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| **HNELHD Research Office Ethics & Governance Review of Clinical Trial Research Fees**  **Invoicing Authorisation Form** |

* This form has been designed to assist HNE Researchers and the HNE Research Office comply with [NSW Health Fees for Research Ethics and Governance Review of Clinical Trial Research Policy PD2023\_015](https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_015), and associated [Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research IB2023\_026](https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=IB2023_026)
* This form is to be completed for ALL **clinical trials with an external sponsor** (commercial OR non-commercial) and uploaded in REGIS against your New Ethics Application **OR** New Site Application (Ethics Approved by an external HREC, not HNEHREC).
* The Initial Ethics (HREC) Review, Initial Governance (SSA) Review and any Amendments that meet the criteria in **Appendix ONE: HNE Ethics and Governance Review Fees for Clinical Trials**, will be charged accordingly for the duration of the trial. Please ensure all Tax Invoices received are paid within 30 days.
* Please ensure the review fees are considered when preparing your study budget and contracts.
* If these details change throughout the course of the study, please complete a new form and email to [HNELHD-ResearchOffice@health.nsw.gov.au](mailto:HNELHD-ResearchOffice@health.nsw.gov.au)

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| **STUDY DETAILS** | |
| **REGIS Reference Number** | Click here to enter text. |
| **Clinical Trial Title** | Click here to enter text. |
| **Sponsor Type** | **Commercial External Sponsor**  **Non-Commercial External Sponsor** |
| **Sponsor Name** | Click here to enter text. |
| **Name of Coordinating Principal Investigator or**  **Principal Investigator** (if Governance Only Site Applications) | Click here to enter text. |
| **Department & Location** | Click here to enter text. |
| **Contact for Enquiries** | Click here to enter text. |
| **Contact Email Address** | Click here to enter text. |
| **Contact Phone Number** | Click here to enter text. |
| **PAYMENT METHOD: Cost Centre Transfer** | |
| **Cost Centre Number** | Click here to enter text. |
| **Contact Person** | Click here to enter text. |
| **PAYMENT METHOD: Tax Invoice** | |
| **Name of Sponsor** | Click here to enter text. |
| **Full Address** | Click here to enter text. |
| **ABN** | Click here to enter text. |
| **Email Address** | Click here to enter text. |
| **Contact Person** | Click here to enter text. |
| **Contact Number** | Click here to enter text. |
| **Study Protocol Number** | Click here to enter text. |
| **Purchase Order Number (if required)** | Click here to enter text. |
| **Any other details required by Sponsor i.e. Site Number** | Click here to enter text. |
| **DECLARATION** | |
| **Name of CPI/PI or Delegate** | Click here to enter text. |
| * I agree the Payment Method details provided above will be used to apply the associated fees from **Appendix ONE: HNE Ethics and Governance Review Fees for Clinical Trials** for the duration of this study including any associated amendments received by the HNE Research Office. * If these details change throughout the course of the study, I will complete a new form and email to [HNELHD-ResearchOffice@health.nsw.gov.au](mailto:HNELHD-ResearchOffice@health.nsw.gov.au) | |
| **Signature of CPI/PI or Delegate** | Click here to enter text. |
| **Date** | Click here to enter a date. |

**Appendix ONE: HNE Ethics and Governance Review Fees for Clinical Trials**

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| **For the Initial Ethics Review** | **Sponsor** | **Amount (Ex-GST)** |
| **New Ethics Application** | Commercial External Sponsor | $6,250 |
| Non-Commercial External Sponsor | $1,000 |
| **For the Ethics Review of Amendments** | **Sponsor** | **Amount (Ex-GST)** |
| **General Amendments – Addition of site** | Commercial External Sponsor | $1,500 |
| Non-Commercial External Sponsor | $150 |
| **General Amendments – Addition of a Sub-Study** | Commercial External Sponsor | $2,500 |
| Non-Commercial External Sponsor | $500 |
| **General Amendments – Major Amendment** | Commercial External Sponsor | $1,000 |
| Non-Commercial External Sponsor | $250 |
| **General Amendments – Minor Amendment** | Commercial External Sponsor | $500 |
| Non-Commercial External Sponsor | $150 |
| **For the Initial Governance (SSA) Review** | **Sponsor** | **Amount (Ex-GST)** |
| **New Site Application** | Commercial External Sponsor | $4,500 |
| Non-Commercial External Sponsor | $1,000 |
| **For the Governance Review of Site Amendments** | **Sponsor** | **Amount (Ex-GST)** |
| **Non-standard contract review** | Commercial External Sponsor | $2,000 |
| Non-Commercial External Sponsor | $500 |
| **General Amendments – Major Amendment** | Commercial External Sponsor | $750 |
| Non-Commercial External Sponsor | $250 |
| **General Amendments – Minor Amendment** | Commercial External Sponsor | $325 |
| Non-Commercial External Sponsor | $100 |

**Definitions:**

**Amendments:** An amendment is considered as any change to a research project or an approved application that occurs after ethics approval or governance authorisation, respectively. Where an amendment is submitted as a single batch or documents containing several items for review (by either HREC or RGO), only a single amendment fee will be charged.

**Addition of site**: A fee for an additional site will be charged when a clinical trial adds a site to a clinical trial study after HREC approval has been granted.

**Addition of Sub-study**: A sub-study is a study performed a subgroup of the subjects included in the clinical trial. For example: a pharmacokinetics or pharmacogenetics sub-study may include a sample of the patients participating in the clinical trial. A fee for a sub-study will be charged when an already-approved clinical trial submits for approval a study related to the original clinical trial.

**Clinical Trial**: A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to: surgical and medical treatments and procedures; experimental drugs; biological products; medical devices; health-related service changes; health-related preventative strategies; health-related educational interventions.

**Major Amendment:** A major amendment is considered more than an administrative change and, in the case of an amendment submitted for Research Ethics Review, a full review by a HREC is required, examples include: protocol amendment; contract amendment, revision of study design due to safety issues; revisions of drug dosage, participant groups and numbers of study participants; investigator brochure updates, where there are associated changes required to the Participant Information Sheet/Consent Form (PISCF)

**Minor Amendment:** A minor amendment is defined as changes to the details of research project that have no significant implications for the safety of participants or for the conduct, management, or scientific value of the research project. Examples include; Participant Information Sheet/Consent Form (PISCF) amendments with changes not required to be reviewed by the HREC Committee; investigator brochure updates where there is no change required to the Participant Information Sheet/Consent Form (PICF); change of PI/CPI; Minor updates to existing patient-facing documents, protocol clarification letters, advertising material and single-word changes.

**Non-Standard Contract:** The NSW Health [PD2011\_028](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_028.pdf) sets out a series of standard contracts approved for use with both commercial and non-commercial clinical trials. Use of these contracts will not attract a non-standard contract fee. Should a non-standard contract be used by either a commercial or non-commercial sponsor, a non-standard contract fee will be charged.