**Amendment application payment form**

**The Alfred Hospital Office of Ethics & Research Governance**

* **The fees are GST exclusive**
* **Please refer to the fee schedule in the Ethics & Research Governance website for more information**
* **Indicate which fee or fees are applicable and insert the total**
* **Submit the completed form with the amendment application submission**
* **Advice will be provided if the correct fee is not indicated or if the $200 surcharge applies**

|  |  |
| --- | --- |
| **Project Title** |  |
| **Alfred Project Number** |  |
| **Principal Investigator** |  |
| **Contact name (if not the PI)** |  |
| **Email & phone** |  |
| **Date** |  |

**For ALL applications (GST exclusive):**

|  |  |  |
| --- | --- | --- |
| **Investigator initiated/collaborative groups study** |  |  |
| Amendment application | Nil |  |

|  |  |  |
| --- | --- | --- |
| **Commercially sponsored studies** | | |
| Substantial amendment1 e.g. protocol, significant changes to PICF(s) | 650 |  |
| Non-substantial amendment1 e.g. changes to personnel, advertising material, Investigator’s Brochures, DSURs | 200 |  |
| For substantial amendment applications submitted within one month of ethics approval and without impact on participant safety | 1,300 |  |
| For non-substantial submitted within one month of ethics approval | 400 |  |
| *Streamlined projects*  New additional site(s) *Insert number* | x 500 |  |
| Expedited review within 3 working days of submission (please note conditions)2 | 3,000 |  |

**Conversion of an existing study to the streamlined process:**

|  |  |  |
| --- | --- | --- |
| Investigator-initiated/Alfred Health | Nil |  |
| Investigator-initiated/Non-Alfred Health | 200 |  |
| Collaborative group studies | 200 |  |
| Investigator Initiated, commercially supported studies | 650 |  |
| Commercially sponsored studies  Additional site(s) *Insert number* | 1500 |  |
| x 500 |  |

**$200 Surcharge Yes  No**

**Total fee**

1. Please refer to the NHS definitions of substantial and non-substantial amendments: <https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/>
2. The service will provide a scientific and ethical review of an amendment application submitted to the Alfred Hospital Ethics Committee within three working days provided the following conditions are met:
3. Applications need to be submitted via ERA by 9am. Researchers should also send an email to the Ethics Officer responsible for the study as well as to [research@alfred.org.au](mailto:research@alfred.org.au) to flag the application for expedited review.
4. The applications need to be accurate and complete, as assessed by the reviewer and the Office. An application is considered complete if it contains all of the following documents, if relevant:
   1. Amendment application form
   2. An explanatory letter detailing the rationale for the amendment if the amendment application form is insufficient
   3. Protocol with a summary of changes
   4. Investigator’s Brochure with a summary of changes
   5. PICF(s) with tracked changes highlighting revisions
   6. For amendments relating to changes in dose of the investigational product, relevant documentation from the Safety Monitoring Committee
   7. Amended Medical Physicist’s report if there are changes to the mode and/or frequency of the ionising radiation procedures
   8. Appropriate and correct legal documents
   9. Any other documentation relevant to the amendment
   10. Amendment fee payment form
5. The Office will screen the application within 24 hours and advise whether the application is complete and can be released for review. If the application is incomplete, feedback will be provided.
6. The clock commences once the application is deemed complete and correct
7. The application will be reviewed within three working days. Please note that this may not necessarily equate to *approval* within three working days.
8. If queries arise out of the review, the responses will be subject to another three working day turnaround. Once the responses are submitted via ERA, researchers should send an email to the Ethics Officer as well as to [research@alfred.org.au](mailto:research@alfred.org.au) to flag that the responses had been submitted.

***Please complete the details on the following page***

**Fee/invoicing details:**

**(Please check the research agreement if applicable for invoicing details)**

**Total fee**

**Please provide details for invoicing purposes:**

|  |  |
| --- | --- |
| Name of sponsor/CRO/institution responsible for this payment |  |
| Company ABN |  |
| Contact person’s name |  |
| Position |  |
| Email & phone number |  |
| Mailing address |  |
| *Mandatory For Monash University studies:* Purchase Order Number,  Cost centre and Fund number |  |
| *If required for invoicing:*  Additional information to be included on the invoice (eg site number, PI, etc)  **Please check CTRA if applicable.** |  |

*Invoices will be sent to the sponsor/institution by The Alfred or Monash University Finance.*

**OR**

**Please provide details if payment is to be made by internal transfer (ICAN):**

|  |  |
| --- | --- |
| Cost Centre Name |  |
| Cost Centre Manager |  |
| Cost Centre Number |  |

*Signed ICANs will be sent to Alfred Finance by the Office of Ethics & Research Governance.*