#### What is Bellberry?

Bellberry Limited is a national, private Not-For-Profit organisation providing streamlined scientific and ethical review of human research projects across Australia.

Our aim is to promote and improve the welfare of research participants, and the quality, efficiency and effectiveness of research. Bellberry donates surplus funds back into the research community.

# Bb Bellberry Limited supporting research and ethics

### **About Bellberry HRECs**

NHMRC certified, and recognised in the McKeon review as a Best Practice example, Bellberry Human Research Ethics Committees (HREC) are professionally managed and operate 24/7 through a dedicated electronic portal providing a paperless and secure HREC process.

We currently run 8 HRECs who each meet once a month on a Wednesday evening. Medical/science members, per National Statement 5.1.30 (c) & (f), rotate through the committees depending on the meeting agenda and the type of expertise required. There is no requirement to attend a regular meeting, and attendance is based on Bellberry need and member's availability. Bellberry HREC members are paid.

Proposals are available to review 12 calendar days prior to a meeting. Post meeting matters are required to be dealt with promptly within a 48 hour period.

Our online software program enables members to access all relevant documents and investigator and committee correspondence via the web. Interstate members join meetings via teleconference.

Meetings commence at 6.15pm and generally finish anywhere between 8.3opm and 10.3opm depending on the number of studies reviewed and their complexity.

Bellberry supports the education and professional development of HREC members. Initial induction training is provided to all new HREC members. On-going education is provided with access to internal events and support for attendance at external events.

## Becoming a Medical/Science HREC Member

Knowledge and experience favourably considered:

- Knowledge and understanding of scientific and methodological requirements of research projects
- Recent or current involvement in conducting research, particularly clinical trials relating to drugs or devices, epidemiology or behavioural/social science research
- Knowledge and understanding of the National Statement
- Knowledge and understanding of relevant national and international documents/guidelines relating to clinical research, eg TGA, GMP, EMA, FDA (medical members)
- Understanding of the TGA and how it relates to clinical research (medical members)
- Relevant clinical experience and formal qualification/s to practice in Australia (medical members)
- The ability to communicate well, including the capacity to listen to and appreciate the views of others, to formulate and express a considered opinion
- Sound ICT skills.

Please contact us if you would like further information about Bellberry and our services.

Alternatively, please email your CV, including details of any current or recent research experience for consideration.

Following confidential review by our Chairs and Management team we will contact you to discuss your interest.

#### **Bellberry Human Research Ethics**

Bellberry Limited is a national, private Not-For-Profit organisation providing streamlined scientific and ethical review of human research projects across Australia.

Our focus in the HREC review process is on quality and timeliness of review, and our running average is approximately 20 days turnaround from study submission to review decision.

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There are a number of features of the Bellberry service, which would be available in any form of partnership, outsourcing or external HREC access.

Bellberry operates using an electronic submission process and a dedicated virtual collaboration environment. This enables geographically-disparate Investigators, Sponsors, Institutions and Committee members to interact on each submission, and is used by Bellberry to support swift turnaround. Investigators use the electronic portal not only for initial submission, but for subsequent cycles of questions and answers with the HREC.

The electronic portal also acts as an archive of the ethics review process into the future, and may be used to support regulatory inspections in the case of successful developments. It retains a fully traceable history of the review process, any approval documentation, adverse events, amendments, annual reports and status changes.

Bellberry provides a dedicated Secretariat.

The Bellberry team undertakes pre-submission triage to ensure applications and supporting documentation are in the best possible shape for review by the HREC, and will work with individual Investigators as required to support the review process.

Scientific support is available from Bellberry staff for early feasibility discussions to give guidance around the application process and submission information. This is recognised by the user base as being of particular value to early stage translational projects and also assisting to attract international sponsors new to the Australian Clinical Trials environment.

Submission closing dates occur every Wednesday (except Christmas shutdown). From submission closing, studies are accommodated for HREC review in two weeks.

The average turnaround from submission to review decision is 20 days. This is recognised as setting the standard in the Australian environment, and in conjunction with the CTN scheme provides some of the swiftest start up times in the world.



Bellberry HREC meetings are constituted according to the National Statement. Using a pool of HREC members, each Bellberry HREC is tailored on a meeting-by-meeting basis to have the specific expertise required for the studies submitted. Skills on the roster ensure that quality reviews can be made for projects ranging from clinical studies of pharmaceuticals, devices and techniques, to social science studies.

Bellberry provides a site monitoring service to audit performance against approved study documentation. This is available on a routine or at-cause basis, and provides support to the geographically-independent HREC.

Bellberry has experience in establishing new HRECs, including the recruitment, selection and induction of members, appointment and mentoring of new HREC Chairs. A standardised 12 month HREC initiation plan exists and is available for new HREC locations.

Bellberry hosts a Policy Forum for the cohort of Bellberry HREC Chairs to ensure consistency for all users, regardless of committee. Bellberry provides policy statements and guidelines on a number of key and repeatable features of studies, study submissions and review. This ensures transparency for users, consistency between committees, and reference documents for all concerned.

Bellberry provides education and training support as needed, both for the ethics application process, support for Investigators, and for the electronic ethics system. This can be face-to-face or by webinar.

On-going studies can be transferred to Bellberry for the required ongoing oversight.

Governance processes should also be considered as well as the HREC process. Bellberry can provide further assistance in this space if required.

For more information contact Bellberry Limited 9+61 8 8361 3222 bellberry@bellberry.com.au

www.bellberry.com.au