# 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