	TITLE: Human Research and Ethics Committee (HREC)		
Document Type:	Terms of Reference	Approved by:	Executive Committee Safety Quality & Performance
Committee:	Executive	Section:	Human Research + Ethics
Author/Prepared by:	Dr Junyi Shi	Position:	Director Medical Services / Acting Director of Research

1. PURPOSE:

To receive, consider and assess research proposals involving human participants and provide ethical approval in accordance with the National Health and Medical Research Council (NH&MRC) guidelines for those research proposals.

Research proposals that have gained multi-site ethics approval including approval for research at Goulburn Valley (GV) Health from a NH&MRC certified Ethics Committee under National Mutual Acceptance will not require ethical approval from the GV Health Human Research and Ethics Committee ("the HREC") but shall require governance approval (site specific assessment) for the conduct of the Research from the Research Governance Officer (RGO) of GV Health.

To comment on and make decisions on any ethical issue where requested by GV Health.

2. OBJECTIVES:

To protect the welfare and the rights of participants in research. To independently decide, whether the conduct of each research proposal submitted to the Human Research and Ethics Committee will appropriately protect participants and is otherwise ethically acceptable.

3. ORGANISATIONAL RELATIONSHIPS:


The GV Health HREC is a formally constituted committee of GV Health. It has external, community representatives providing pro bono membership commitments. GV Health has legal responsibility and liability for anything done or omitted to be done by the HREC and its members including but not limited to for decisions, approvals and advice given by or made by the Committee and indemnifies its members.

4. REPORTING:

The Committee will provide a copy of all minutes to the Research Management & Governance Committee through the Chairperson or the Chief Medical Officer (CMO) / Director of Medical Services (DMS) bi-monthly and an annual report to Executive Safety, Quality and Performance Committee and the Senior Medical and Dental Governance Committee October and the Board in November.

5. MEMBERSHIP:

Save as otherwise provided in this clause 5, the members of the Committee including the Chairperson shall be appointed by the Chief Executive (CE). During any period that there would otherwise be no Chairperson, the CMO or DMS shall be the Chairperson of the Committee until a Chairperson of the Committee is appointed by the CE. No member shall be appointed to fill more than one of the categories as per the National Statement paragraph 5.1.30. As far as possible, there should be diversity, including gender diversity at each meeting and at least one third of the members should be from outside the institution for which the HREC is reviewing research.

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Wherever possible, one or more of the members who form the minimum membership of the HREC by virtue of clause 5.1.30 of the National Statement should be experienced in reflecting on and analysing ethical decision making. The minimum membership of the HREC is eight (8) and must include the following:

- 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;
- two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- 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;
- 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;
- 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;
- two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.


Other membership shall include:

- At least two (2) members, preferably from the Divisional Clinical Directors (delegated by the office of the CMO) with research knowledge and/or current research experience;
- Chief Nursing & Midwifery Officer or representative;
- Chief Allied Health Officer or representative;
- One (1) Senior Medical Staff Employee Representative at Senior Consultant level (delegated by the office of the CMO);
- One each of (1) Senior Nursing and (1) Allied Health Staff Employee Representatives;
- One (1) member, preferably from a University that has a Shepparton campus at which the member works and which University has an Association with GV Health;
- The Director of Research at GV Health;
- Director of Nursing & Midwifery Education and Research;
- Allied Health Education & Research Manager;
- Chief Medical Officer (CMO) and/or Director of Medical Services (DMS).

The HREC may continue to carry out all its functions where any membership position referred to in this clause 5 is vacant but shall cease to carry out its functions during any period that the membership of the HREC falls below 8 members or any category of the minimum membership of the HREC as specified in paragraph 5.1.30 of the National Statement is vacant.

All appointments including filling of casual vacancies to the HREC shall be by the CE following consultation with the CMO. The CE and CMO may consider recommendations made by the HREC in the process of appointment.

A pool of members may be appointed to fill the minimum membership of categories of the HREC as per the National Statement Paragraph 5.1.31.

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All appointments to the HREC shall be made for a term of three years save that the term of a person filling a casual vacancy shall be the balance of the term of the member he/she is replacing. Members may be appointed for additional terms each of three years.

The Chairperson of the HREC recommends to the CE to terminate the membership of a member of the HREC:

- i. where a member has failed to attend four or more meetings of the HREC in any period of twelve months;
- ii. based on misconduct by a member; and
- iii. based on the doing of anything or the failure to do something by a member (whether or not in connection with that members membership of the HREC) which in the opinion of the Chairperson reasonably held makes it inappropriate for that member to continue as a member.

Notwithstanding anything to the contrary in this paragraph contained, the Chairperson may excuse a non-attendance at a meeting where a member had a reasonable excuse for the non-attendance at that meeting, reviewed the applications and documents forwarded with the Agenda for that meeting and sent comments for the consideration of the Committee concerning the applications and documents to be considered at the meeting.


Members are to be given formal notification of appointment and are to be indemnified by GV Health to the maximum extent permitted by law against legal liability for anything done or omitted to be done by a member in the course of or in connection with a members' membership of the HREC save only to the extent that a member has failed to act in good faith. Where GV Health is obliged by this paragraph to indemnify a member, GV Health shall pay all costs and expenses incurred by a member in defending any claim made against a member and shall maintain insurance which covers all members of the HREC (including but not limited to members of the HREC who are not employed by GV Health) against the legal liability of members for which GV Health is obliged to indemnify members pursuant to this paragraph at least to the extent of the indemnity to members provided for in this Clause 5 with an extension to cover the costs and expenses incurred by a member which by this paragraph are to be paid by GV Health.

A member shall not vote on any decision of the HREC where that member has a material conflict of interest with respect to the subject matter of the vote whether or not that member is a part of the minimum membership of the HREC, shall declare any conflict at the first available opportunity and shall leave the room when any application regarding a matter for which a member has a conflict of interest is being discussed if requested to do so by any member of the HREC.

6. COMMITTEE PROTOCOLS:

6.1. Procedures

The agenda, including copies of research proposals, shall be distributed to all members so far as is reasonably practical two weeks prior to the meeting provided that the failure to distribute the Agenda and/or the whole or some of the applications and documents to be considered at the meeting so far as is reasonably practical two weeks prior to the

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meeting shall not prevent the holding of that meeting or invalidate any decision made at that meeting where it is resolved that the meeting is to proceed.

Applications lodged less than three weeks before the date of a meeting will generally not be considered until the following meeting provided that in an appropriate case the Committee may agree to expedite the consideration of an application.

The Committee shall inform researchers in writing of decisions and, in the event of rejections or recommended amendments, the reasons for those decisions. The Committee should endeavour to reach decisions by general agreement which need not involve unanimity.

An applicant may in writing seek reconsideration by the HREC of a decision to reject or impose a condition or conditions on a research project as per GV Health's 'appeal against the HREC's decision' procedure. Where necessary, the Committee may seek advice and assistance from experts to assist with consideration of research proposals or an appeal against a HREC's decision.

The Committee shall/may have MOU's with subregional centres and University rural academic Networks and centres that require GV Health's assistance and collaboration with research subjects and projects.


6.2. Recording of Decisions

The Committee shall maintain a record of all research protocols received and reviewed, including:

- Name of responsible institution or organisation;
- Project identification number(s);
- Principal researcher(s);
- Title of the project;
- Ethical approval or non-approval with date;
- Approval or non-approval of any changes of the protocol;
- The terms and conditions, if any, of approval of any protocol;
- Whether approval was by expedited review;
- Whether the opinion of another HREC was considered;
- Action taken by the HREC to monitor the conduct of the research;
- The relevance, if any, of the Guidelines for the Protection of Privacy in the Conduct of Medical Research.

For multi-centre research proposals, the Committee shall also record, from information provided from the researcher:

- Details of other centres involved;
- The approval status of the Study at each centre;
- Details of any amendments required at other centres;
- Whether the conditions of any approval were changed or an approval revoked.

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The Committee shall retain on file a copy of each research protocol and application for HREC approval, including any information sheets, consent forms or relevant correspondence, in the form in which they are approved.

6.3. Monitoring

The Committee shall ensure that there is appropriate monitoring of research projects until their completion. To achieve this, the Committee must require at regular periods, at least annually, reports from principal researchers on matters including the progress to date or outcome in the case of completed research.

The Committee shall, as a condition of approval of each protocol, require that researchers report anything which might warrant review of ethical approval including:

- Serious or unexpected adverse effects on participants;
- Proposed changes in the protocol;
- Unforeseen events that might affect continued ethical acceptability of the project.

The Committee shall, as a condition of approval of the research proposal, require researchers to inform the HREC if the research project is discontinued before the expected date of completion.

The HREC may terminate or suspend a research approval for any valid reason including but not limited to where it is established or suspected on reasonable grounds that a researcher is not a fit and proper person to conduct the research or there has been:

- a) misconduct or serious negligence in the conduct of the research;
- b) a failure to provide required progress reports;
- c) serious adverse effects or suspected serious adverse effects on subjects of the research or other people impacted by the research.


The HREC shall advise of the above powers to terminate or suspend the research approval in the written approval given to the Researcher."

6.4. Complaints

The Committee has established the following procedures for receiving and handling complaints about the conduct of an approved research project:

- Any complaint from research participants, researchers, or other interested persons should be directed to the Director of Research. However, the Chairperson may direct that any complaint is to be made to another person where the Director of Research has a conflict of interest. The complaint may need to be referred to the chairperson and or the Committee for resolution.

Director of Research and/or Chairperson is to liaise with the GV Health Safety, Quality and Experience Manager to ensure entering of complaints lodged into GV Health managed feedback reporting system including findings and outcomes

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6.5. Compliance Reports to the NHMRC

The Committee shall provide information from its records to the NHMRC on request.

The Committee shall report annually to the NHRMC as per the NHMRC requirements.

6.6. Chairperson and Secretary

The Chairperson shall generally be sourced from the existing membership of the Committee and, in appointing the Chairperson, the CE may consider any recommendation made by the Committee. The Director of Research or delegate will act as the Secretary to the HREC.

The Chairperson shall chair meetings of the HREC with meetings of the HREC to be chaired by the Deputy Chairperson in the Chairpersons absence provided that in the absence of both the Chairperson and the Deputy Chairperson or where otherwise appropriate the Chairperson may delegate another member of the HREC to chair the whole or any part of a meeting of the HREC.

The chair of the whole or any part of any meeting of the HREC shall have a deliberative vote and in the event of equality on any question may in the chair's discretion exercise a casting vote.


The CMO or DMS shall be the Deputy Chairperson of the HREC, and during any time requiring to act as Chairperson of the Committee, the Director of Research shall be the Deputy Chairperson of the Committee. The Deputy Chairperson shall assume all functions and have all powers of the Chairperson in the Chairperson's absence.

The Chairperson may appoint another member of the HREC to act as Chairperson of the HREC during any period that both the Chairperson and the Deputy Chairperson are absent and during any period that the person so appointed is acting as Chairperson that person shall assume all functions and have all powers of the Chairperson.

The Chairperson has the responsibility for managing the agenda and making sure that all relevant items are covered and adequately recorded. The Chairperson may delegate functions including the preparation of the Minutes and Agenda to the Secretary.

The Chairperson shall:

- Consider whether the Committee is sufficiently informed on all aspects of research protocols;
- Oversee arrangements for meetings;
- Ensure that all views of absent minimum members have been received and considered;
- Preside over decision making;
- Invite researchers to attend meetings;
- Seek advice from experts;
- Monitor conflicts of interest;
- Oversee recording of decisions;

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- Establish a complaints process;
- Invite researchers to attend meetings if their project demonstration is advised by the Committee.

6.7. Quorum

A quorum for meetings of the HREC shall be **eight (8) members present**.


6.7.1 Ideally the following categories of membership shall be present in each meeting (the minimum membership as provided for in National Statement paragraph 5.1.30) which are:

- A Chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution.
- At least one person with 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 person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion.
- At least one lawyer, where possible one who is not engaged to advise the institution.
- At least two 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 expertise.

In the event that the whole of the minimum membership of the HREC is not present at a meeting, no item of business shall be conducted unless the Chairperson is satisfied that all of the minimum membership not present at the meeting have received all of the papers before the meeting for that item of business, those of the minimum membership not present have had an opportunity to contribute their views and their views are considered at the meeting.

6.8. Frequency and Mode of Meetings

- The HREC shall meet on the dates from time to time approved by the Committee and generally shall meet either bi-monthly or monthly as may be determined from time to time by the Committee. The Committee may further resolve that there is to be no meeting in a particular month and the Chairperson may for valid reason decide that a scheduled meeting is not to proceed or is to be postponed or brought forward and may schedule additional meetings.
- All attendances at any meeting of the HREC shall be in person save only that the Chairperson and in his absence the Deputy Chairperson (and in the absence of both the Chairperson and the Deputy Chairperson the member delegated by the Chairperson to chair the whole or any part of a meeting of the HREC) may in their absolute discretion decide to hold a meeting, or permit members to take part in a meeting, by using any technology that allows members to clearly and

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simultaneously communicate with the other participating members. In the case where a meeting takes place by technology or members are permitted to take part by technology, a member who participates in a meeting by technology is deemed to be present in person at the meeting, and, if the member votes at the meeting, is taken to have voted in person.

7.0 HREC and RGO Review Fee


The office of the Research and Ethics will invoice HREC and/or RGO review fees as per the most updated fee schedule. The Office of the Research and Ethics after consulting with the CMO, the Committee or the Chair, HREC may contact the investigators (site or lead) or sponsors for an amended review fee. The Research and Ethics department may provide a waiver to the fee after consulting either with the CMO, the Committee or Chair of the HREC.

7.1 Scope of HREC and Governance Review for Internal and External Research

The GV Health HREC will provide ethical review to all applications that are submitted to the HREC irrespective of their organisational origin. Subject to any law or binding guideline to the contrary, the HREC shall provide ethical review and the RGO Governance review (as may be applicable) for all applications that are submitted to the HREC or the RGO (as may be applicable) for research to be conducted primarily on GV Health patients and/or staff and may provide ethical review at the discretion of the HREC or the RGO (as may be applicable) for research which is not to be carried out primarily on GV Health patients and/or staff.

The GV Health RGO may provide governance review on behalf of other health organisations when they seek such assistance. The GV Health RGO will advise the applicant to submit a request letter from their CE or delegate with the governance application and documentation. The GV Health RGO can advise the review outcome letter with the following sentence or similar that "the application met/did not meet the requirements to conduct the study at GV Health. It is the responsibility of the governing body of your organisation to determine the outcome of the application to your organisation".

Where applicable and if required, a MoU (memorandum of understanding) can be developed between GV Health and the organization seeking HREC review and/or RGO governance review by the GV Health HREC and/or the RGO as may be applicable.

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REFERENCES:

NHMRC Human Research Ethics Handbook

NHMRC Research Governance Handbook

NHMRC National Statement on Ethical Conduct in Human Research 2023

Research Governance and Site-Specific Assessment Process and Practice Handbook, Department of Health, Victoria

Contributors to the document

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