

## Schedule of Fees – Ethics and Governance

Research application fees are charged for new research project applications and amendments to approved research projects for both human research ethics and research governance (Site Specific Assessment [SSA]) review. A fee is charged for the ethics and SSA review process, regardless of the outcome of the review. Research application fees vary depending on the type of submission and the research project sponsor/funding type.

| Submission type  | Amount* |
|--|---------|
| <b>Commercially Sponsored</b>  |         |
| Ethics/SSA Review New Application – First in human studies/Phase 1         | \$8250  |
| Ethics/SSA Review New Application – All other                              | \$6050  |
| Ethics/SSA Review Major Amendment  | \$880   |
| Ethics/SSA Review Minor Amendment  | \$220   |
| <b>Collaborative Research Group (CRG)**</b>                                |         |
| Ethics/SSA Review New Application – First in human studies/Phase 1         | \$1100  |
| Ethics/SSA Review New Application – All other                              | \$770   |
| Ethics/SSA Review Major Amendment  | \$220   |
| Ethics/SSA Review Minor Amendment  | Exempt  |
| <b>Investigator-Initiated**</b>  |         |
| Ethics/SSA Review New Application – Investigator-Initiated Metro North led | Exempt  |
| Ethics/SSA Review New Application – Investigator-Initiated Externally led  | \$165   |
| Ethics/SSA Amendment   | Exempt  |
| <b>Exempt from HREC Review</b>   |         |
| Ethics New applications- Metro North HHS application                       | Exempt  |
| Ethics New applications- Non-Metro North HHS application                   | \$55    |

\*Amounts are inclusive of GST; Queensland Health Hospital and Health Services will not be charged GST.

\*\*If there is commercial funding, Metro North Health reserves the right to charge additional fees/discretionary fees (e.g. cost recovery for legal review) to the above which will be disclosed prior to accepting the study for review.

**A signed fee template is to be uploaded with the HREC/SSA submission via Ethical Review Manager (ERM). Failure to do so may delay review of the submission.**

The fee template is available at: <https://metronorth.health.qld.gov.au/research/ethics-and-governance>

| Submission type   | Definition  |
|---|---|
| Commercially Sponsored  | Research that is sponsored by a commercial organisation or contract research organisation (CRO) with commercial funding. The company designs the protocol and owns the study results and intellectual property arising from the research.   |
| Collaborative Research Group (CRG)  | An academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating a study. Cooperative /Collaborative research groups recognised as a legal entity will have an ABN. If unsure, please check ABN Lookup: <a href="https://abr.business.gov.au/">https://abr.business.gov.au/</a> .   |
| Investigator-Initiated  | Research that is initiated and managed by a non-pharmaceutical company and led by the CPI/PI's institution such as a university or hospital. Investigator-Initiated clinical trials of an unapproved drug or device at Metro North Health must seek Metro North Health sponsorship approval prior to HREC submission, or be sponsored through a CRG. A Metro North Investigator-Initiated/led study is one where the CPI is representing Metro North Health. If a Metro North employee is undertaking a research higher degree with a University, this is classified as an investigator-initiated externally led study and subject to a fee. This is because the research higher degree student is representing the University and the student's supervisor is acting as the CPI. |
| Hospital and Health Service Quality Initiative/Research Exemption (exemption) | Quality initiatives (audit, quality improvement project) and research that is exempt from full ethical review (e.g. systematic reviews, studies that use data publicly available).  |
| Major Amendment   | <ul style="list-style-type: none"> <li>- Changes to the protocol and/or Participant Information and Consent Form (PICF) beyond administrative changes</li> <li>- Changes that require review by the ethics committee, sub-committee or other expert/legal review</li> <li>- Review of a sub-study</li> <li>- Addition of a site</li> <li>- Changes to investigators that require study document and/or agreement/indemnity updates.</li> <li>- Other agreement/contract amendments/variations</li> <li>- Changes to procedures undertaken by participants</li> <li>- Updates to Investigator's Brochure</li> </ul>  |
| Minor Amendment   | <ul style="list-style-type: none"> <li>- Administrative changes e.g., typographical error correction, version control</li> <li>- Minor changes to the protocol or other study documentation e.g. correcting errors, minor clarifications</li> </ul>   |
| Discretionary fee   | <p>A discretionary fee may apply to all applications involving but not limited to the following circumstance:</p> <ul style="list-style-type: none"> <li>- poorly written or incomplete applications</li> <li>- complex applications requiring additional legal/expert review</li> <li>- studies with commercial funding but not commercially sponsored.</li> </ul>   |