# Post approval fee form - Commercially sponsored studies

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date | |  | | | | |
| RMH Local Project Number | | **<YYYY.NNN>** | | ERM Number | |  |
| Commercial Sponsor | |  | | | | |
| RMH Principal Investigator or *Point of Contact* | |  | Sponsor identifier / Protocol number | |  | |
| Contract Research Organisation *(if applicable)* | |  | | | | |
| Project Title |  | | | | | |

**Ethics and Research Governance amendment submission**

**Fees are based on complexity. The Base Rate always applies plus extra/s (select all that apply)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Amendment Type** | | | | **$ Amount  (ex GST)** | **$ Amount**  **(incl. GST)** |
| **☒** | **Amendment – Base Rate all amendments** | | | **200** | **220** |
|  | | Addition of site ($500 per site added) | | <500 x n> | <550 x n> |
|  | | Addition of non-standard site ($50 per site added) | | <50 x n> | <55 x n> |
|  | | Study Personnel Changes *(charge not applicable for RMH study team members other than RMH PI)* | | 400 | 440 |
|  | | Investigator Brochure update - ($300 each) | | <300 x n> | <330 x n> |
|  | | PICF and other Participant Facing Documents:  The charge is based on number of bundles. ($400 per bundle – up to 5 docs):  <Enter number of bundles or discuss with OfR>  **RMH site-specific version based on Master version already reviewed by RMH ethics are free of charge if submitted within 2 weeks of ethics approval** | | <400 x n> | <440 x n> |
|  | | Protocol amendment | | 900 | 990 |
|  | | | Relating to FTIH protocol components | 350 | 385 |
|  | | | Relating to Genetically Modified Organism (GMO) components | 500 | 550 |
|  | | | Relating to Telehealth/Decentralised Clinical Trials/Adaptive components | 400 | 440 |
|  | | Contract amendment ($200 per contract) | | <200 x n> | <220 x n> |
|  | | | Amendment to existing international contract ($250 per contract) | <250 x n> | <275 x n> |
|  | | New Contract ($300 per contract) | | <300 x n> | <330 x n> |
|  | | | International contract ($400 per contract) | <400 x n> | <440 x n> |
| **Additional Services** | | | | **$ Amount  (ex GST)** | **$ Amount**  **(incl. GST)** |
|  | Expedited review (within 5 working days of receipt of a **complete** submission package) | | | <Contact OfR > | <Contact OfR > |
|  | Submission of amendment prior to initial ethics/SSA approval | | | 1400 | 1540 |
|  | Submission of amendment 1 month after initial ethics/SSA approval | | | 1400 | 1540 |
|  | Addition of extension study or sub study ($2500 each) | | | <2500 x n> | <2750 x n> |
|  | Retrieval of study essential documents retrospectively | | | <Contact OfR > | <Contact OfR > |
|  | Transfer from RMH HREC to another reviewing HREC | | | 500 | 550 |
|  | Transfer from another reviewing HREC to RMH HREC | | | <Contact OfR > | <Contact OfR > |
| **TOTAL FEE (calculate total of *all* selections)** | | | | **$ total** | **$ total** |

## Fee structure

### The fees charged represent only partial recovery of the total workflow cost of review and approval.

### Fees are cumulative based on all applicable submission modules selected.

## Payment process

### Upon receiving the fee form, an invoice will be issued by the Royal Melbourne Hospital. The invoice will represent the total fee amount payable.

### Payment Terms are 30 days from invoice date.

## Invoice request details

### All fields compulsory

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sponsor Name** |  | | **Sponsor ABN** |  |
| Legal Address |  | | | |
| Project Person Name |  | | | |
| Project Person Email |  | | | |
| Telephone |  | | | |
| Sponsor Reference / Purchase Order Number | |  | | |
| Alternate Email for Invoice payment | |  | | |
| Items that need to be listed on the invoice for payment | |  | | |

## Journal transfers – RMH internal cost centres – GST not applicable

### Complete this section if the fee is to be paid via internal RMH cost centre transfer

|  |  |  |  |
| --- | --- | --- | --- |
| **Cost Centre number** | **Cost Centre  manager name** | **Cost Centre  manager signature** | **Total amount (ex-GST)** |
|  |  |  | **$** |
|  |  | Click the centre of the image to insert scanned signature from file |  |

### Thank you.

### The Office for Research

### Driving change in the sector to streamline research endeavours