HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

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PURPOSE

The Human Research Ethics Committee performs the functions of an institutional ethics committee consistent with the guidelines set out in the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007; 2023; 2025) (*National Statement*). It operates and reports in accordance with the *National Statement* and with other relevant federal and state legislation and regulations. The scope of the committee's work includes review of proposals for and oversight of Bendigo Health HREC-approved human research conducted at or under the auspices of Bendigo Health.

The HREC will provide leadership to ensure that this human research (whether involving patients, staff or community members) is conducted according to the highest scientific and ethical principles at Bendigo Health and any other designated health service agencies according to institutional agreements.

OBJECTIVES

Bendigo Health maintains a 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 *National Statement*.

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 2018
- *Health Records Act 2001* (Vic)
- Privacy Act 1988 (Cth)
- NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
- Victorian Aboriginal Health Medical and Wellbeing Research Accord, 2023
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) Annotated with TGA comments (November 2016)
- *Medical Treatment Planning Decisions Act 2016* (Vic)
- *Mental Health Act 2014* (Vic)
- *National Safety and Quality Healthcare Services (NSQHS) Standards (second edition) 2017*.

and their successors and such other statutes that have relevance to ethical consideration, are observed in the research practices and policies of Bendigo Health.

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 NHMRC authorised reviewing HREC in the National Mutual Acceptance (NMA) scheme, 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 Lower Risk Research.
3. The HREC shall report to the Board of Bendigo Health annually.
4. The HREC shall report annually to the NHMRC information relevant to its ethical review processes as required under section 5.8.4 of the *National Statement.*
5. The HREC shall undertake other reporting, in line with other relevant federal and state legislation and regulations, as required.

MEMBERSHIP

The membership of the Human Research Ethics Committee shall conform to the requirements of the NHMRC *National Statement on Ethical Conduct in Human Research* (2023) and its successors and shall have as far as practicable, diversity, including gender diversity. At least one-third of members should be drawn from outside Bendigo Health. The committee shall include the following core members:

- A chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement* 5.1

- At least two members who bring a broader community or consumer perspective, who have no affiliation with Bendigo Health are not currently involved with medical, scientific, legal or academic work
- At least one member with the knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or allied health professional
- At least one member who performs a pastoral care role in a community, but not limited to, an Aboriginal and/or Torres Straight Islander elder or community leader, a chaplain or a minister of religion or other religious leader
- At least one member who is a lawyer, where possible one who is not engaged to advise the institution
- At least two members with current research experience, that is relevant to the research proposals to considered at the meetings they attend.

Where possible one or more of the members should be experienced in reflection 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, including individuals with expertise in cyber security.

In attendance

- Secretariat of the Human Research Ethics Committee.

Further persons may be appointed to a maximum of 20.

The chairperson shall be appointed by the Board of Directors.

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

The Committee may invite observers to attend meetings. Any invited observers should not be involved in deliberations or decision making but are still bound by the same confidentiality and disclosure in interests requirements as HREC members (see Conditions of Appointment: signing the BH confidentiality agreement).

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 chairperson 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 chairperson, at least one meeting in advance unless the member is disqualified for non-attendance.

Conditions of Appointment

- Members shall receive a formal notice of appointment from the Chair of the Board 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 Bendigo Health (as per Police Check Policy)
- Other representatives may be co-opted as required, subject to the approval of the chairperson. Co-opted members will be in indemnity arrangements and will also be required to sign a confidentiality agreement and provide a current Police check (as per the Police Check Policy).

Associated Documents

Police Check Policy

Membership Responsibilities

Each member of a review body is responsible for deciding whether, in their judgement, a research proposal meets the requirements of the *National Statement* and other relevant guidelines and is ethically acceptable (as per Section 5.2.21 of the *National Statement*)

To fulfil that responsibility, each member of a review body should:

a) Undertake any induction training or process provided by the institution or review body
b) Become familiar with the *National Statement*, and consult other guidelines and information relevant to the review of specific research proposals
c) Prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences.

Bendigo Health HREC 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 to contribute their views so that these can be received and considered.

and

d) Attend continuing education or training programs in research ethics at least every three years, or more frequently if provided by the institution or review body.

Members of a review board must be aware of and respect any institutional protocols or policies related to confidentiality in the performance of their role(s). These may be relevant to the interactions with other members of the review body, with administrators or with researchers, or to review of research proposals or any discussion occurring at a meeting, online or elsewhere about matters within the remit of the review body.

Members of any review body must disclose any interests that may constitute an actual or potential conflict of interest, including any financial or other interest or affiliation that bears on any research coming before the review body (see Chapter 5.6 of the *National Statement*). The disclosure may be to the chairperson (before the meeting) or before discussion at the meeting of the relevant agenda item, as appropriate.

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	Where there is less than full attendance of the minimum membership at a meeting, the chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered (as per Section 5.2.5 of the *National Statement*)
Reporting To	Quality and Safety Committee
Reporting Mechanism	Minutes
Commencement Date	May 2026

Fees for Review

A current schedule of fees for ethical review will be maintained by the Research Governance Office and posted on the HREC Website.