|  |  |  |  |
| --- | --- | --- | --- |
| **INVOICING AND FEE FORM RESEARCH ETHICS & GOVERNANCE APPLICATIONS** | | | |
|  |  |  |  |
| Information required to raise Invoice to be submittedwith initial application via[**Research GEMS**](https://gems.sahealth.sa.gov.au/Account/SignIn) | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | CPI Name: Enter text | | | | Contact Number: Enter text | | | Clinical Research Coordinator: Enter text | | | | Contact Number: Enter text | | | Study title and Protocol No: Enter text | | | | | | | *If known:* | HREC Reference Number | Enter text | CALHN Reference Number: MyIP | | Enter text |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Lead Study Site | | | State | Site Investigator/s | | Enter text | | | Enter text | Enter text | |  | | | | | | Study Type: Select one | Sponsor Type: Select one | | | | | National Mutual Acceptance (NMA): Select one if yes specify number of additional sites: Enter text | | | | | | *All sites must be listed in the Project Registration in GEMS* | | | | | | Sponsor Site Code: Enter text | Date of Application:Enter text | | | | |  | | | | | | **INVOICE TO SENT TO** | | | | | | Sponsor Name: Enter text | | | | | | Special Invoice Codes as required by Sponsor (eg Purchase Order #): Enter text | | | | | | Business Address: Enter text | | | | | | Email Address: Enter text | | | | | | Contact Name: Enter text | | Contact Number: Enter text | | | | Sponsor Confirmation | | | | | | Signed: | | Date: Enter text | | | |  | | | | | | **CALHN HUMAN RESEARCH ETHICS REVIEW FEES** | | | | | | **New HREC Application Phase 1 Clinical Trial with Full Commercial Sponsorship** | | | | | | * $7500 + $500 for each additional site, charged on a per site basis (+GST) | | | | | | **New HREC Application Clinical Trial with Full Commercial Sponsorship** | | | | | | * $6000 + $500 for each additional site, charged on a per site basis (+GST) | | | | | | **Cooperative Research Group (CRG) Clinical Trial/Non-Commercially Sponsored Clinical Trial** | | | | | | * $1000 + $200 for each additional site, charged on a per site basis (+GST) | | | | | |  | | | | | | **CALHN CLINICAL TRIALS RESEARCH GOVERNANCE REVIEW FEES** | | | | | | **Clinical Trials with Full Commercial Sponsorship** | | | | | | * $4000 (+GST) | | | | | | **IT/Software Fee**   * $2250 (+GST) a once off fee to cover licensing fees of the clinical trial management system (CTMS) | | | | | | **Cooperative Research Group (CRG) Clinical Trials and other Non-Commercially Sponsored**  **Clinical Trials** | | | | | | Non-commercially sponsored CTN Clinical Trial SSA review   * $1000 (+GST) | | | | | | Non-commercially sponsored clinical trial with no CTN submission   * $300 (+GST) | | | | | | The single fee for CRG and non-commercially sponsored trials covers the life of the study including any amendments received post-approval. Payment of the TGA’s CTN submission fee (and any other relevant  CTN fee) is the responsibility of the CRG or PI and not the Institution  Fees for CRG or non-commercially sponsored studies: may be reduced or waived at the discretion of the HREC/Institution on a case-by-case basis. In accordance with the [SA Health Fees Schedule for Research – Information for Applicants](https://www.sahealth.sa.gov.au/wps/wcm/connect/e2947118-b53c-4400-bbdd-e42d56e5085e/Draft+fees+guidance+%28public%29+-+Jun+18.pdf?MOD=AJPERES&amp;CACHEID=ROOTWORKSPACE-e2947118-b53c-4400-bbdd-e42d56e5085e-nwMG3Q1), to request a fee waiver or reduction provide supporting business case documentation. | | | | | |  | | | | | |

|  |  |  |
| --- | --- | --- |
| **SPONSOR/CRG/PAYING INSTITUTION CONFIRMATION** | | |
| I confirm that it is the intention of the Sponsor/CRG/Paying Institution to enter into a full written Study Agreement, and that before this agreement is executed, the Sponsor has authorised, and will pay for, the performance of study set-up activities, which may include the Site Specific Assessment (SSA) application and CALHN HREC application review and if applicable ongoing amendments and monitoring fees, upon the receipt of a valid tax invoice.  \**fees may vary at time of invoice receipt* | | |
| Name: | Enter text | |
| Signed: | Enter text | Date: Enter text |

|  |
| --- |
| **POST APPROVAL MONITORING / ONGOING FEES** |
| All post approval monitoring and other ongoing fees can be found on the SA Health website located here:  <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/research+ethics/research+ethics+and+governance+fees>  \*Note: SA Health Research Ethics and Governance Fee Schedule is subject to change\* |