

Schedule of Fees for Research Ethics and Governance Review

The Research fees apply to:

- commercially sponsored projects
- trials sponsored by a Collaborative Research Group
- funded university led projects (e.g. large studies with NHMRC/MRFF or similar grant funding)

Please note: These fees do not apply to research that are led by Darling Downs Health, Queensland Health or if the project is contributing to a research higher degree and the higher degree student/applicant is also a Darling Downs Health employee.

Research application fees are charged for new research project applications and amendments to approved research projects for both human research ethics (HREC) 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. Definitions are provided on the following page.

These fees are reviewed annually and are benchmarked against other Queensland Hospital and Health Services.

Submission Type	Amount (GST incl)
Commercially Sponsored Research	
Ethics/SSA: Review New Application	\$6,000
Ethics/SSA: Review Major Amendment	\$850
Ethics/SSA: Review Minor Amendment	Nil
Ethics/SSA: Addition of a Sub-study	\$2,200
Collaborative Research Groups (a legal entity which acts as the Sponsor of the Research Project)	
Ethics/SSA: Review New Application	\$700
Ethics/SSA: Review Major Amendment	\$150
Ethics/SSA: Review Minor Amendment	Nil
External Principal Investigator Initiated including University led	
Ethics/SSA: Review New Research Project	\$150
Ethics/SSA: Major Amendment	\$50

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://www.darlingdowns.health.qld.gov.au/research/for-researchers/start-a-research-project>

Submission Type	Definition
Commercially Sponsored Research	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 Groups (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: https://abr.business.gov.au/
University Initiated and Principal 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 must either seek Darling Downs Health sponsorship approval prior to HREC submission (Darling Downs Health Investigator- Initiated) or be sponsored through an external CRG (CRG fees then apply). A Darling Downs Health Investigator-Initiated/led study is one where the CPI is representing Darling Downs Health.
Major Amendment	<p>A 'major amendment' is defined as an amendment to the protocol or any other supporting documentation, that is likely to affect to a significant degree the safety or physical or mental integrity of the participants of the study, the scientific value of the study, the conduct or management of the study or the quality and safety of any investigational medicinal product used in a study.</p> <p>For example:</p> <ul style="list-style-type: none"> - Changes to the protocol and/or Participant Information and Consent Form (PICF) beyond administrative changes - Changes that require review by the ethics committee, sub-committee or other expert/legal review - Review of a sub-study - Addition of a site - Changes to investigators that require study document and/or agreement/indemnity updates - Other agreement/contract amendments/variations - Changes to procedures undertaken by participants - Updates to Investigator's Brochure
Minor Amendment	<p>An 'Administrative amendment' is defined as changes to the details of a research project that have no significant implications for participants or for the conduct, management or scientific value of the research project.</p> <p>For example: Correction of typographical errors in the research protocol or other research project documentation, amended contact details for the sponsor or research project staff and appointment of new or change of support staff contact.</p>