**Amendment fee payment form**

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

* **The fees are GST exclusive**
* **Please refer to the fee schedule on the Ethics & Research Governance website for more information, noting that amendment applications submitted to the Alfred Hospital Ethics Committee must be submitted based on the *primary purpose* of the amendment**
* **Submit the completed form with the amendment application submission**
* **Advice will be provided if the correct fee is not indicated or if the $500 surcharge applies**
* **Amendment review will not proceed until the complete and accurate fee payment form has been provided**

|  |  |
| --- | --- |
| **Short Title** |  |
| **Alfred Health Project Number** |  |
| **Date** |  |

**For commercially-sponsored studies, GO TO PAGE 2**

**For investigator-initiated or collaborative group studies, GO TO PAGE 4**

# **Commercially-sponsored studies**

## **All applications except** those amending an adaptive platform/basket/umbrella study

|  |  |  |
| --- | --- | --- |
| **Item** | **Fee ($)** | **Please select** |
| Amended Protocol | 800 each |  |
| Protocol Clarification Letter which amends the Protocol | with or without |  |
| Note to File which amends the Protocol | amended PICFs |  |
| Dear Investigator Letter |  |  |
| Protocol Clarification Letter/Note to File/Dear Investigator   Letter for an administrative change or correction only | 200 each |  |
| Updated Investigator’s Brochure | 300 each |  |
| Addendum to Investigator’s Brochure | if **not** resulting in |  |
| Instructions for Use | PICF revision |  |
| Development Safety Update Report (DSUR) |  |  |
| Product Information |  |  |
| Updated Investigator’s Brochure | 650 each |  |
| Addendum to Investigator’s Brochure | if resulting in |  |
| Instructions for Use | PICF revision |  |
| Development Safety Update Report (DSUR) |  |  |
| Product Information |  |  |
| Minor revisions to the PICFs | 200 |  |
| Addition of new PICFs | 200 each |  |
| New or amended OGTR Licence | 300 each |  |
| Patient-facing material (questionnaires, diaries, etc.)  Advertising/recruitment material or recruitment strategies   (e.g. telehealth or e-consent) | 200  per bundle of  up to 5 documents |  |
| Addition of Participating Site\* or Satellite Site | 500 per site |  |
| Change to Local Sponsor | 650 |  |
| Change to Lead Site | 1,600 |  |
| Change to Coordinating PI\* or Site PI | 500 |  |
| Transfer of ethical oversight to another HREC\* | 1,600 |  |
| Request to re-open a previously closed study | 3,000 |  |
| Amendment to Agreement and/or new Agreement | 100 each |  |
| Conversion of existing study to NMA | 1,600 |  |
| ***Additional fee*** for an expedited review within 3 working days   of submission\*/\*\* | 2,500 |  |
| ***Additional fee*** for major amendment submitted within one   month of ethics approval and without impact on participant   safety\* | 800 |  |
| ***Additional fee*** for minor amendment submitted within one   month of ethics approval\* | 400 |  |

*\* Only applicable if the Alfred Hospital Ethics Committee is providing ethical oversight*

*\*\* Please note the conditions in the Fee Schedule*

## Applications involving changes to an **adaptive platform/basket/umbrella study**

|  |  |  |
| --- | --- | --- |
| **Item** | **Fee ($)** | **Please select** |
| Addition of new domain (includes Protocol, IB and PICF) | \*\*\* | $0 |
| Amended Protocol (with or without amended PICFs) | 800 each |  |
| Protocol Clarification Letter (with or without amended PICFs) |  |  |
| Investigator’s Brochure /Instructions for Use/DSUR/Product   Information (with or without amended PICFs) | 300 each |  |
| Addition of new PICFs | 200 each |  |
| New or amended OGTR Licence | 300 each |  |
| Patient-facing material (questionnaires, diaries, etc.)  Advertising/recruitment material or recruitment strategies   (e.g. telehealth or e-consent) | 200  per bundle of  up to 5 documents |  |
| Addition of Participating Site\* or Satellite Site | 500 per site |  |
| Change to Local Sponsor | 650 |  |
| Change to Lead Site | 1,600 |  |
| Change to Coordinating PI\* or Site PI | 500 |  |
| Transfer of ethical oversight to another HREC\* | 1,600 |  |
| Request to re-open a previously closed study | 3,000 |  |
| Amendment to Agreement and/or new Agreement | 100 each |  |
| Conversion of existing study to NMA | 1,600 |  |
| ***Additional fee*** for an expedited review within 3 working days   of submission\*/\*\* | 2,500 |  |
| ***Additional fee*** for major amendment submitted within one   month of ethics approval and without impact on participant   safety\* | 800 |  |
| ***Additional fee*** for minor amendment submitted within one   month of ethics approval\* | 400 |  |

*\* Only applicable if the Alfred Hospital Ethics Committee is providing ethical oversight*

*\*\* Please note the conditions in the Fee Schedule*

*\*\*\* 50 percent of the initial application review fee (see initial fee payment form)*

# **Investigator-initiated/collaborative group studies**

## **All protocol amendment applications except** those involving changes to the domains of an adaptive platform/ basket/umbrella study or a conversion to NMA, Change to Lead Site or Transfer of ethical oversight to another HREC

|  |  |  |
| --- | --- | --- |
| **Item** | **Fee ($)** | **Please select** |
| Alfred Health-sponsored study | Nil |  |
| Alfred Research Alliance partner-sponsored study | Nil |  |
| Non-affiliated institution-sponsored study | 100 |  |
| Collaborative group study | 100 |  |

## Applications involving changes to the domains of an **adaptive platform/basket/ umbrella study**

|  |  |  |
| --- | --- | --- |
| **Item** | **Fee ($)** | **Please select** |
| Alfred Health-sponsored study | Nil |  |
| Alfred Research Alliance partner-sponsored study | Nil |  |
| Non-affiliated institution-sponsored study | 300 |  |
| Collaborative group study | 300 |  |

## Applications involving a **conversion to NMA, Change to Lead Site or Transfer of ethical oversight to another HREC**

|  |  |  |
| --- | --- | --- |
| **Item** | **Fee ($)** | **Please select** |
| Alfred Health-sponsored study | Nil |  |
| Non-Alfred Health-sponsored study | 300 |  |
| Collaborative group study | 300 |  |
| Commercially supported study | 650 |  |

**Fee/invoicing details**

**Total fee $0**

**Please provide details for either Method 1 orMethod 2.**

**Method 1: ECAN** (External Charge Advice Note)

**Entity responsible for paying this fee**

|  |  |
| --- | --- |
| Name of organisation\* |  |
| ABN |  |
| Contact person’s name |  |
| Position |  |
| Email |  |
| Phone number |  |

*\* Individuals can be invoiced if they have and provide an ABN*

**Additional information to be included in the invoice**

|  |  |
| --- | --- |
| Sponsor’s Purchase Order Number (if required) |  |
| Site PI Name | As per application |
| Site Number |  |
| Other |  |

*Payment by credit card is an option once an invoice has been sent (payment details in the invoice)*

**OR**

**Method 2: ICAN** (Internal Charge Advice Note)

**Please provide details if payment is to be made by internal transfer within Alfred Health**

|  |  |
| --- | --- |
| Cost Centre Name |  |
| Cost Centre Manager |  |
| Cost Centre Number |  |
| Approved by Cost Centre Manager | If ‘No’, please provide an explanation |
|  |  |