

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

Exemption Letter: some research projects may not require HREC review, including research that has been considered exempt from review under section 5.1.15 of the [National Statement on Ethical Conduct in Human Research \(2023\)](#), however a letter of exemption may be necessary to support publication.

Extension Study: studies that allow for patients participating in a parent 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 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; 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.

New Protocol: 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.

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, extension studies 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. Fees remain payable in cases where a study has been rejected by the HREC.

Public

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 Protocol		
New HREC Review Application	\$6,250	\$6,875
New Phase 1 HREC Review Application	\$8,750	\$9,625
Multi-centre Applications (per site application)	\$3,600	\$3,960
Extension Studies and Lower Risk Studies	\$3,600	\$3,960
Exemption Letter	\$1,000	\$1,100
Major Amendment		
Protocol Amendment (per submission)	\$850	\$935
Investigator's Brochure Amendment (per submission)	\$850	\$935
Substantial Amendment	\$6,250	\$6,875
Minor Amendment		
Administrative Change (e.g. personnel information update, site name or address update)	Nil	Nil
PICF Amendment	Nil	Nil
Update to Other Participant Documents such as Recruitment and Advertising Material	Nil	Nil
Other Reporting		
Safety Reporting	Nil	Nil
Serious Breach Notification	Nil	Nil
Progress Reporting	Nil	Nil
Final Reporting	Nil	Nil

*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