

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 Application: any new submission to a Bellberry HREC. The administration fee funds the cost of any pre-submission assistance, the initial HREC review, minor amendments, the ongoing review of safety events, serious breaches, progress reporting, final reporting, and site monitoring.

Extension Study: studies that allow participants from a prior clinical trial to 'roll-over' into a subsequent related study to continue to observe and measure long-term safety, tolerability, and/or effectiveness.

Major Amendment: any change to a Protocol or an Investigator's Brochure that occurs after approval by a HREC. This 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; and updates to other participant documents such as recruitment and advertising material.

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

Multi-site Application: The study, or specific elements of it, is conducted under the supervision of a Principal Investigator across multiple locations. For decentralised clinical trial arrangements—where more than 50% of study activities occur at each location, such as in tele-trials—a fee applies for the review and the HRECs ongoing oversight of each decentralised location.

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

- the aims, objectives, or scientific value of the study or the study design
- participants' safety or physical or mental integrity
- 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, extension studies and ongoing monitoring of approved studies. The review process begins when the investigator clicks "submit". Fees do not influence the HRECs decisions, and the same fee applies regardless of the review outcome. Fees remain payable in cases where a study has been rejected by the HREC.

Investigator Initiated Studies: please discuss the applicable fee for review with Bellberry prior to submission.

Item	Current Fee* (ex. GST)	Current Fee* (inc. GST)
New Protocol		
New HREC Review Application	\$6,750	\$7,425
New Phase 1 HREC Review Application	\$9,250	\$10,175
Multi-centre Applications (per centre)	\$3,750	\$4,125
Extension Studies or Low Risk Studies (per centre)	\$3,750	\$4,125
Multi-Site Decentralised Clinical Trial Applications (i.e. Tele-health sites – per site)	\$350	\$385
Major Amendment		
Protocol Amendment (per version)	\$950	\$1045
Investigator's Brochure Amendment (per version)	\$950	\$1045
Substantial Amendment	\$6,750	\$7,425
Minor Amendment		
Administrative Changes	Nil	Nil
PICF Amendment	Nil	Nil
Updating participant documents (e.g. recruitment/advertising)	Nil	Nil
Other Reporting		
Safety Reporting	Nil	Nil
Serious Breach Notification	Nil	Nil
Progress Reporting	Nil	Nil
Final Reporting	Nil	Nil
Application Reactivation	\$1000	\$1100

*Bellberry reserves the right to alter these fees.

References

BA F6.1.2 REGIS submission HREC fee form

MAR G1 Amending approved research – general overview