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: Other sites 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.

CRO: Clinical Research Organisation

HREC: Human Research Ethics Committee.

Lead Site: The site that submits the initial application in a multi-centre. 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.

SAE: Serious Adverse Event.

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

SUSARs: Serious, Unexpected, Suspected Adverse Reaction.

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.

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. 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 site and each additional site via eProtocol. The lead site submits all documents to be reviewed by the committee. Additional sites submit the application form and a list of study documents applicable at the additional site. The additional site is required to use the same document naming convention as used by the lead site.

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

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

During the course of 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 and the master PICF (if being used), as well as annual safety reports. When an approved site is submitting on behalf of another site, the Principal Investigator and address of the additional site is required 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.

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. Bellberry staff are readily accessible to assist researchers/sponsors through the review process on a daily basis.

Sponsors, CROs and SMOs are permitted to access their studies in eProtocol. Once decided upon between the Sponsor, CRO, SMO and site, a request for eProtocol access occurs through submission of BA F2.1.3 Nominated contact authorisation. The Principal Investigator at the site is then responsible for adding the representative to their application in eProtocol. 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.

Communication between Bellberry administration and sponsors 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 Nominated contact authorisation