

## 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 \(2023\)](#).

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 \(2023\)](#), 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,
- beneficence.

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 \(2023\)](#), 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 lower risk research proposals to a Sub-Committee to expedite research that poses low or minimal risk to participants.

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 Sub-Committee comprised of Members with specific expertise.

The HREC will reach decisions by consensus ([NHMRC National Statement](#) Section 5.2.8).

### **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](http://www.bellberry.com.au).

To support the separation of executive functions and the Committees, the CEO will not attend HREC meetings. The Director of Operations and Member 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 diversity, including gender diversity, as far as practicable, as per the [National Statement](#) Section 5.1.30 & 5.1.36.

Membership will include:

- a) 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](#).
- b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution.
- c) 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.
- d) 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.
- e) 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; and, 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 individual may represent more than one of the categories listed in 5.1.30 at any individual meeting, but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting.

Members are appointed to an HREC using open and transparent processes in accordance with the [National Statement](#) Section 5.1.40.

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 5.1.41. 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, in order that they are appropriately managed. Any Member with an affiliation to the proposed research 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 Member 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](#) 5.2.3 (b). 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](#) 5.2.4-5).

Members are appointed for one, two or three-year terms. A Member may be reappointed for an additional term or terms with the agreement of the Member Manager in consultation with the Director of Operations, 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 Member Manager with evidence of ongoing training.

The Member Manager is responsible for managing:

- a record of in-house and external training for HREC members,

The Training Lead is responsible for managing:

- 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 5.2.3](#), as far as is practicable, each HREC meeting should be arranged to enable attendance of all members of the minimum membership categories and other relevant appointed members, either in person or via available technology, for example videoconference. Where there is less than full attendance at a meeting, the Chairperson must 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 5.2.5](#)).

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 subsequent to finalisation of ethical review by the HREC. Listing provides details of the number of members present in each category of membership, their area of speciality and qualification/s (where relevant). Any persons wishing to contact a Bellberry HREC Chair or other member regarding research reviews undertaken by Bellberry must do so via the Bellberry administration. The administration team will then direct the query to the appropriate person.

### 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 \(2023\)](#)

[National Certification Handbook](#)

Bellberry Ltd Constitution