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

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 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** | | | | | | * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | | **New HREC Application Clinical Trial with Full Commercial Sponsorship** | | | | | | * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | | **Cooperative Research Group (CRG) Clinical Trial/Non-Commercially Sponsored Clinical Trial** | | | | | | * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | |  | | | | | | **CALHN CLINICAL TRIALS RESEARCH GOVERNANCE REVIEW FEES** | | | | | | **Clinical Trials with Full Commercial Sponsorship** | | | | | | * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | | **IT/Software Fee**   * *Refer to Invoiceable Items on page 10 of the* [*CALHN Guideline for Clinical Trials Budgets, Payments and Invoicing guideline*](https://www.rah.sa.gov.au/research/for-researchers/clinical-trial-submissions)*.* | | | | | | **Cooperative Research Group (CRG) Clinical Trials and other Non-Commercially Sponsored**  **Clinical Trials** | | | | | | Non-commercially sponsored CTN Clinical Trial SSA review   * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | | Non-commercially sponsored clinical trial with no CTN submission   * *Refer to current fee schedule on the* [*SA Health website*](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). | | | | | | 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. | | | | | |  | | | | | |

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| **SPONSOR/CRG/PAYING INSTITUTION CONFIRMATION** | | |
| I confirm that it is the intention of the Sponsor/CRG/Paying Institution to enter into an agreement with the Institution for the conduct of the Study, 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* | | |
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| **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\* |