**Barwon Health Purpose 2020-2025**

Provide best care, every person, every day, so that our consumers feel better

**Alignment:**

|  |  |  |
| --- | --- | --- |
| Deliver best care:   * Person-centred: our consumers direct the care they receive to achieve their goals. * Equity: our services lead to better health and wellbeing for all. * Engagement: we are engaged in delivering best care. * Value: we make the best use of our resources. * Innovation: we drive innovation for better care * Together: we partner for greater impact | Invest to improve:   * Research: we embed research in care to create a learning healthcare system * Future-ready: build our capacity to respond to changing future needs * Experience: improve the experience of our consumers and our care-givers * Leadership: develop leadership for better outcomes * Access: timely, local and simple access to services | Ensure our future:   * Prudent: we live within our means * Agile: we are agile in responding to changing needs and opportunities * Sustainable: we aim to achieve net zero emissions by 2050 * Grow our own: we train and develop future care-givers |

**Health Service Standards**

[National Safety and Quality Health Service Standards](http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf)

**Legislation and other sources**

* National Health and Medical Research Council Act 1992 (Commonwealth); the National Statement on Ethical Conduct in Research Involving Humans 2007 (referred to as the National Statement),
* The NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research 2003;
* The Australian Code for the Responsible Conduct of Research 2007; and other NHMRC guidelines;
* The Therapeutic Goods Act 1989 (Commonwealth) and the Therapeutic Goods Administration (TGA guidelines;
* Victorian Managed Insurance Authority guidelines;
* Human Tissue Act 1985 (Vic); and Human Tissue Act 1983 (Commonwealth);
* Infertility Treatment Act 1995 (Vic);
* Health Services Act 1988 (Vic);
* Health Records Act 2001 (Vic);
* State and National Privacy legislation;
* Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments. (July 2000);
* Guardianship & Administration Act 2019 (Vic);
* Medical Treatment Planning and Decisions Act 2016 (Vic).

# Background & Authorisation

The Barwon Health Research Management Committee operates under the authority of the Barwon Health Chief Executive Officer and the Board.

# PURPOSE AND ROLE

## Purpose

1. To consider and make recommendations in relation to research projects of all types, which involve Barwon Health, by assessing the information provided to and collated by the Research Ethics Governance and Integrity Unit (REGI) and researchers.
2. To determine the level of organisational approval required in accordance with the Barwon Health Instrument of Delegation
3. To make a recommendation to the relevant approver, under the Instrument of Delegation, on the appropriateness and desirability of research projects, taking into consideration:
4. alignment with the Barwon Health Strategic Plan;
5. alignment with the National Clinical Trials Governance Framework
6. legal compliance
7. indemnity provisions
8. operational implications for all persons and departments involved in the project, including potential impact on clinical services
9. clinical and reputational risk
10. other clinical governance risks and requirements
11. financial impact of the project
12. ethics approval and research governance review in accordance with the National Statement of Ethical Approval in Research (NHMRC)

## Additional Roles

The committee will also:

* 1. Provide investigators, Head of Departments and Clinical Directors with early stage feedback regarding the organisational and operational feasibility of proposed research projects if requested.
  2. To assess research related adverse event and complaints from an organisational and operational perspective. In line with research complaints procedures and policies
  3. Oversee and monitor the support functions of REGI to ensure it supports the effective and efficient assessment of projects and their ongoing monitoring

# MEMBERSHIP

## Appointment

1. The Barwon Health Executive shall appoint the members of the Research Management Committee

## Composition

1. The Research Management Committee shall comprise the following members:
   * *Chair* – *Barwon Health Chief Medical Officer (or delegate)*
   * Director of Research
   * Director of the Adrian Costa Clinical Trials Centre
   * Research Ethics Governance and Integrity Unit Manager (ex officio)
   * General Counsel
   * Representation from Clinical Trials Advisory Committee
   * Assistant to the Director of Research (Secretary)
2. Members may delegate a proxy to attend meetings of the Research Management Committee in their absence.
3. Members are deemed to have resigned from the Research Management Committee on their resignation from the position on which their membership is based.
4. Guests may be invited by the Chair or Director of Research to attend meetings of the Research Management Committee.

# OPERATIONAL PROCEDURES

## Meetings

1. The Research Management Committee shall meet at least every 2 weeks and more often if required
2. A meeting quorum is at least 50% of members in attendance.
3. A register of interests will be kept and updated as necessary at each meeting as a standing agenda item.
4. Proposals will be accompanied by a briefing paper and a checklist of issues to be prepared by REGI, that have been considered by the investigator or other party proposing the project
5. Sponsors of projects will be invited to present their proposal in person to permit the committee to seek further information in a timely fashion and enhance the committee’s understanding of the project

## Agenda and Minutes

1. Meeting documentation, including the agenda, minutes of the previous meeting and other relevant documents, will be distributed to the committee members and attendees 2 (two) working days prior to next meeting.
2. The proceedings of all meetings will be minuted to reflect the work done by the Research Management Committee. These minutes will be endorsed by the committee at the following meeting.
3. A copy of all agendas and minutes will be presented to the Barwon Health Executive
4. The Research Management Committee shall provide an annual report of the committee to the Barwon Health CEO and the Board, including a review of the committee Terms of Reference.

## Accountability

The Barwon Health Research Management Committee will report through the Barwon Health Executive to the Chief Executive Officer

The committee will endeavour to make a decision on each proposal at the first meeting at which it is presented. This is dependent on being provided with the necessary information to inform that decision.

Aligned committees / specialist groups

The BH Research Management Committee may create other sub-committees or working parties as deemed necessary.

Conflict of Interest

All members shall be required to declare any actual, apparent or potential conflict of interest. Conflicts of interest should be documented using the [Disclosure of a Related Conflict of Interest Form.](http://system.prompt.org.au/Download/Document.aspx?id=14457829&code=EC3DA105117CA075EB4F81D9E9B7A4DD) Members must not place themselves in situations that might force them to choose between their personal or financial interests and those of Barwon Health.

Confidential & Private Information

In accordance with the Barwon Health Privacy, Confidentiality and Security Agreement, all persons, including Barwon Health employees, non-Barwon Health researchers, contractors, volunteers, students and partner organisations must ensure that the affairs of Barwon Health, its patients, clients, residents and staff, remain private, secure and strictly confidential and are not divulged to any third party, except where required for clinical purposes or by law.

Key Aligned Documents

[Barwon Health Strategic Plan](https://www.barwonhealth.org.au/about-us/publications/strategic-plans)

[Safety and Quality Clinical Trial Governance Framework](https://www.safetyandquality.gov.au/standards/clinical-trials)

[National Statement on Ethical Conduct in Research](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)

[Australian Code for Responsible Conduct of Research](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)

[Privacy Confidentiality and Security Agreement Brochure](http://system.prompt.org.au/Download/Document.aspx?id=14207461&code=CEBBD2FF831A13E9DA75C15436347B55), PROMPT: Barwon Health \ Knowledge and Information Services \ HIS

Complaints procedures in research

Barwon Health Staff Code of Conduct