

Purpose

To provide researchers and sponsors an overview of the fee structure for Bellberry HRECs. This guidance applies to all funded/sponsored and investigator-initiated/non-funded studies submitted.

Definitions

New protocols: any new submission to a Bellberry HREC. The administration fee funds the cost of any pre-submission assistance, the initial review, costs of the ongoing review of adverse events, protocol violations, site visits, and the monitoring of research progress. Therefore, continuous monitoring of the study is included in the review fee.

Amendment: any change to a protocol or an investigator brochure that occurs after a Bellberry HREC has approved it. This additional fee covers the cost of reviewing the documents and the associated administrative responsibilities

Extensions: an extension study.

Multi-Centre Application: The study is conducted at multiple centres and a different Principal Investigator is responsible for each centre.

Substantial amendment: a type of amendment which is defined as a change to the protocol or other factors that may affect:

- the aims and objectives of the study or the study design
- participants’ safety or physical or mental integrity
- the scientific value of the study
- the conduct or management of the study
- the quality or safety of any investigational medicinal product used in the study.

Guidance

An administration fee is charged for the review of research projects, processing of project amendments, extensions and ongoing monitoring of approved studies. The review process begins when the investigator clicks “submit”. Fees do not influence the decisions of the Committees, and the same fee is charged regardless of the outcome of the review.

Investigator Initiated Studies

If you are an investigator funding your own research project, you may contact Bellberry to discuss fees that apply.

Fees (all fees include GST)

1.New Protocol	\$6,050
2.New Protocol – Phase I	\$8,250
3.Multi-centre Trials	\$6050 for the first (lead) site \$3,630 for each additional site (up to 5 study sites) \$2,530 for each additional site (6 or more study sites)
4.Extension Phase Protocol	\$3,025 each site
5.Amendment	\$605
6.Substantial Amendment	\$6050

Bellberry reserves the right to alter these fees.

References

- BA SOP6.1 Processing application fees
- BA F6.1.2 NSW EPCT fee form
- MAR G6 Amending approved research – general overview