



HREC Chairs

Bellberry takes great care in selecting its HREC Chairs ensuring each has relevant background knowledge, expertise and confidence to manage a Committee.

Our Chairs are well versed in Bellberry's **health research policy and procedures**, and contribute to our consistent approach through attendance and input at our policy meetings.

The Chairs ensure participation by all members at meetings and that matters are dealt with in an orderly and efficient manner with complex discussion and opinion culminating in a conclusion.

- **Committee A** – A/Professor Brian Stoffell, Head of the Social Health Sciences Unit, Chair of Student Affairs School of Health Sciences and Director, Health Ethics Unit (FMC) at Flinders University.
- **Committee B** – Emeritus Professor James Toouli, Faculty of Health Sciences, Discipline of Surgery, Flinders University.
- **Committee C** – Dr Michael James, Research Officer, Rheumatology Unit, Royal Adelaide Hospital.
- **Committee D** – A/Professor Barry Chatterton, Associate Professor within the Discipline of Medicine at University of Adelaide and Physician in Nuclear Medicine, Dr Jones and Partners, Adelaide.
- **Committee E** – Dr Jeff Karrasch, Consultant Physician, Holy Spirit Northside Hospital and North West Private Hospitals, Brisbane.
- **Committee F** – Professor Annette Braunack-Mayer, Head, School of Health and Society, University of Wollongong.
- **Committee G** – Professor Ben Canny, Head of Medicine at University of Tasmania, responsible for the Divisions of Medicine, Pharmacy, Psychology and Paramedicine.
- **Committee H** – Associate Professor Mark Slee, Senior Consultant Neurologist and clinical academic at Flinders Medical Centre and Flinders University.

Members

- Bellberry manages a group of paid professional members.
- Each of our Committees are supported by a core group of dedicated community, legal and pastoral care representatives. Science/medical and 'professional care' representatives are drawn from a pool of experts on a meeting by meeting basis. This ensures the right expertise is present at each meeting.
- Our Committees also usually exceed the minimum membership requirements as described by the [NHMRC's National Statement](#).
- Bellberry Committees generally increase members in both the (c) and (f) categories at any given meeting. Phase 1 studies are given special consideration including a review by a pharmacologist.

Orientation

All new HREC Members undergo a thorough orientation before commencing on a Committee.

During orientation they are informed of the history of HRECs, the Nuremberg trials and other historical injustices such as the Tuskegee experiment as well as more recent examples.

The National Statement on Ethical Conduct in Human Research 2007, Australian Code for the Responsible Conduct of Research 2007, CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), Australian Therapeutic Goods Administration, European Medicines Agency and United States Food and Drug Administration are all discussed as relevant and important information to their roles.

New Committee Members are given the opportunity to attend a meeting as an observer prior to their commencement, which enables them to see a Committee in action. This assists with the resolution of any queries prior to them becoming a fully-fledged Committee Member.

Clinical Research Education

Bellberry runs a comprehensive health research education program for its Committee Members.

This includes evening sessions with invited speakers, support to attend conferences, seminars and participation in online education programs.

Our Members also have the opportunity to attend a two day workshop covering a variety of topics. All sessions and workshops are presented by highly qualified members of the research industry.

This **comprehensive education program** ensures our Committee Members remain educated on contemporary matters within the human research industry and principles to assist their thinking and decision making when reviewing human research proposals.

Committee Management

Bellberry recognises the importance of quality systems and processes to help ensure our Committees comply with relevant legislation, guidelines and policies and provide a seamless and consistent service to our customers.

The importance of consistent decision making and compliance with our policies and procedures by all Committees is paramount.

In recognition of the importance of this task, we appointed a Committee Manager in 2009 responsible for the effective coordination, function and management of the Committees. The manager or delegate attends each meeting to ensure a consistent approach by all Committees.

Policy Meetings

To assist further with a consistent approach, should matters of difference arise between Committees, the Committee Manager brings these to the policy meeting.

Each Chair and Committee representatives meet on a regular basis to determine the best approach on matters of difference and arrive at a policy position for the Committees.

Health Research Investigators

More than 200 Australian organisations involved in human research are registered with Bellberry.

Investigators are invited to attend our Committee meetings to present their clinical research and studies either in person or via teleconferencing facilities. Bellberry reviews the curriculum vitae of all Principal Investigators and Co investigators involved in the clinical study ensuring their experience is relevant to the area of research being conducted.

If the Committee has any concerns in this regard it will contact the Investigator to determine the level of supervision and assistance that will be provided.

If the Committee remains dissatisfied it will either request the inclusion of an experienced Investigator or will not approve the study.

Relevant credentials are also checked at this time, for example, medical registration ensuring it is current and there are no restrictions placed on the person's practice.

Insurance and Indemnity

As required by the National Statement, Bellberry Limited accepts legal responsibility for the decisions and advice of the Committees and indemnifies Committee Members against any potential costs.

The Company appropriately has a professional indemnity insurance policy to provide financial support for this indemnity. The National Statement on Ethical Conduct in Human Research 2007 (National Statement) s 5.1.9 states that "*Institutions should provide an assurance of legal protection to all those involved in ethical review of human research, for liabilities that may arise in the course of bona fide conduct of their duties in this capacity*".

Before approving a clinical trial Bellberry must be satisfied that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of their participation.

Bellberry ensures any person or organisation who has involvement in the research, and are therefore exposed to potential liabilities, are covered by an adequate insurance policy before final approval of any study will be given. Bellberry ensures both the sponsor of the study and the Principal Investigator have adequate insurance cover before clinical trial approval is finalised.

Co investigators are also required to have personal insurance cover. Any gaps in any cover must be covered by the Investigator's professional indemnity cover.

Please [contact the Bellberry office](#) for further information about any aspect of insurance related to clinical trials reviewed by Bellberry.

Communication between Health Researchers and Human Research Ethics Committees

Bellberry HRECs aim to develop sound relationships with medical researchers and relevant organisations.

In this respect all dealings will be conducted in an honest and open manner along with the provision of appropriate documentation to ensure effective communication and information flow. Relevant information will not be withheld.

Bellberry HRECs anticipate that researchers will also act in this manner. Bellberry invites medical researchers to attend meetings in person or via telephone conference and our friendly and committed staff are always readily available to assist with any enquiry.

If at times a Bellberry HREC does not meet customer expectations please follow the [complaints process](#).