

Purpose

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

Definitions

New protocol: 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 safety events, serious breaches, site visits, and the monitoring of research progress. Therefore, continuous monitoring of the study is included in the review fee.

Major amendment: any change to a Protocol or an Investigator's Brochure that occurs after approval by a Bellberry HREC. This additional fee covers the cost of reviewing the documents and the associated administrative responsibilities.

Minor amendment: any of the following changes made during the lifetime of the study: personnel information updates; site name or address updates; PICF amendments; updates to other participant documents such as recruitment material, progress reporting, safety reporting, serious breach notification, and final reporting.

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.

Item	Current Fee (ex. GST)	Current Fee (inc. GST)
New HREC Review Application	\$5,750	\$6,325
New Phase 1 HREC Review Application	\$8,000	\$8,800
Multi-centre Applications (sites 2-5)	\$3,450	\$3,795
Multi-centre Applications (6 or more sites)	\$2,425	\$2,667.50
Amendments (per site)	\$575	\$632.50
Investigator Brochure Update (per submission)	\$575	\$632.50
Substantial Amendment	\$5,750	\$6,325
Extension Phase	\$2,875	\$3,162.50

Bellberry reserves the right to alter these fees.

References

BA F6.1.2 NSW EPCT fee form

MAR G6 Amending approved research – general overview