

Terms of Reference – Grampians Health & St John of God Hospital Human Research Ethics Committee

1. Committee Purpose

Grampians Health (GH) 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, Grampians Health and St John of God Ballarat Hospital shall appoint and maintain a combined Human Research Ethics Committee (GHSJOG HREC), which shall function appropriate to its role.

The objectives of the GHSJOG 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 (2023)(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 GHSJOG HREC records
- Receive reports from the GH Ethics and Governance Office in relation to:
 - multicentre research involving clinical trials to be conducted at GH and;
 - SJOG?
- Consider research proposals from non-affiliate researchers and institutions in the region.

2. Reporting

The GHSJOG HREC Reports to the:

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

The GHSJOG HREC shall report at least annually to the NHMRC information relevant to its ethical review processes as required under section 5.8.4 of the National Statement on Ethical Conduct in Human Research (2023).

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

The core members of the GHSJOG 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 chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- (b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- (c) a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
- (d) a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;
- (e) a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters; and
- (f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

Additional Member roles:

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

In attendance:

- GH Manager, Research Ethics & Governance
- GH Research Governance Officer
- Invitees of the Chair which may include researcher applicants or individuals with knowledge that may assist with GHSJOG HREC decision making. All such invitees may be asked to leave the meeting during GHSJOG 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 GHSJOG 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

GHSJOG 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

Grampians Health accepts legal responsibility for all decisions and advice received from the GHSJOG HREC members. GH 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 GHSJOG 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 GHSJOG HREC will be provided by the Research Ethics and Governance Unit, GH.

4. Meetings

4.1 Frequency of Meetings

The GHSJOG 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 5.2.5 of the *National Statement*).

4.4 Conflict of Interest

Any member of the GHSJOG HREC who has an interest, financial or otherwise, in a proposal or other related matter considered by the GHSJOG 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 GHSJOG HREC. All declaration of interest and the absence of the member concerned must be minuted.

4.5 Decision Making

Decisions of the GHSJOG 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 GHSJOG 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 GHSJOG HREC's activities including agendas and minutes of all meetings of the HREC.

4.7 Confidentiality

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

5.1 Procedures

The GHSJOG HREC will perform its functions according to standard operating procedures and relevant BS policies (as agreed to by the GH Quality Care Committee or executive). The procedures will be reviewed periodically and amended and updated as necessary. All GHSJOG 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 GHSJOG 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.