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.

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.

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

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.

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NSW Health has appointed Bellberry as a specialist HREC for the review of adult EPCT studies.

Early Phase Clinical Trials (EPCT) will include all types of Phase 0 and I trials (including Phase Ia, Ib, I/II, and any other variant) using either healthy volunteers, volunteer patients and/or patients, including First time in human and First time in patient.

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 and 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 for investigators and site staff as needed for the ethics application process. This can be face to face or by webinar.

**HREC Application & Submission Process**

1. Complete application form; “in-scope” adult EPCT studies submitted to Bellberry
2. Principal Investigator submits application; two HREC meetings held each Wednesday; application required 10 working days prior
3. Application checked for completeness
4. Principal Investigator provided with guidance
5. Not eligible
   - Eligible
   - Study allocated to a HREC meeting; Principal Investigator/site notified in REGIS
   - HREC review performed; Principal Investigator notified of HREC review outcome within 2 working days of HREC meeting
   - Study not approved
   - Ongoing dialogue between Bellberry and Principal Investigator/Site
   - Amendments and notifications will follow a similar process, however, depending on the nature of the amendment or notification, applications may not undergo a full committee review
   - Study approved; Principal Investigator/site notified
   - LHD representatives invited to observe HREC review

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