

Alfred Health Ethics and Research Governance Fees

The fees are GST exclusive

Alfred Research Alliance includes Alfred Health and the following:

- Baker Heart & Diabetes Institute
- Burnet Institute
- Deakin Alfred Health Nursing Research Centre
- La Trobe/Alfred Nursing and Allied Health Clinical School
- Monash University School of Public Health & Preventive Medicine and Central Clinical Schools
- Nucleus Network
- 360biolabs

Applications Submitted under the Streamlined Review Processes:

For applications submitted under the Streamlined Review Process (SERP or NMA), the fees cover **either:**

- an ethics review fee if the application is reviewed by the Alfred Hospital Ethics Committee
- or*
- a research governance/site-specific assessment fee if reviewed by another certified HREC

The review fee will also apply in the situation where the Alfred Hospital Ethics Committee is providing scientific and ethical review and Alfred Health is not a participating site in a given study.

The Alliance members, other than Alfred Health, will need to undertake their own research governance review.

The following fees apply to ALL applications:

Commercially sponsored studies	Fee (\$)¹
New applications – First time in human studies	7,500
New applications – All other Phase studies	6,000
Observational studies, sub-studies and extension studies	3,000
Additional fee if an independent expert review is required	4,000
Expedited COVID-19 review – studies involving Alliance-affiliated institution	2,000 additional
Expedited COVID-19 review – studies not involving Alliance-affiliated institution	4,000 additional
<i>Additional fees for streamlined projects:</i>	
Fee per additional site – applies where the Alfred Hospital Ethics Committee is the reviewing HREC	500

Investigator Initiated, commercially supported studies Funding and/or investigational product provided by a pharmaceutical or device company.	Fee (\$)¹
Collaborative Group	600
Investigator-initiated	3,000

Investigator Initiated, no commercial involvement Funding obtained from a source other than a pharmaceutical or device company, e.g. funding from NHMRC, NIH, etc. The fee applies to the Institution deemed to be the custodian of the Protocol and/or the Institution through which a funding application was submitted.	Fee (\$)¹
Investigator-initiated/Alfred Health	Nil
Investigator-initiated/Alliance affiliated institution	200
Investigator-initiated/Non-affiliated institution	600

Low & Negligible Risk The fee applies to the Institution deemed to be the custodian of the Protocol and/or the Institution through which an application was submitted.	Fee (\$)¹
Alliance member	Nil
Non-affiliated institution	200
Commercially supported	1,000

Reviews Conducted on Behalf of Other HRECs under Specific MoUs	Fee (\$)¹
Fees charged in accordance with the relevant MoU	Fee per MoU

1 A fee will apply for applications that are withdrawn following full submission

Amendment Applications

Investigator-initiated or collaborative group studies	Fee (\$)²
Amendment application	Nil

Commercially sponsored studies	Fee (\$)²
Substantial amendment³ e.g. protocol, significant changes to PICF(s)	650
Non-substantial amendment³ e.g. changes to personnel, advertising material, Investigator's Brochures, DSURs	200
For major amendment applications submitted within one month of ethics approval and without impact on participant safety	1,300
For administrative changes submitted within one month of ethics approval	400
Expedited review within 3 working days of submission (please note conditions)⁴	3,000

Additional fees for streamlined studies	Fee (\$)²
Additional fee per new site added - applies to commercially sponsored studies	500

Conversion of an existing study to the streamlined process	Fee (\$)²
Investigator-initiated/Alfred Health	Nil
Investigator-initiated/Non-Alfred Health	200
Collaborative group studies	200
Investigator Initiated, commercially supported studies	650
Commercially sponsored studies	1500
Additional fee per new site added - applies to commercially sponsored studies	500

2 A discretionary \$200 surcharge may apply to all amendment applications (apart from those associated with safety issues) involving, but not limited to, the following circumstances:

- When applications are submitted too frequently (for one study)
- Poorly written or incomplete applications
- Complex applications

3 Please refer to the NHS definitions of substantial and non-substantial amendments:

<https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/>

4 The service will provide a scientific and ethical review of an amendment application submitted to the Alfred Hospital Ethics Committee within three working days provided the following conditions are met:

- a. Applications need to be submitted via ERA by 9am. Researchers should also send an email to the Ethics Officer responsible for the study as well as to research@alfred.org.au to flag the application for expedited review.
- b. The applications need to be accurate and complete, as assessed by the reviewer and the Office. An application is considered complete if it contains all of the following documents, if relevant:
 - i. Amendment application form
 - ii. An explanatory letter detailing the rationale for the amendment if the amendment application form is insufficient
 - iii. Protocol with a summary of changes
 - iv. Investigator’s Brochure with a summary of changes
 - v. PICF(s) with tracked changes highlighting revisions
 - vi. For amendments relating to changes in dose of the investigational product, relevant documentation from the Safety Monitoring Committee
 - vii. Amended Medical Physicist’s report if there are changes to the mode and/or frequency of the ionising radiation procedures
 - viii. Appropriate and correct legal documents
 - ix. Any other documentation relevant to the amendment
 - x. Amendment fee payment form
- c. The Office 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.
- d. The clock commences once the application is deemed complete and correct
- e. The application will be reviewed within three working days. Please note that this may not necessarily equate to *approval* within three working days.
- f. If queries arise out of the review, the responses will be subject to another three working day turnaround. Once the responses are submitted via ERA, researchers should send an email to the Ethics Officer as well as to research@alfred.org.au to flag that the responses had been submitted.

Archiving fees

Archiving	Fee (\$)
Studies to be archived indefinitely	500 per box
Studies to be archived for 7 years	200 per box