# Post approval fee form – Non-commercial studies

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date | |  | | |
| RMH Local Project Number | | **<YYYY.NNN>** | ERM Number |  |
| Chief/Coordinating Investigator | |  | | |
| RMH Principal Investigator or *Point of Contact* | |  | | |
| Sponsor institution *(if applicable)* | |  | | |
| Project Title |  | | | |

**Ethics and Research Governance amendment submission**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Amendment Type** | | | | **$ Amount  (ex GST)** | **$ Amount**  **(inc GST)** |
|  | Amendment – Quality Assurance projects amendments | | | 30 | 33 |
|  | **Amendment – Base Rate for all non-QA amendments** | | | **50** | **55** |
|  | | Addition of site ($200 for each additional site) | | <200 x n> | <220 x n> |
|  | | Addition of non-standard site ($30 per site added) | | <30 x n> | <33 x n> |
|  | | Study Personnel Changes *(charge not applicable for RMH study team members other than RMH PI)* | | 50 | 55 |
|  | | Investigator Brochure update ($50 each) | | <50 x n> | <55 x n> |
|  | | PICF and other Participant Facing Documents:  The charge is based on number of bundles. ($180 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** | | <180 x n> | <198 x n> |
|  | | Protocol amendment | | 180 | 198 |
|  | | | Relating to FTIH protocol components | 150 | 165 |
|  | | | Genetically Modified Organism (GMO) components | 150 | 165 |
|  | | | Relating to Telehealth/Decentralised Clinical Trials/Adaptive components | 100 | 110 |
|  | | Contract amendment ($30 per contract) | | <30 x n> | <33 x n> |
|  | | | Amendment to existing international contract ($40 per contract) | <40 x n> | <44 x n> |
|  | | New Contract ($50 per contract) | | <50 x n> | <55 x n> |
|  | | | International contract ($70 per contract) | <70 x n> | <77 x n> |
| **Additional services** | | | | | |
|  | Expedited Review (within 5 working days of receipt of complete amendment package) | | | <Contact OfR > | <Contact OfR > |
|  | Modification of MH-Sponsored CTN form (excluding regulatory agency fee) | | | 80 | 88 |
|  | Submission of amendment prior to initial ethics/SSA approval | | | 500 | 550 |
|  | Submission of amendment 1 month after initial ethics/SSA approval | | | 500 | 550 |
|  | Addition of extension study or sub study ($200 each) | | | <200 x n> | <220 x n> |
|  | Retrieval of study essential documents retrospectively | | | <Contact OfR > | <Contact OfR > |
|  | Transfer from RMH HREC to another reviewing HREC | | | 500 | 550 |
|  | Transfer from another reviewing HREC to RMH HREC | | | <Contact OfR > | <Contact OfR > |
| **TOTAL FEE (calculate total of *all* selections)** | | | | **$ 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. If you have any questions about the fee form or fee structure, please contact the Office for Research.

## 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 - External entity

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Entity Name** |  | | **Entity ABN** |  |
| Legal Address |  | | | |
| Contact Person Name |  | | | |
| Contact Person Email |  | | | |
| Telephone |  | | | |
| Reference ID / Purchase Order Number | |  | | |
| Alternate Email for Invoice 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.*