSHIP RESPONSIBILITIES

The membership of the Human Research Ethics Committee shall conform to the requirements of the NHMRC *NS* and its successors and shall include as far as possible equal numbers of men and women, at least one-third of who are from outside Bendigo Health. The committee shall include the following core members:

- The Chair;
- at least two members who are lay people, one man, one woman, who have no affiliation with Bendigo Health and 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, e.g. 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; and
- where possible one or more of the members should be experienced in reflecting on and analysing ethical decision making.

Additional members at Bendigo Health may include one or more of the following:

- a member of the Bendigo Health Board
- an Executive Director of Bendigo Health
- registered nurse
- medical practitioner
- epidemiologist
- other persons as considered appropriate for the type/s of research usually being considered.

In attendance

- Secretary of Human Research Ethics Committee.

Further persons may be appointed to a maximum of 20.

A quorum shall consist of six members, not including the secretary. If the seven core members are not present, the Chair 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 Chair shall be appointed by the Board of Directors.

Bendigo Health shall appoint sufficient staff and provide sufficient facilities for a Secretariat (the Research Governance 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

- Bendigo Health shall appoint Committee members in processes that are clearly defined, easily understood, easily accessible, and open to scrutiny. This process will be guided by the Bendigo Health recruitment and selection policy.
- The Bendigo Health Board will appoint Committee members following a recommendation from the Chair and secretariat of the Committee.
- 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 Chair, 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 Bendigo Health will provide appropriate indemnity (under VMIA hospital insurance cover Public Healthcare Program).

- Committee members will be required to sign a confidentiality agreement.
- Non Bendigo Health committee members will be required to provide a current copy of a police record check or undergo a police record check, paid for by BHCG (as per Police Check Policy).
- Other representatives may be co-opted as required, subject to the approval of the Chair.

Associated documents

[Police Check Policy](#)

[Recruitment and Selection Policy](#)

Meeting attributes	
Duration of Meeting	2 hours or as required
Frequency of Meeting	The committee shall meet not less than ten times per year with intervals of not more than two months and more often as may be required to discharge the obligations imposed upon it by its terms of reference.
Quorum	A quorum shall consist of six members, not including the secretary. If the seven core members are not present, the Chair 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 <i>National Statement</i>).
Reporting To	Group Executive Policy, Strategy and Risk
Reporting Mechanism	Minutes
Commencement Date	August 2009