

KEY PERFORMANCE INDICATORS FOR BARWON HEALTH HUMAN RESEARCH ETHICS COMMITTEE MEMBERS



Key Performance Indicators (KPIs) for Barwon Health Human Research Ethics Committee Members (BH HREC)¹

The following is a list of KPIs that describe Barwon Health's expectations of all Human Research Ethics Committee members. The performance of the HREC is expected to benchmark against best practice and will be reviewed by the Chair of the HREC, the HREC Secretariat, and the Director of Research periodically and at the end of their terms of appointment.

General KPIs

All BH HREC members are expected to:

- Attend record at monthly meetings
 - In the event of inability to attend, apologies lodged with sufficient notice to arrange for attendance by alternative member to ensure that quorum members who cannot attend will provide written comments prior to the meeting
- Attend professional development seminars, education sessions and training opportunities made available to HREC members
- Prepare adequately for meetings evidenced by
 - Knowledge of the research proposals for review including the formulation of questions
 - Participation in discussions during meetings
- Be available for communication with researchers and the HREC Secretariat outside of meeting times
- Maintain an interest in ethical issues relevant to health research
- Ensure the confidentiality of all HREC business; which should not be used, copied disclosed, reproduced or made public.

¹ Adapted with thanks from Monash Health KPIs for HREC

Chairperson of Barwon Health Human Research Ethics Committee

A. HREC Meeting and Deliberation²

An HREC Chair has a central role and the responsibility to ensure that

- All members have fair opportunity to contribute
- There is comprehensive attention to all issues raised by research proposals
- Discussions and decisions are guided by the National Statement and other relevant guidelines

Introducing Projects

A Chair may choose to introduce research projects and identify the issues for deliberation. Alternatively the chair may prefer to facilitate the discussion lead by a HREC lead discussant/reviewer.

Scientific/Methodological Advice

The Chair should ensure that there is sufficient clarification and discussion of scientific or methodological advice provided by an advisory sub-committee, external expert or HREC lead discussant/reviewer.

Policy

The Chair needs to remain aware of prior policy determinations and be willing to decide when referral to an ethics advisory committee or expert advice is appropriate.

Members' Contributions

Paragraph 5.2.29 of the National Statement requires that HREC decisions are informed by an exchange of opinions from each of the members who constitute the minimum membership. Different means can be employed by the Chair to ensure that all HREC members have an opportunity to, and do, contribute to the discussion of ethical issues in research applications.

Where there is less than full attendance of the minimum membership at a meeting, the Chair has a specific responsibility to be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered. (National Statement paragraphs 5.2.30)

B. The Chair's Responsibilities³

The Chair will have the following responsibilities:

1. The Chair must not have other responsibilities that will impair the HREC's capacity to fulfil the obligations under the National Statement and fulfil roles and carry out the functions set out in the HREC Terms of Reference.
2. The Chair will ensure that HREC decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of written notes from members who cannot be present (NS 5.2.29-30).

² *Human Research Ethics Review in Victoria: Developing Best Practice in Human Research Ethics Review* (April 2012, Houston Thomson Pty Limited) ("HREC Best Practice") Page 37

³ Page 11, HREC Best Practice,

3. The HREC should endeavour to reach decisions by general agreement (which need not involve unanimity, NS 5.1.31) and to this end the Chair will:

- Engage with all members
- Facilitate the expression of opinion from all members
- Identify points of agreement and disagreement
- Judge when a sufficient degree of general agreement has been reached

4. The Chair is responsible for guiding the manner in which the HREC communicates with investigators (NS 5.2.13-14, 5.2.22) and the decisions about inviting investigators to attend HREC meetings (NS 5.2.18).

C. Toward Best Practice in HREC Decision Making⁴

Role of the HREC Chair

Final Decision

Reaching a final decision in situations of full attendance involves:

- Checking with each HREC member for a final comment
- Providing a final summation of the elements of the decision

Decisions must be clearly articulated to HREC members and to administration staff who will record the decisions for communication to investigators.

Communication to Researchers

The Chair will summarise the committee's questions, instructions, advice and decisions for the administration staff in a manner such that these can be clearly communicated to researchers.

Responses from Researchers and Final Approval

Where the HREC determines that researchers are required to provide additional information or revisions, the Chair is responsible for ensuring that each of the following elements is established for each project and each decision:

- Which member(s) of the HREC will review responses from researchers
- Who will decide on the adequacy of the researchers' responses
- How a final decision will be reached and communicated about whether the project is approved

D. Key Attributes of a HREC Chair

The HREC Chair should:

- Have a thorough knowledge of the *National Statement on Ethical Conduct in Human Research* (2007, NHMRC)
- Consider and decide on whether the committee is sufficiently informed on all aspects of research protocols
- Oversee arrangements for meetings and verifying the minutes from meetings within 7 days of receipt
- Ensure that all views of absent minimum members have been received and considered
- Preside over decision-making
- Seek advice from experts
- Monitor conflicts of interest of HREC members or researchers

⁴ Page 47, HREC Best Practice

- Oversee recording of decisions
- Be capable of dealing with any complaints⁵
- Assist with review of:
 - Protocol violations
 - Substantive protocol amendments
 - Progress and final reports
 - Expedited review
 - Other business outside of the HREC meeting schedule as deemed appropriate by the Manager, HREC, in accordance with the *Human Research Ethics Review in Victoria: Developing Best Practice in Human Research Ethics Review*
- Represent the HREC within the institution and in discussions with researchers and other HRECs externally
- Assist with the certification process for both the Victorian and National Certification of Human Research Ethics Committees.

Lawyer Member of the BH HREC

The lawyer member should:

- Hold a Bachelor of Laws and be admitted to practise as a solicitor and barrister but need not be currently in legal practice
- Advise the committee on legal implications of research considered or decisions taken and whether formal legal advice is necessary
- Have a record of exercising good judgment and experience in dealing with people
- Be interested in the ethics of research
- Have knowledge of, or an ability to, familiarise him/herself with the relevant State and Commonwealth laws pertaining to biomedical research
- Be aware of the limitations of the law in many aspects of medical research

Health Care Professional Member of the BH HREC (Person with knowledge of, and current experience in, the professional care of people, counselling or treatment of people e.g. nurse or allied health professional)

Medical practitioners, nurses and/or allied health professionals play a key role in hospital HRECs. The HREC member in this category will possess the following attributes:

- Both formal qualifications to practise in Australia and practical experience in their respective discipline
- Has an insight into the possible impact of research with patients at Barwon Health
- Be readily available to the Chair, the HREC secretariat or researchers for informal consultation
- Possess research expertise (preferable)

Lay Member of the BH HREC

A lay member will:

- Be independent from the institution and not be involved in medical, scientific or legal work
- Focus specifically on the welfare of research participants
- Represent community standards

⁵ Human Research Ethics Handbook, NHMRC (2002)

- Be confident in presenting his/her viewpoint
- Have a broad interest in health, medical and scientific issues

Medical Researcher Member of the BH HREC (Person with current research experience that is relevant to research proposals to be considered by the committee)

The medical research member will possess the following attributes:

- An ability to identify appropriate scientific and research methodology requirements in proposals
- An ability to understand and comment on issues of scientific merit and a firm grounding in research methods
- An ability to identify if external advice is required

Minister of Religion Member of the BH HREC

At Barwon Health, it may be appropriate to appoint a Buddhist monk, Christian minister, a Jewish rabbi, or an Islamic Imam given the diverse multicultural community that is treated in this region.

A minister of religion will possess the following attributes:

- An ability to identify pastoral and moral issues in the research submissions
- Be experienced in pastoral care and mixing widely throughout the community
- An ability to understand the views of people from a range of differing cultural backgrounds
- Be a minister within the community that the institution serves