

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 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

Bellberry was recognised by the 2012 McKeon Review as “setting the benchmark” for Australian HREC review services.

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.

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 comments and responses 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 approximately 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
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www.bellberry.com.au

Bellberry Limited proudly deliver funding from our profits to the Human Research and Ethics sector through our initiatives... “People”, “Projects” and “Direct Action.”

Examples of these initiatives include:



BB NSW Health
Bb Early Phase Clinical Trial
bB Framework
bb

Mission

To develop and implement recommendations that improve the **impact, quality** and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia.

Our mission is to get Australia **Thinking Smarter** about the conduct of clinical trials.

Vision

CT:IQ will act as a platform for all stakeholders to come together and continually improve the clinical trials field in Australia, enabling efficient and effective, patient-centred, clinical trials.

Our Scope

All Clinical Trials and All Stakeholders

The following describe the core types of activity that CT:IQ may undertake:

- Develop consensus recommendations.
- Partner with other Australian organisations.
- Assess and, where appropriate, implement international recommendations.

CT:IQ will

1. Create and implement consensus recommendations to improve clinical trials.
2. Reduce duplication and maximise efficiencies.
3. Advocate for, and include, all clinical trial stakeholders; including patients, participants and the community.
4. Follow a systematic, evidence-based approach from topic selection through to implementation of recommendations.
5. Communicate broadly and in a range of formats to inform all stakeholders.
6. Quantify the impact of the work.

For more information visit www.ctiq.com.au or email info@ctiq.com.au



This venture has received funding through the MTPConnect Project Fund Program – a dollar-for-dollar matched program investing in big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect is supported by the Australian Government Industry Growth Centres Initiative – learn more at mtpconnect.org.au

Under the NSW Health Early Phase Clinical Trial Scheme Bellberry HRECs have been appointed for the review of adult Early Phase Clinical Trial (EPCT) applications that will be conducted at NSW Public Health Organisation (PHO) sites.

For the purposes of this Framework ‘Early Phase’ has been broadly defined as studies up to, but not including, Phase II studies. The NSW EPCT quick reference guide provides further guidance.

NSW PHO EPCT applications are submitted via the Research Ethics Governance Information System (REGIS).

NSW EPCT Bellberry Application Guidance

We encourage you to reach out to the Bellberry team at any time for assistance with your research application.

The Bellberry website has additional resources and guidance regarding Protocol and Participant Information and Consent Form requirements, and useful resources to assist with the EPCT submission process.

At this time NSW Health has excluded adult EPCT from the National Mutual Acceptance (NMA) model, meaning NSW PHO sites cannot accept interstate HREC reviews for adult EPCTs. Bellberry does, however, review multicentre applications, and you can call or email our team to discuss multicentre applications where there are both private and NSW PHO sites.

Investigator Initiated Research

As with all applications, contact us if you require assistance with your application or study documents. A subsidised HREC review fee is available to investigator funded research. Please contact the Bellberry team to discuss this prior to submission.

Observer Process

Senior Executives from NSW PHO sites that are listed on an NSW EPCT HREC application will be invited to attend the review of that specific EPCT HREC meeting as an Observer.

For more information contact

Bellberry Limited

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