Purpose

To describe the requirements and responsibilities for the submission of research projects to Bellberry HRECs for ethical and scientific review, as per chapter 5 of the *National Statement on Ethical Conduct in Human Research (2007, incorporating all updates)*.

Definitions

Additional Site: Sites other than the lead site involved in a multi-centre study. Only the sites that will be undergoing Bellberry HREC review are required to be listed on the eProtocol application and submitted.

Clinical research: research involving human participants for health-related interventions, including drugs, devices, biologicals, surgical techniques, diagnostic and screening tests, therapy, education and care.

CRO: Clinical Research Organisation

HREC: Human Research Ethics Committee.

Lead Site: The site that submits the initial application in a multi-centre study. This site takes responsibility for responding to the comments of the HREC. It is a decision for the sites and sponsor to determine whether the lead site continues to take responsibility for ongoing submissions (e.g. generic amendments and reports) on behalf of the additional sites.

Multi-Centre Application: The study is conducted at multiple centres and a different Principal Investigator is responsible for each centre. A separate eProtocol application is required from each Principal Investigator.

Multi-Site Application: The study is conducted at multiple sites, and one Principal Investigator has responsibility for the activities at all of the sites. A single application form is required.

Non-clinical research: social and behavioural sciences, and non-interventional/non-therapeutic research.

Site delegate: A representative of the Principal Investigator at the site (e.g. Clinical Research Manager, Study Co-Ordinator, Co-Investigator).

SMO: Site Management Organisation

Guidance

Initial study submission

The Principal Investigator is responsible for the submission of essential and other study related documents for consideration by the HREC. Investigators are encouraged to refer to the Submission Requirements Checklist (BA F1.1.1) for a list of documents required to be included in the initial study submission.

Applicants should refer to the following areas for guidance on a specific topic before applying. Some areas of guidance may have templates in their document area. Please see Bellberry applications for the most up-to-date information.

BA G1	Submission requirements and responsibilities
BA G2	eProtocol navigation guide for researchers
BA G3	Protocol development - clinical
BA G4	Protocol development - non-clinical
BA G5	PICF development including eConsent
BA G6	Application fees
BA G7	Conflict of interest
BA G8	CVs and investigator qualifications
BA G9	Advertising
BA G10	Participant payment and reimbursement
BA G11	Researcher data storage and retention
BA G12	Version control and document naming conventions
BA G13	Ionising radiation
BA G14	Pregnancy and sexual health
BA G15	Insurance and indemnities

BA F1.1.7 has a flowchart for the processing of single site and multi-centre applications. All sites must understand the PICF pathway chosen by the lead site at the initial submission (BA F1.1.17).

Document naming convention requirements can be found in BA G12 Version control and document naming conventions.

Bellberry's general information regarding consent, including participant information and consent form development, eConsent and translation requirements can be found in BA G5 PICF development including eConsent.

A full and complete research application submitted via eProtocol will be allocated to the next available agenda, generally 10 working days prior to the HREC meeting. If the initial submission is incomplete the HREC's review of the study will be delayed. In this instance, the application will be returned to the Principal Investigator with notes outlining the additional action required prior to resubmission.

The Principal Investigator will receive email notification when a study is allocated to the meeting agenda. A Principal Investigator can expect to receive comments detailing the committee's deliberations 2 business days following the HREC meeting. Comments are provided via eProtocol.

Multi-Centre Applications

An application is required to be submitted to the Bellberry HREC by the lead/initial site and by each additional/subsequent site via eProtocol (or state-based submission platform if initial submission if from a public health site. In these circumstances all post-initial submission amendments and notifications can be made via this platform. In this context please interpret any reference to eProtocol to relate to the applicable submission platform for the project application). The initial site submits all documents to be reviewed by the committee. Subsequent sites submit the application form and are required to attach relevant documentation to page 7 in accordance with BA F1.1.1 Submission requirements checklist. The additional site is required to use the same document naming convention as used by the lead site.

Study decision

All submissions will receive notification of the committee's decision via eProtocol (approval, conditional approval or non-approval), including all submissions under a multi-centre application. If the application is not approved by the HREC, each application will be closed following notification.

Before initiating research, the investigator/institution is required to have written and dated approval from the HREC for the study protocol, Investigator's Brochure (where applicable to the study), written informed consent form, consent form updates, recruitment procedures (e.g. advertisements), and any other written information to be provided to participants. The Principal Investigator is responsible for ensuring compliance with any site-based governance requirements.

The period of approval is outlined on the HREC approval letter. Approval extends until midnight on the date listed.

Approved study submission requirements

Each site is responsible for site-specific submissions (if applicable). These submissions will include safety notifications and protocol violations related to the site, annual progress reports, and the final report.

During the study, any approved site can submit generic documents on behalf of the other site(s). This may include for example, amendments to the protocol, Investigator's Brochure, questionnaires, the master PICF, annual safety reports, and so on. When an approved site submits on behalf of another site, the Principal Investigator and address of the additional site is to be included. The HREC recommends amendments to essential documents (such as the master PICF, protocol or Investigator's Brochure) be submitted on behalf of all sites. In instances where this does not occur, the submitting site should explain why.

It is the responsibility of the sites and sponsor to determine who will act as the lead site (if required) and to determine site responsibilities for ongoing amendments and reports.

Applicants are encouraged to refer to monitoring approved research (MAR) guidance (and associated documents) for approved study submission requirements.

Studies under CTN

The Human Research Ethics Committee (HREC) reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.

The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the 'unapproved' therapeutic goods in the clinical trial.

Studies under CTA (formerly known as the CTX scheme)

A sponsor applies to the TGA seeking approval to supply 'unapproved' therapeutic goods in a clinical trial. The TGA evaluate summary information about the product including relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial.

After the TGA have completed their evaluation, the study must then be reviewed by a HREC. The outcome of the TGA's review must be provided in the HREC application. The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.

Where a study is submitted under the CTN scheme, the HREC may decide that an application must go through the CTA scheme.

Bellberry HREC Contact Officer *(person who will receive correspondence for the HREC about this CTN, if required):*
Name: Trina O'Donnell
Position: Operations Manager, Bellberry Ltd
Contact Number: 08 8361 3222
Contact Email: bellberry@bellberry.com.au

Communication between Bellberry and Researchers/Sponsors
Bellberry encourages open and informal communication with researchers/sponsors.

Bellberry staff are committed to providing a professional, high quality and efficient service to the research community and are readily accessible to assist researchers/sponsors through the review process daily.

Sponsors, CROs and SMOs are permitted to access applications in eProtocol. Once decided between the sponsor, CRO, SMO and site, a request for eProtocol access occurs through submission of BA F2.1.3 Organisational Verification of Personnel and by following the steps in BA F2.1.2 Registration. Once the representative is registered on eProtocol, the Principal Investigator at the site is responsible for adding the representative to the relevant application(s). After the representative has access to the study in eProtocol, they can assist in all areas of the research application for the life of the study, including uploading documentation. Importantly, only the Principal Investigator or their site delegate can use the 'submit' function in eProtocol, as it is the Principal Investigator that holds ultimate responsibility for the conduct of the research at the site. The declaration for all submissions within eProtocol acknowledges the responsibilities of the Principal Investigator. The Principal Investigator may also choose to remove the sponsor from their application. For submissions made via alternative platforms please refer to the platform guidance.

Communication between Bellberry administration and individuals from the site or sponsor who are not registered and listed on the Personnel Information page of the application will be restricted to matters of an administrative nature e.g. general policy or procedure questions. Any other communication from the Sponsor should be received via the Principal Investigator through eProtocol. Bellberry staff can assist Investigators with minor scientific or ethical matters (i.e. clarification of a Committee question). All other matters will be directed to the HREC and be dealt with between the Committee and the Investigator.

References

National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)
Research Governance Handbook
BA SOP1.1 Application receipt process
BA F1.1.1 Submission requirements checklist
BA F1.1.5 eProtocol application questions
BA F2.1.3 Organisational verification of personnel
BA G5 PICF development including eConsent
BA G12 Version control and document naming conventions