**Research ethics fee form –studies submitted in REGIS**

Please include a completed research ethics fee form with each submission in REGIS to Bellberry HREC.

|  |  |  |  |
| --- | --- | --- | --- |
| **Coordinating/****Principal Investigator** |       | **Contact No:** |       |
| **Primary Contact/ Study Coordinator** |       | **Contact No:** |       |
| **Primary Contact email address** |  |
| **Study Site Name(s)**List all sites associated with this application |                 |
| **Protocol Number** |       |
| **Title of Research** |       |
| **REGIS Ref Number** |       |
| **Sponsor Type** | Collaborative Group [ ]  Commercial Entity [ ] Investigator Funded\* [ ]  Other [ ] *Please contact Bellberry to discuss prior to submission.* |
| **Multi-centre studies**  | Total number of centres under Bellberry HREC; \_\_\_\_\_\_\_ *(include lead site and sites currently under review)*  |

**INVOICE TO BE SENT TO:**

|  |  |
| --- | --- |
| **Party to be Invoiced** |       |
| **Invoice Codes IF Required** *(e.g Purchase Order #)* |       |
| **Address of Invoiced Party** |            |
| **ABN of Invoiced Party** (*if applicable)* |  |
| **Email Address** |       |
| **Contact Name** |       | **Contact No.** |       |
| **Confirmation of Invoiced Party** | *I confirm the above information is accurate, and our intention to settle invoices for the performance of the HREC application review upon the receipt of a valid tax invoice.* |
| **Signed** |  | **Date** |       |

Please refer to the Bellberry website for additional guidance (**BA G6**) related to our review fees.

|  |  |  |
| --- | --- | --- |
| **TYPE OF HREC SUBMISSION**  | **REVIEW FEE** *(inc GST)* | **TICK AS APPLICABLE** |
| **New Early Phase Clinical Trial Application to Bellberry**Number of additional sites INCLUDED with this submission:*The administration fee funds the cost of any pre-submission assistance, the initial review, ongoing review, site visits and the monitoring of research progress.* *For complex protocol designs, such as umbrella and master protocol studies, sub-studies may be divided either across multiple reviews at a HREC meeting or as a substantial amendment following the decision outcome of the initial protocol.* | $9,900$3,960 per additional centre | **[ ]**  |
| **Addition of a participating site(s) to an approved application**Number of additional sites ADDED with this submission: | $3,960 per additional centre | **[ ]**  |
| **Addition of a multi-site location** *A multi-site location is where specific elements of a study 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 location.* | $275 per additional multi-site location | **[ ]**  |
| **Amendment** *Modifications to research documents which require review will incur an amendment fee. Examples include Protocol amendments and Investigator’s Brochure updates (invoiced per document). 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.* | $990 per document | **[ ]**  |
| **Substantial Amendment***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. 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.**For complex protocol designs, such as umbrella and master protocol studies, sub-studies may be divided either across multiple reviews at a HREC meeting or as a substantial amendment following the decision outcome of the initial protocol.* | $7,150 | **[ ]**  |
| **Investigator Funded Research Applications** Number of additional sites ADDED with this application:       | ***Please contact Bellberry to discuss.*** | **[ ]**  |