

Ethics & Governance Review Fee Schedule

Fees are payable in FULL at the time of submitting a Site-Specific Governance Assessment Application for Research Governance Review, or an Ethics Application for review by the Western Health (WH) Low Risk Ethics Panel (LREP) or a Quality Assurance (QA)/Minimal Risk Research (MRR) Office for Research (OfR).

Projects will not be accepted without a completed payment form. Payment is per Project.

If unsure, please contact the OfR to determine whether fees are applicable; Telephone: 03 8395 8072 or 03 8395 8074.

COMMERCIALY SPONSORED RESEARCH PROJECTS (High Risk Research - Governance Review) E.g. Drug & Interventional, Health & Social Science Projects.	Unit Value (\$)	GST (\$)	Total (\$)
Initial Submissions			
New Submission	6500	650	7150
Additional Fee - New Submission for Expedited Review (3 working days) #	2000	200	2200
New Submission – Registries/Observational studies/WH lead site under NMA process	3300	330	3630
New Submission – Sub-Study	2700	270	2970
Post Approval/Authorisation Amendments			
Protocol Amendment	770	77	847
Investigator Brochure Amendment /Administrative Changes*	240	24	264

INVESTIGATOR- INITIATED/ COLLABORATIVE GROUP, NO COMMERCIAL INVOLVEMENT/SPONSORSHIP (High Risk Research- Governance Review)	Unit Value (\$)	GST (\$)	Total (\$)
New Submissions			
Investigator-Initiated – Western Health	200	20	220
Investigator Initiated – External institution	300	30	330
Collaborative Groups/Health Departments Initiated	600	60	660
Post Approval/Authorisation Amendments			
Investigator-Initiated Western Health - Major Amendment †	Nil	Nil	Nil
External Institution & Collaborative/Health Department - Protocol Amendment †	100	10	110
Other Minor Administrative Amendments ⁱ	Nil	Nil	Nil

LOW RISK RESEARCH (WH LREP Ethical Review or LR Research - Governance Review) QUALITY ASSURANCE AND MINIMAL RISK RESEARCH (Organisational Review by OfR)	Unit Value (\$)	GST (\$)	Total (\$)
New Submissions			
QA/MRR Submission (initiated by Western Health, External, Collaborative Group)	100	10	110
LR Initiated by Western Health	200	20	220
LR Initiated by External institution	300	30	330
LR Initiated by Collaboration Group	400	40	440
LR Initiated by Commercial Sponsor	1200	120	1320
Western Health is providing the ethical review on behalf of an external institution/organisation. (Research conducted outside of Western Health. e.g. GP Practice or Private Rooms – only for LR projects)	500	50	550
Post Approval Amendments			
QA/LR Initiated by Western Health	Nil	Nil	Nil
Initiated by External institution/Collaborative Group – Major Amendment (LR only) †	100	10	110
Initiated by Commercial Sponsor – Major Amendment (LR only) †	200	20	220
Western Health has provided Ethical Review on behalf of an external institution – Major Amendment (LR only) †	100	10	110

ETHICS AND GOVERNANCE SUBMISSION SERVICE (EGSS)[∞] An application preparation service provided by the OfR.	Unit Value (\$)	GST (\$)	Total (\$)
Commercially Sponsored Projects - EGSS Admin Fee	1800	180	1980
Investigator Initiated/ Collaborative Group/ Grant Funded- EGSS Admin Fee	900	90	990

[∞] ETHICS AND GOVERNANCE SUBMISSION SERVICE (EGSS)

The EGSS is a service provided by the Western Health OfR that assists our researchers to prepare a Commercially Sponsored, Investigator Initiated, Collaborative Group or Grant Funded project application for ethics and/or governance review, and

subsequent submission for the required authorisation/approval for it to be conducted at Western Health. PLEASE NOTE: This administrative fee is in addition to the Research Governance and Ethical Review fees (outlined above). The usual fee that applies to the specific application type will also need to be paid.

Upon a researcher commissioning the EGSS the OfR will organise for preparation of the initial ethics and/or governance submission to Western Health and when the application is ready it will be submitted to Western Health for the requisite review (ethics and/or governance) and the applicable ethics or governance review fee will then need to be paid upon submission.

Conditions for expedited governance review for new commercial sponsored applications

The service will provide a governance review and outcome within three working days from submission for new commercial sponsored applications submitted to the Western Health Office for Research provided the following conditions are met:

- An additional \$2000 expedited review fee will be incurred on top of the new submission fee.
- Applications must be submitted via ERM by 9am. Late submission will be assessed on the next working day.
- Researchers must send a submission notification email that includes all study documents to SSAReview@wh.org.au with an appropriate email subject title to flag the application for expedited review.
- The application must be accurate and complete, as assessed by the reviewer at the Office for Research. The reviewer at the Office for Research will screen the application within 24 hours and advise whether the application is complete and can be released for review. If the application is incomplete, feedback will be provided and it may not be accepted for expedited review.
- This service is subject to the Office for Research's availability and resources for expedited review which will be determined by the Manager at Office for Research and the decision is final.

If above conditions are met and the application is accepted for expedited review as follow:

- The application will be reviewed within three working days. **Please note that this may not necessarily equate to approval and will not guarantee approval within three working days.**
- The three working days clock commences once the application is deemed complete and correct.
- If queries arise out of the review, the researcher must provide their responses to the queries via a resubmission on ERM. Once submitted, the responses will be subject to another three working days turnaround.

* Includes but are not limited to the following: Sponsor initiated amendment to contacts, Sponsor initiated name changes, PICF amendments, change of PI, addition of site, addition of study documents (flyers, advertisements, research tools, CRFs and etc.)

† Includes but are not limited to the following: Protocol Amendments, substantial PICF amendments & addition of new study documents.

ⁱ Includes but are not limited to the following: Change of personnel & change to contact details.