

Background

Bellberry Limited is a private, not-for-profit company created in 2004 to address the need for a Human Research Ethics Committee (HREC) to service the private sector. Bellberry now has twelve professionally managed HRECs that review and monitor human research proposals from any interested institutions or researchers. Bellberry makes a case-by-case decision on whether its HRECs can and will review any study based on the expertise of HREC members and their capacity to conduct the review in necessary timeframes.

The HRECs are unaffiliated and non-institutional based. They are registered with the National Health and Medical Research Council (NHMRC) and constituted under its National Statement on Ethical Conduct in Human Research.

Bellberry charges fees to conduct its reviews. Any funds surplus to operational costs are directed back to the Australian health research community.

Purpose

This document outlines the scope of the Bellberry Human Research Ethics Committees.

HREC objectives

Each HREC exists to:

- provide independent, competent and timely review and monitoring of research projects
- ensure that all research projects are reviewed in accordance with the National Statement on Ethical Conduct in Human Research (2007), incorporating all updates
- ensure that researchers involved in any research project approved by Bellberry know they must conduct their studies according to the Declaration of Helsinki ethical principles and in a manner consistent with good clinical practice and all applicable regulatory requirements
- protect the welfare, dignity, rights, safety and well-being of all participants in the research projects it reviews.

HREC functions

Bellberry HRECs assess proposals submitted to them to identify whether they meet the National Statement principles:

- respect for human beings and their welfare
- research merit and integrity
- justice.

The HREC will consider the scientific validity of research projects.

HREC member responsibilities

Bellberry HREC members and operational staff are responsible for maintaining familiarity with Bellberry's policies, guidance, processes and procedures, the National Statement on Ethical Conduct in Human Research (2007) and all updates, and other relevant guidelines. All submissions, deliberations and decisions are handled in strict confidence.

Bellberry's operational staff will ensure that all relevant policies, guidelines and procedures are available on the Bellberry website and internally via electronic systems.

The HREC can delegate low-risk research proposals to a subcommittee to expedite research that poses low or negligible risk to participants. The HREC will be responsible for the activities and recommendations of any subcommittee.

The HREC may request the advice of an expert to help assess an application.

The HREC will monitor research projects to ensure they continue to conform to the conditions of approval.

The HREC may delegate authority to the chair or to a subcommittee comprised of members with specific expertise.

The HREC will reach decisions by consensus (NHMRC National Statement Section 5.2.33).

Chair responsibilities

The chair of any Bellberry HREC will:

- lead the HREC and provide vision to meet its stated objectives
- direct discussions to effectively use the time available to review research proposals
- ensure minutes accurately reflect the committee's decisions.

HREC officer responsibilities

HREC officers are responsible for:

- the circulation of the HREC agenda, along with all required proposal documentation, no less than 12 calendar days before a meeting,
- the maintenance of minutes as a formal record of each meeting. The minutes will identify decisions and be formally accepted as correct at the following meeting,
- the circulation of the HREC minutes no more than two days after a meeting,
- where relevant, ensuring any objections to consensus decisions are formally documented.

Accountability of the Bellberry HREC

The Bellberry HRECs are accountable to the Chief Executive Officer (CEO).

Reports on activity and procedural changes will be provided to the NHRMC annually or as required, and include:

- membership/membership changes,
- the number of meetings held each year,
- the numbers of protocols presented, approved and rejected,
- monitoring procedures in place and any problems encountered,
- complaints procedures and the number of complaints received.

Bellberry has written policies, guidelines and procedures to ensure all approved research meets National Standards. Terms of reference, policies, guidelines and standard operating procedures are publicly available at www.bellberry.com.au.

To support the separation of executive functions and the Committees, the CEO will not attend HREC meetings. The operations manager and committee manager will regularly attend HREC meetings and provide minutes and reports to the CEO.

The HRECs may bring issues of significant concern to the CEO.

The CEO will provide regular reports to the Board.

Committee membership

Each HREC will consist of at least eight members, with equal numbers of men and women as far as possible, in accordance with the National Statement Section 5.1.29 & 5.1.31.

Membership will include:

- a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement
- b) at least two lay people, one man and one woman, who have no affiliation with Bellberry and are not currently engaged in medical, scientific, legal or academic work
- c) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional
- d) at least one person who performs a pastoral care role in a community; for example, an Aboriginal elder or a minister of religion
- e) at least one lawyer; where possible, one who is not engaged to advise Bellberry
- f) at least two people with current research experience relevant to the research proposals being 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.

As per NS 5.1.31, no member may be appointed according to more than one of the categories listed above.

Members are appointed to an HREC using open and transparent processes in accordance with the National Statement Section 5.1.34.

Each member shall receive a formal notice of appointment and an assurance that Bellberry will provide legal protection for their activity as a member of the relevant committee.

Each Bellberry HREC maintains a core group of members appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion, as per the National Statement Section 5.1.35. Each member shall be required to sign a confidentiality agreement and conflict of interest statement. In addition, each member is required to declare all conflicts and affiliations upon identification that a conflict exists. Any member with an affiliation to the proposed research/and or research institution under consideration will not be allocated to review the application.

Members shall attempt to attend all scheduled meetings. Where a member is absent for a meeting, they will provide an apology to the committee manager or committee chair as early as possible before the meeting. Where necessary a proxy member will attend the meeting to ensure quorum requirements are met, in accordance with National Statement 5.2.28. Should a proxy member not be available, the absent member should expect to receive all the relevant meeting papers and take the opportunity to contribute their views for recording and consideration (NHMRC National Statement 5.2.32).

Members are appointed for three-year terms. A member may be reappointed for an additional term or terms with the agreement of the CEO and HREC chairs.

For NHMRC-certified HRECs, at least half of the members appointed in the minimum membership categories, listed above, must have two or more years of HREC membership experience.

Member education

HREC members and support staff are provided opportunities to attend in-house and external training and continuing education. To comply with the NHMRC certification assessment, members must be able to provide the Bellberry committee manager with evidence of ongoing training. The committee manager is responsible for managing:

- a record of in-house and external training for HREC members from the past two years,
- a record of in-house and external training for institutional administrative HREC support staff.

Member remuneration

Bellberry HREC members are remunerated.

Administrative support

Bellberry provides administrative support for its HRECs and HREC chairs.

Observers may be present by invitation. The HREC chair will be informed of observer attendance.

Quorum

As per the National Statement Section 5.2.30, as far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend. Where there is less than full attendance at a meeting, the chairperson should 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 5.2.32).

If the quorum is lost during the meeting, decisions will be finalised out of session.

Provision of member details

Bellberry does not issue the names of individual HREC members to external parties. Member Listing is attached in eProtocol to each study on approval. Listing provides details of the number of members present in each category of membership, their area of speciality and qualification/s (where relevant).

Insurance

HREC members are covered under the Bellberry public liability and professional indemnity policies in respect to liabilities that may arise in the course of the conduct of their duties.

Revision

The HREC terms of reference will be reviewed annually by the Bellberry CEO or delegate.

References

[National Statement on Ethical Conduct in Human Research \(2007 incorporating all updates\)](#)

[National Certification Handbook](#)

Bellberry Ltd Constitution