

## **POLICYI001 ADMINISTRATION FEES**

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### **PURPOSE**

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.

This policy applies to all funded/sponsored and investigator-initiated/non-funded studies submitted.

Bellberry reserves the right to alter these fees.

### **New Protocols**

The administration fee funds the cost of any pre-submission assistance, the initial review, costs of ongoing review of adverse events, protocol changes, site visits, and the monitoring of research progress. Ongoing monitoring of the study is included in the review fee.

### **Amendments and Extensions**

Modifications to research which require review will incur an amendment fee. Examples include Protocol amendments and Investigator's Brochure updates. This additional fee covers the cost of reviewing the documents and the associated administrative responsibilities. Other amendments may incur a fee. This applies to all funded and non-funded studies and sub studies submitted.

### **Substantial Amendments**

In recognition of developments in study design and the types of study Amendments being prepared, Bellberry will consider the review of 'substantial amendments'. A 'substantial amendment' is an amendment to the Protocol or any other supporting documentation that is likely to affect to a significant degree: the safety or physical or mental integrity of the subjects of the study; the scientific value of the study; the conduct or management of the study; or the quality or safety of any investigational medicinal product used in the trial (based on the NHS definition).

Upon review of the amendment submission, the Committee will determine whether it can be considered as a substantial amendment, or whether it is a new study requiring a full new study submission. It is recognised that review as a substantial amendment will help consolidate ongoing management of a single study.

Given the significant change in study design, any amendment assessed as being a 'substantial amendment' will be required to undergo review at a full Committee meeting.

### **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