Barwon Health Mission 2010-20

With our consumers at the forefront, we accomplish excellent and efficient care, education & research to advance health and wellbeing for all.

Alignment:

Our Consumers at the Forefront	Our People at their Best	Right Care, Right Time, Right Place	Research & Education for Excellence	Our Community's Wellbeing

Strategic Priorities

Our people at their best

- Living the values in every action and interaction
- Well-informed and consulted when decisions are made

Right care, right time

- Quality and Safety to the highest standard, all day, everyday

Research & Education for excellence

- Excel in population and preventative health research

Our community's wellbeing

- Understanding the health literacy profile of the community to address differences in access, self-management and engagement.

Health Service Standards

- National Safety and Quality Health Service Standards

Strategic Risk

Research No. 383

The Barwon Health Human Research Ethics Committee (BH HREC)

1. Purpose

The Human Research Ethics Committee will carry out the functions of an institutional ethics committee consistent with those set out in the NHMRC *National Statement on Ethical Conduct in Human Research* (2007) (NS) and its successor. The BH HREC will ensure that human research undertaken at Barwon Health and affiliated institutions conforms to the highest ethical standards and conforms to the statutory requirements of State and Federal legislation.

2. Terms of Reference

The BH HREC 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 records of all applications for ethical approval of research and include an identification number, a clinical trial registration number compliant with ICMJE requirements, the principal investigator(s) details, date of ethical approval/non-approval, review date(s) and a copy of the final approved version of all project documents.
- 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 BH HREC records.
- Maintain a professional secretariat.
- Consider research proposals from non-affiliate researchers and institutions.

2.1

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.

2.2 Sub-Committees

To assist the HREC in its work, the following standing sub-committees continually exist to provide advice, recommendations and/or decisions:

- Research Review Committee.
- Drug & Safety Sub Committee.

In addition, the HREC may create other sub-committees or working parties as deemed necessary. The workings of these sub-committees are attached as Appendix to this document.

- Review of Low/Negligible Risk Research.

The HREC (through its Secretariat) shall establish procedures for the review of Low/Negligible Risk Research.

3. Key Performance Indicators

3.1 Timelines

- The time taken to review and / or approve research protocols and associated documents is at the discretion of the Chair/Spokesperson, but must remain as short as possible.
- Members of the HREC, the HREC chair and REGI are jointly responsible for ensuring that efficient and timely review of research is carried out.
- Distribution of the BH HREC agenda will occur within 5 working days of the application closing date to provide members a minimum of 5 working days to consider the meeting documents.
- Decisions will be recorded in the minutes which will be completed and circulated to the Chair and HREC for approval within 5 working days of the meeting.
- The investigator will also be notified in writing of the HREC decision within 5 working days of the meeting.
- All additional documents that are submitted for review and approval outside of session, including protocol amendments, annual review forms and other documentation, should be actioned within 5 days of receipt.

3.2 Compliance

- The 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 Records Act 2001 (Vic);
- State and National Privacy legislation and guidelines;
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments. (July 2000);
- Guardianship & Administration Act 1986 (Vic);
- Medical Treatment Act 1988 (Vic);
- Other statutes that have relevance to ethical considerations are not offended in the research practices and policies of Barwon Health.
- Ideally, a maximum 60 day review time for standard applications submitted for ethical review.

4. Membership

The BH HREC will maintain a minimum membership of:

- A Chair and Deputy Chair; and
- At least eight members (of gender balance) as per the National Statement, including:
- A lay man
- A lay woman
- A member of a community who performs a pastoral care role
- 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
- At least one person, with knowledge of, and current experience in, the professional care, counselling or treatment of people.
- The Committee may seek advice or assistance from other person/s, with relevant expertise related to a particular project. Further persons may be appointed to a maximum of 20.

In attendance at least one of the following:

- Manager, Research Ethics, Governance & Integrity Unit, Barwon Health;
- Research Ethics Officer;
- Research Governance Officer;
- Secretariat to the Human Research Ethics Committee.

5. Terms of Appointment

Barwon Health shall appoint the Chairperson and members to the BH HREC.
Members shall be appointed for a term of three years and remain eligible for reappointment for subsequent term/s as applicable.

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

- Members are requested to provide reasonable notice (preferably at the prior meeting, 4 weeks earlier) prior to non-attendance at a meeting. Should this not be possible, members should expect to receive all the relevant meeting papers and take the opportunity to contribute their views so that these can be recorded and considered (as per Section 5.2.30 of the *National Statement*).
- Members who are not staff members of Barwon Health may be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined from time to time by Barwon Health.
- Committee members are required to adhere to the organisational standards on privacy and confidentiality.

6. Quorum

A quorum shall consist of the core positions plus Chair (eight members). If the one of the core members is not present, the Chair must be satisfied that this member has 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*). Where more than one core member is not present the Chair must be satisfied that all core members have had the opportunity to contribute their views and that there is adequate representation at the meeting.

7. Frequency of Meetings

The BH will meet once per month, at least ten times per calendar year. A listing of all proposed meetings will be publicly available on the REGI web site.

8. Administrative Support

Administrative support shall be provided by the Barwon Health Research Ethics Governance and Integrity Unit (REGI) , which shall be responsible for notifying each meeting; providing an agenda at least five working days before the meeting; recording the minutes; circulating the minutes within two weeks of the meeting; and providing written correspondence to applicants.

REGI will be responsible for ensuring meetings are effectively organised and accurately recorded in the minutes

- Maintaining records and effective administration.
- Upholding the legal requirements where relevant.
- Managing communication and correspondence.
- Establishing, implementing and documenting its working procedures.
- The administrative management of Institutional Policies and Procedures, and any other administrative function required by the HREC and/or institution.

9. Reporting

The BH HREC will report to the Barwon Health Board of Directors through the Chief Executive Officer and the compilation of an annual report.

The Human Research Ethics Committee 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).

The Human Research Ethics Committee shall report annually to the Health Services Commissioner of Victoria studies involving reliance on Privacy Principles.

10. Accountability

Within Barwon Health, the HREC is accountable to the Barwon Health Board of Directors through the Chief Executive Officer via the Teaching, Training and Research Governance Committee (TTRGC).

For non-Barwon Health aligned researchers, the ethical review is provided on the basis that the site responsibilities are assumed by that site and not Barwon Health.

11. Revision Date

The Terms of Reference will be reviewed every three years or earlier if required by REGI and the Director of Research.

12. Confidentiality

All matters and activities of BH HREC are to be treated as confidential at all times.

13. Indemnification

Members of HREC, be they employees or volunteers are covered under both the Public Liability and Professional Indemnity Policy of Barwon Health, in respect of liabilities that may arise in the course of the conduct of HREC members' duties.

14. Aligned committees / specialist groups

Listed as Appendix

Appendix

15. The Research Review Committee (RRC)

15.1 Role

The Research Review Committee, (RRC), is a 'Virtual' standing sub-committee of the Human Research Ethics Committee ("HREC" or "The Committee").

- The RRC is a virtual committee and reviews applications out of session.
- At least two reviewers are allocated to the review of each application.
- Where necessary a formal meeting can be scheduled. Items for the RRC are listed as item 4.3 on the monthly HREC agenda as a standing item.

- The purpose of the RRC is

  1. To review all high risk research projects for scientific merit, methodological integrity and to make recommendations to the HREC.

  2. To review low risk applications that have requested expedited review.

- The HREC delegates the authority to the RRC to approve low risk projects that are submitted for expedited review.
- Projects for expedited review will be assessed by the RRC for both scientific merit and compliance with ethics guidelines.
- Projects for expedited review that are approved through RRC will be ratified at the next HREC meeting.
- All other low risk project will proceed to the HREC after scientific review.

The RRC will consider the risk associated with each research project prior to HREC review. It may:

- Determine that a project is low risk and give RRC approval (for HREC ratification).

- Determine that a project as low risk and give conditional RRC approval contingent on conditions to be met (for HREC ratification).
- Determine that a project as greater than low risk and recommend full HREC review.
- Recommend that an investigator be present at the HREC meeting to present/discuss a research project.
- Determine that a project does not have scientific merit or validity and is not approved.
- Determine that a low risk project does not comply with ethics guidelines and is not approved.

15.2 Membership

- The Chair of the RRC may determine that a formal meeting of the RRC is required.
- The Core membership of the RRC will include a minimum of 8 (eight) members, including a chairperson.
- At least three members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (e.g. health, medical, social, psychological, epidemiological, as appropriate).
- At least three members with knowledge of, and current experience in, the professional care, counseling or treatment of people (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate).
- At least one member of the senior administration;
- Pharmacy representation and;
- Representation from the Research Ethics Governance and Integrity Unit (REGI).
- A quorum shall consist of half the membership including the Chair.

16. The Research Drug & Safety Sub Committee

16.1 Role

- The Drug & Safety Sub Committee ("the Sub Committee") is a standing subcommittee of the Human Research Ethics Committee ("HREC" or "The Committee").
- The Drug & Safety Sub Committee meets monthly and is listed as item 6 on the monthly HREC agenda as a standing item.

The primary purpose of the Sub Committee is to inform the full HREC on matters relating to safety of a project which is currently approved under the Barwon Health HREC in keeping with advice from the Australian Health Ethics Committee (AHEC) Position Statement 2009 or its successor.

This includes the review and reporting on:

- AEs or SAEs involving projects under the auspices of Barwon Health.
- Information which materially impacts the continued ethical acceptability of a project.
- Updates of Safety Monitoring Information such as Investigator Brochures and other reports consistent with section 5.5.5 of the *NS Good Clinical Practice (GCP)* as adopted by the *Therapeutic Goods Administration (TGA).*

The Sub Committee may

- Recommend that the item does not compromise the HREC approval of the project.
- Recommend further clarification.
- Recommend that the item requires review by the full HREC.

16.2 Membership

The chair of the subcommittee is appointed by the HREC Chair from the section *Membership* of *the* Terms of Reference for the Human Research Ethics Committee as follows :

- One Pharmacist, who has in depth knowledge of clinical trials, who shall be Chair and who shall engage additional members as required.

Key Legislation, Acts & Standards

The National Statement on Ethical Conduct in Human Research (2007) (Updated March 2014)
The Australian Code for the Responsible Conduct of Research.

Key Aligned Documents

Barwon Health Human Research Ethics Committee Operating Procedures

Conflict of Interest Policy, PROMPT: Barwon Health \ Organisational Services \ Barwon Health Board of Directors

Disclosure of a Conflict of Interest Form, PROMPT: Barwon Health \ Ethics & Research \ Research

Privacy Confidentiality and Security Agreement Brochure, PROMPT: Barwon Health \ Knowledge and Information Services \ HIS