

Terms of Reference - Ballarat Health Services & St John of God Hospital Human Research Ethics Committee

1. Committee Purpose

Ballarat Health Services (BHS) and St John of God Ballarat Hospital (SJOG) affirm their commitment to the highest standards of research including the strict observance of relevant ethical principles and practices.

To this end, Ballarat Health Services and St John of God Ballarat Hospital shall appoint and maintain a combined Human Research Ethics Committee (BHSSJOG HREC), which shall function appropriate to its role.

The objectives of the BHSSJOG HREC are:

- a) To assess the conduct of proposed research against ethical principles as outlined in the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007)(and subsequent updates)(known as the National Statement) and advise on the ethical suitability of its commencement
- b) To protect the welfare and rights of participants in research being mindful of the safety of individuals conducting the research; and
- c) To facilitate research that is or will be of benefit to the wider community

To meet the objectives the committee will:

- Consider the ethical implications of all proposed research involving human participants and determine its acceptability on ethical grounds
- Consider the scientific validity and merit of research projects
- Monitor approved research projects to ensure continued compliance with the conditions of approval
- Acknowledge and consider any prior peer review that has approved a proposed project
- Ensure that unnecessary duplication of ethical review is minimized, including formal participation in the Department of Health Single Ethical Review Process (SERP) and single ethical review processes initiated by the NHMRC
- Maintain a record of all proposed research projects, so that the following items of information are readily available:
 - Project identification number
 - Principal Investigator(s)
 - Title of Project
 - Ethical approval or non-approval with date
 - Date(s) designated for review
 - Where the principal investigator is not a member of the Hospital staff, the name of the institution where he / she will be carrying out research should be recorded.
- Maintain communication with the Australian Health Ethics Committee (AHEC) of the NHMRC and the Therapeutic Goods Administration (TGA) and provide access on request to information from the BHSSJOG HREC records
- Receive reports from the BHS Ethics and Governance Office in relation to:
 - multicentre research involving clinical trials to be conducted at BHS and;
 - SJOG?
- Consider research proposals from non-affiliate researchers and institutions in the region.

2. Reporting

The BHSSJOG HREC Reports to the:

- Quality Care Committee (BHS) and;
- The Chief Executive Officer (SJOG)

The BHSSJOG 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)(including subsequent updates).

The BHSSJOG HREC shall report annually to the Health Services Commissioner of Victoria studies involving reliance on Privacy Principles.

3. Membership of the Committee

3.1 Composition

The BHSSJOG HREC will have a minimum of eight (8) members.

The core members of the BHSSJOG of HREC will be in accordance with the NHMRC National Statement comprising an even mix of men and women, internal and external, as follows:

- a) A Chair with suitable experience
The Chairperson shall be a BHS staff member appointed by the *Ballarat Health Services Quality Care Committee*.
- b) at least 2 laypeople, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work
- c) At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people
- d) At least one person who performs a pastoral care role in a community
- e) At least one lawyer, where possible one who is not engaged to advise the institution; and
- f) At least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant experience.

Additional Member roles:

- Deputy Chair (s) – SJOG executive member appointee
- Member Quality Care Committee Ballarat Health Services -Executive member Ballarat Health Services (Chief Medical Officer)
- Additional members as deemed necessary by the HREC Chair and in accordance with the NHMRC guidelines

In attendance:

- BHS Manager, Research Ethics & Governance
- BHS Research Governance Officer
- Invitees of the Chair which may include researcher applicants or individuals with knowledge that may assist with BHSSJOG HREC decision making. All such invitees may be asked to leave the meeting during BHSSJOG HREC decision making and have no voting rights.

3.2 Appointment of Committee Members

With the exception of the Chair and the SJOG executive member appointee, all BHSSJOG HREC members will be appointed for their expertise and not as representatives of any group or organization.

Appointments will be conducted in a fair and transparent manner. Recruitment of members may occur through direct approach or advertisement as required.

3.3 Tenure

BHSSJOG HREC members are appointed for a minimum term of three years and remain eligible for re-appointment for subsequent terms.

Additional members serving in an ex officio or membership role (e.g. Chair) will serve for the duration of their time respectively in those roles.

3.4 Liability Coverage

Ballarat Health Services accepts legal responsibility for all decisions and advice received from the BHSSJOG HREC members. BHS will provide legal protection in respect of any liabilities that may arise in the course of bona fide conduct of their duties as committee members.

3.5 Remuneration

Members of the BHSSJOG HREC and its subcommittees are not offered remuneration. Committee members are permitted to apply for reimbursement of committee-related expenses.

3.6 Secretariat

Secretariat services for the BHSSJOG HREC will be provided by the Research Ethics and Governance Unit, BHS.

4. Meetings

4.1 Frequency of Meetings

The BHSSJOG Human Research Ethics Committee shall meet at least eight (8) times a year.

4.2 Meeting Agenda

The agenda will be distributed by the Secretariat to all members and attendees at least one week before the next scheduled meeting.

4.3 Quorum

A quorum shall consist of the eight members required to fulfill the minimum membership requirements as outlined in the National Statement.

If the eight 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*).

4.4 Conflict of Interest

Any member of the BHSSJOG HREC who has an interest, financial or otherwise, in a proposal or other related matter considered by the BHSSJOG HREC should as soon as practicable declare such an interest. The member will withdraw from the discussion of any issues relating to the proposal, unless invited to attend by the BHSSJOG HREC. All declaration of interest and the absence of the member concerned must be minuted.

4.5 Decision Making

Decisions of the BHSSJOG HREC will only be made after members from each of the member categories has had an opportunity to contribute their views during or prior to the decision making process. Members unable to attend the meeting will be asked to forward comments to the Secretariat prior to the meeting.

The BHSSJOG HREC will endeavor to reach a decision concerning the ethical acceptability of a proposal by general agreement. The decision need not be unanimous.

The HREC will record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decision linked to the relevant sections, chapters or paragraphs of the National Statement.

4.6 Record Keeping

The secretariat will prepare and maintain records of the BHSSJOG HREC's activities including agendas and minutes of all meetings of the HREC.

4.7 Confidentiality

Members of the BHSSJOG HREC will treat as, and keep confidential, all information and documents which relate to the business considered by the BHSSJOG HREC. Committee members who are not BHS employees will complete a declaration of confidentiality upon their appointment. Members of the committee who are BHS employees complete a confidentiality declaration upon commencing with BHS.

5. Method of Operation

5.1 Procedures

The BHSSJOG HREC will perform its functions according to standard operating procedures and relevant BS policies (as agreed to by the BHS Quality Care Committee or executive). The procedures will be reviewed periodically and amended and updated as necessary. All BHSSJOG HREC members and researchers will have access to these procedures.

In carrying out its functions the HREC shall at all times:

- a) Ensure their enquiries of the researcher will be made in a spirit of courtesy and support, so as to develop mutual respect and a sense of partnership in the development of sound ethical practice
- b) Provide the decisions of the BHSSJOG HREC in writing and within a reasonable timeframe to the persons nominated in the submission.
- c) Determine the method of monitoring appropriate to each project. Projects that have received ethical approval will be monitored and may be audited to ensure that they conform to the protocol approved.