# CALHN HUMAN RESEARCH ETHICS COMMITTEE

# HUMAN RESEARCH ETHICS COMMITTEE (TQEH/LMH/MH)

# ROYAL ADELAIDE HOSPITAL RESEARCH ETHICS COMMITTEE

 **INVOICING AND FEE FORM**

**RESEARCH ETHICS & GOVERNANCE APPLICATIONS**

**Information Required to Raise Invoice**

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator** |       | **Contact No:** |       |
| **Study Coordinator** |       | **Contact No:** |       |
| **Study Site Name** |       |
| **Protocol Number** |       |
| **HREC Ref Number***(if known)* | HREC/     /     /      |
| **CALHN Ref Number***(if known)* |       |
| **Title of Research** |       |
| **Trial Type** | Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4 [ ] Bioavailability/bioequivalence [ ]  Unknown [ ]  |
| **Sponsor Type** | Commercially Sponsored [ ]  Collaborative Group [ ] Investigator Initiated Group [ ]  Institution [ ] Other / Unknown [ ]  |
| **Trials under National Mutual Acceptance (NMA)** | N/A [ ]  or Specify No. of Additional Investigator Sites \_\_\_\_\_ |
| **Sponsor Site Code** |       |
| **Date of Application** |       |
| **Date of Amendment** |       |

**INVOICE TO BE SENT TO:**

|  |  |
| --- | --- |
| **Company/Sponsor Name** |       |
| **Special Invoice Codes as Required by Sponsor***(e.g Purchase Order #)* |       |
| **Company Address** |       |
| **Email Address** |       |
| **Contact Name** |       | **Contact No.** |       |
| **Position** |       |
|  |  |  |  |
| **Sponsor Confirmation** | *I confirm the above information is correct* |
| **Signed** |  | **Date** |       |

**Attach this form to your submission, and forward to:**

* CALHN Research Office, Level 4, Women’s Health Centre, Royal Adelaide Hospital, North Terrace,

 ADELAIDE SA 5000 or

* CALHN Ethics Office, Ground Floor, Basil Hetzel Institute, TQEH, 37a Woodville Rd, WOODVILLE SA 5011
* If you have any questions please contact the CALHN Research Office on **08 8222 4139** or

 **08 8222 6841** or e-mail: Health.CALHNResearchEthics@sa.gov.au

|  |  |  |
| --- | --- | --- |
| **NEW APPLICATION (All)** | FEE (excluding GST) | PLEASE TICK |
| New Application – Sponsor-Initiated[[1]](#endnote-1)Number of Additional Sites:       | **$5000** + $500 for each additional site | **[ ]**  |
| New Application – Cooperative Research Group (CRG)[[2]](#endnote-2)Number of Additional Sites:       | **$2500** + $250 for each additional site | **[ ]**  |
|  |  |  |
| **AMENDMENT (Commercial Sponsored Study)** |
| Addition of a Study Site | $500 | **[ ]**  |
| Addition of Sub-Study | $1500 | **[ ]**  |
| Major Amendment[[3]](#endnote-3) | $1000 | **[ ]**  |
| Minor Amendments[[4]](#endnote-4) | $600 | **[ ]**  |
| Other Amendments[[5]](#endnote-5) | $300 | **[ ]**  |
|  |  |  |
| **AMENDMENT (Cooperative Research Group)** |
| Addition of a Study Site | $250 | **[ ]**  |
| Major Amendment | $500 | **[ ]**  |

|  |  |  |
| --- | --- | --- |
| **TYPE OF APPLICATION** | FEE (excluding GST) | PLEASE TICK |
| New SSA Application – Sponsor-Initiated | $3000 | **[ ]**  |
| New SSA Application – Cooperative Research Group (CRG)[[6]](#endnote-6) | $1500 | **[ ]**  |
| Contract Review Fee[[7]](#endnote-7) | $300 | **[ ]**  |

***\*PLEASE NOTE: Fees for CRG studies:*** *may be reduced or waived at the discretion of the HREC on a case by case basis.*

***\*PLEASE NOTE :the following will NOT be invoiced:*** *CTN Forms, Clinical Trial Research Agreements, Indemnification Agreements or documentation, SAEs, Annual Reports, any documentation requiring only an acknowledgement (no approval letter required).*

1. Example – 3 sites would be $5000 + ($500x3) = $6500 [↑](#endnote-ref-1)
2. Example – 3 sites would be $2500 + ($250x3) = $3250 [↑](#endnote-ref-2)
3. All non-administrative protocol amendments, including:

changes to the protocol which may include Revision of the study design

Revisions in drug dosage

Changes to participant groups / numbers of study participants [↑](#endnote-ref-3)
4. Including:

Protocol revisions limited to the correction of language, grammar and numbering in a protocol

Investigator Brochure updates

Participant Information Sheet amendments (e.g. changes to content requiring HREC review)

New Recruitment Material (e.g. Flyers, Advertisements, Invitation Letters, Newsletters)

Other letters (where content needs HREC review and approval) [↑](#endnote-ref-4)
5. Including:

Minor Participant Information Sheet amendments (e.g. minor wording changes with no ethical significance)

Review of Patient Cards

Updates to existing recruitment material (e.g. Flyers, Advertisements, Invitation Letters, Newsletters)

Retention items (e.g. tote bags, magnets, pens) [↑](#endnote-ref-5)
6. The fees for CRG trials may be reduced or waived at the discretion of the Institution. [↑](#endnote-ref-6)
7. This fee applies to the review of ‘non-standard’ CTRAs (not the Medicines Australia templates or agreements that have not undergone SEBS review), and other trial related agreements and documents that require site review by an appropriate officer. [↑](#endnote-ref-7)