Alfred Health Ethics and Research Governance Fees

The fees are GST exclusive

The Alfred Research Alliance includes Alfred Health and the following organisations and Schools which are considered 'affiliated institutions':

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

Applications Submitted under the Streamlined Review Processes:

For applications submitted under National Mutual Acceptance (NMA), the fees cover **either**:

- an ethics review if the application is reviewed by the Alfred Hospital Ethics Committee ('Reviewing application')

or

- a research governance/site-specific assessment by Alfred Health if the application has been reviewed by another NMA-certified HREC ('Accepting application')

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.

Presentation of Ethics Reviews or Site-Specific Assessment Fees in Agreements for Studies undertaken at Alfred Health:

For studies involving Alfred Health, please do not list individual review fees in the Agreement. Instead, please include a statement that **the fees will be paid in accordance with the Fee Schedule on the Office of Ethics & Research Governance website, on receipt of the invoice.**

A. New Reviewing[1] and Alfred Health Accepting applications[2]:

Commercially sponsored studies	**Fee ($)[2, 3]**
New Drug & Device applications – Phase I studies including First Time in Human (FTIH) studies	9,000
Additional fee if an independent expert review is required[4]	5,000
New Drug & Device applications – All other Phase studies	6,000
Observational studies, sub-studies and extension studies	3,000
Adaptive Platform/Basket/ Umbrella Master Protocol First Domain/Sub-study Protocol Fee per additional Domain/Sub-study Protocol	6,000 0 1,000
Low risk applications (single site and multi-site) submitted for full ethics review	1,000
Additional fees for streamlined projects: Fee per additional site – applies where the Alfred Hospital Ethics Committee is the reviewing HREC	500
Requests made to the Alfred Hospital Ethics Committee for other reviews	Please enquire

Investigator Initiated, commercially supported studies Funding and/or investigational product provided by a pharmaceutical or device company.	**Fee ($)[2, 3]**
Collaborative Group	600
Investigator-initiated with support from a commercial entity in the form of provision of drug, device and/or funding	3,000
Adaptive Platform/Basket/Umbrella Master Protocol First Domain/Sub-study Protocol Fee per additional Domain/Sub-study Protocol	600 0 100

Investigator Initiated, no commercial involvement for full Ethics Review[5] Funding obtained from a source other than a pharmaceutical or device company, e.g. funding from NHMRC, NIH, etc The fee applies to the Sponsor of the study defined as the Institution responsible for the initiation, management, and financing (or arranging the financing) of the study and carries the medico-legal responsibility associated with its conduct. As such, the Sponsor is the custodian of the Protocol and owns the data generated from the study.	**Fee ($)[2, 3]**
Investigator-initiated/Alfred Health with a budget of less than $2,000 per year	Nil
Investigator-initiated/Alfred Health with a budget of $2,000 or greater per year	200
Investigator-initiated/Alfred Research Alliance affiliated institution with a budget of less than $2,000 per year	200
Investigator-initiated/Alfred Research Alliance affiliated institution with a budget of $2,000 or greater per year	400
Investigator-initiated/Non-affiliated institution	600
Additional fee for Adaptive Platform/Basket/Umbrella Studies First Domain/Sub-study Protocol Fee per additional Domain/Sub-study Protocol	100 0 100

Investigator-initiated, Single Site Low Risk Studies (application via the Alfred Hospital Ethics Committee Low Risk Application Form[6, 7] The fee applies to the Sponsor of the study defined as the Institution responsible for the initiation, management, and financing (or arranging the financing) of the study and carries the medico-legal responsibility associated with its conduct. As such, the Sponsor is the custodian of the Protocol and owns the data generated from the study.	**Fee ($)[2, 3]**
Alfred Health	Nil
Alfred Research Alliance	100
Non-affiliated institution	300

Alfred Hospital Ethics Committee Reviews Only[8] - Other Reviews	**Fee ($)[2, 3]**
Commercially sponsored expedited review pathway for COVID-related studies[9]	12,000
Additional fees for multi-site projects: Fee per additional site – applies where the Alfred Hospital Ethics Committee is the reviewing HREC	500
Additional fee if an independent expert review is required	5,000
Expedited review process by application for ***eligible*** early phase clinical trials[10]	14,000
Additional fees for multi-site projects: Fee per additional site – applies where the Alfred Hospital Ethics Committee is the reviewing HREC	500

1 Applications submitted to the Alfred Hospital Ethics Committee are stratified (and charged accordingly) by review pathway – either (1) for full review **or** (2) single site low risk applications submitted on the Alfred Single Site application Form via a delegated review pathway.

2 For applications undertaken at Alfred Health, only an ethics review fee **or** site-specific assessment (governance review) fee is charged.

3 A fee will apply for applications that are withdrawn following full submission of an ethics application or site-specific assessment application.

4 An independent expert review will also be sought for Accepting true First-Time-in-Human (FTIH) if the Reviewing HREC has not obtained an independent expert review.

5 An application for full ethics review must be completed on the national forms (HREA, VSM, SSA). This applies to all multi-site low risk applications as well as applications submitted on the Alfred Low Risk Application Form but deemed by the Ethics Committee as more than low risk.

6 Please check that the application form and process is acceptable to your Institution.

7 If the Low Risk application is deemed by the Ethics Committee to be more than low risk, the forms for the more than low risk review pathway will be required and the full submission fee will be charged.

8 These processes are only available for Reviewing applications reviewed by the Alfred Hospital Ethics Committee and not for Accepting applications reviewed by an external HREC.

9 Expedited review pathway for COVID-related studies: **Researchers can submit an application on any business day but it must be complete and accurate.** In terms of turnaround times, the 'start clock' commences at 9am on the first full business day after an application or researcher response is submitted. Much of the expedited review process mirrors the usual process, except for the rapid and restricted timelines and the divorce from the dependence on the administrative timelines of the Research Review Sub-committee and Ethics Committee meetings. The details of the expedited review are as follows:

a. Researchers are asked to inform the ERGO of their anticipated submission date.
b. Researchers submitting first time in human (FTIH) studies are required to submit the final versions of the Protocol, Investigator's Brochure and PICF(s) as soon as available to initiate the independent expert review process.
c. Applications should be emailed to research@alfred.org.au
d. The submission will be screened by ERGO staff within one full business day and the screening letter sent via email.
e. An application container will be created in ERA to enable the revised application and response to the screening letter to be uploaded.
f. ERGO will have one full business day to review the application and responses.
g. If all of the essential issues critical for the ethical review identified in the screening letter have been addressed, the application will be immediately released to the delegated Ethics Committee reviewers for review.
h. The review will occur within three full business days.
i. Researchers will be sent the queries from the delegated Ethics Committee reviewers within one full business day of the completion of the review.
j. The researchers' responses and associated revised documents need to be returned within three business days and the application will be released to the delegated Ethics Committee reviewers for consideration.
k. The delegated Ethics Committee reviewers will review the responses within two full business days.
l. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
m. For FTIH studies, the independent expert review will be forwarded to researchers as soon as it is available.
n. The researchers' responses to the FTIH review and associated revised documents need to be returned within three business days and, the application will be released to the delegated Ethics Committee reviewers for consideration.
o. The delegated Ethics Committee reviewers will consider the responses within two full business days.
p. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
q. Once the final responses have been received from the researchers, the whole Ethics Committee group (Drugs & Interventions (D&I) or Health & Social Sciences (H&SS)) is to be advised that the project is ready for expedited approval and given the opportunity (24 hrs) to look at project on ERA and provide input.
r. Once all ethical requirements have been met, an ethics approval certificate will be issued.
s. The approval will be ratified at the subsequent Ethics Committee meeting.
t. Whilst every effort will be made to meet the specified turnaround times, please note that the identification of significant medical, scientific and/or ethical issues may preclude these timelines from being met.

10 Expedited review pathway for eligible early phase studies: Whilst the Alfred Hospital Ethics Committee endeavours to undertake a timely review of all clinical trials, it is essential studies undergo a rigorous and appropriate level of review commensurate to the risk of the clinical trial. However, it is acknowledged that for some lower risk and less complex clinical trials for which there is an urgent need, an expedited review process may be appropriate.

As such, the Alfred Hospital Ethics Committee has made provision for an expedited review process for clinical trials which meet one or more of the following criteria:

- Prophylactic vaccines (unless the vaccine utilises a new or innovative technology or platform)
- Biosimilars
- New investigational products which the Ethics Committee has reviewed in the past and there are special circumstances which warrant an expedited review, such as an extension study
- Other studies for which there is strong case for an expedited review

Please note that, apart from vaccines not utilising a new or innovative technology or platform, *true* first time in human (FTIH) studies requiring an independent expert review are *not* eligible for this process.

In all circumstances, Sponsors are required to submit an expression of interest, detailing the justification for an expedited review, in advance of the proposed submission date. If accepted by the Committee, a date of submission will be agreed upon.

However, the efficiency of the service will rely on planning and effective communication with the Ethics & Research Governance Office (ERGO). The Sponsor and researchers can assist by ensuring that the application is complete and accurate. For studies where Alfred Health is the Lead Site, early attention to the site-specific or 'governance' requirements is also highly recommended.

In terms of turnaround times, the 'start clock' commences at 9am on the first full business day after an application or researcher response is submitted. Much of the expedited review process mirrors the usual process, except for the rapid and restricted timelines.

The details of the expedited review of applications accepted by the Ethics Committee are as follows:

a. The clinical trial is to be submitted on the date agreed to as per above.
b. Applications should be emailed to research@alfred.org.au
c. The application will be screened by ERGO staff within one full business day and the screening letter sent via email.
d. An application container will be created in ERA to enable the revised application and response to the screening letter to be uploaded.
e. ERGO will have one full business day to review the application and responses.
f. If all of the essential issues critical for the ethical review identified in the screening letter have been addressed, the application will be immediately released to the delegated Ethics Committee reviewers for review.
g. The review will occur within five to seven full business days.
h. Researchers will be sent the queries from the delegated Ethics Committee reviewers within one full business day of the completion of the review.
i. The researchers' responses and associated revised documents need to be returned within three business days and the application will be released to the delegated Ethics Committee reviewers for consideration.

j. The delegated Ethics Committee reviewers will review the responses within two to three full business days.
k. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
l. The delegated Ethics Committee reviewers will consider the responses within two to three full business days.
m. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
n. Once the final responses have been received from the researchers, the whole Ethics Committee group (Drugs & Interventions (D&I) is to be advised that the project is ready for expedited approval and given the opportunity (24 hrs) to look at project on ERA and provide input.
o. Once all ethical requirements have been met, an ethics approval certificate will be issued.
p. The approval will be ratified at the subsequent Ethics Committee meeting.
q. Whilst every effort will be made to meet the specified turnaround times, please note that the identification of significant medical, scientific and/or ethical issues may preclude these timelines from being met.

B. Amendment Applications

I. Reviewing applications submitted to the Alfred Hospital Ethics Committee

The increase in complexity of studies and the advent of innovative study designs such as Adaptive Platform/Basket/Umbrella studies has resulted in more complex and frequent amendment applications. The applications often include documents which are unrelated to the *primary purpose* of the amendment which contribute to the delay in the review of the amendment. This is further compounded by an inadequate explanation of the purpose of the amendment and the changes made to each of the documents.

In an attempt to improve the efficiency of the review process, the following process has been adopted for amendment applications submitted to the Alfred Hospital Ethics Committee for review:

1. Amendments are to be submitted on the basis of the *primary purpose* of the amendment. For example, the primary purpose of an amendment initiated as a result of new safety information in the IB culminating in an amended Protocol and PICF(s) should be submitted as one amendment. No other documents should be included in this amendment application.

2. Below are some examples of amendments to be submitted on the basis of the following primary purposes as well the additional documents to be provided in the application:
    a. An amended Protocol with or without IB and/or PICFs
    b. Updated or new IB, DSUR etc with or without PICFs
    c. A new domain for an Adaptive Platform study
    d. New or revised participant-facing material (letters, questionnaires, diaries, participant card, patient brochures, etc)
    e. New or revised advertising/recruitment material or recruitment strategies (eg telehealth or e-Consent)
    f. Addition of new Participating Site(s)
    g. Addition of Teletrial Sites
    h. Conversion of a study to National Mutual Acceptance (NMA)
    i. Amendments to PICF(s) not associated with a Protocol amendment or IB update
    j. A change to the Local Australian Sponsor
    k. A change to the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI)

3. Each amendment should be accompanied by an Amendment Request Form which includes a clear description of the amendment and the revisions made to each document.

4. As Amendment Request Forms seem to be generally completed by the Sponsor, in addition to the Amendment Request Form, a letter or email from the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI) indicating that they have reviewed the amendment and whether the amendment documents contain any information that might alter the risk:benefit ratio of the study or impact the participants, Protocol or PICF(s) is also to be submitted.

5. If the amendment is more complex, a detailed explanatory statement from the Sponsor and the Co-ordinating Principal Investigator and/or Site Principal Investigator is also required. As above, the letter should identify the reasons for the amendment; any new safety information; any new information that might alter the risk/benefit of the study and; if the amendment raised any ethical issues.

6. For amendments which include only an updated IB and/or DSUR Executive Summary, a letter or email from the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI) indicating that they have reviewed the IB and/or DSUR and whether the IB and/or DSUR contains any information that might alter the risk:benefit ratio of the study or impact the participants, Protocol or PICF(s) is also to be submitted.

7. Each amendment will be charged accordingly with some key documents such as the IB, a new domain to an Adaptive Platform trial; addition of Participating Sites; always attracting an additional fee.

8. For studies to be conducted at Alfred Health the governance documents should be submitted as part of the site-specific assessment of the amendment.

9. Please refer to Section D for guidance on documents required for examples of amendments.

Investigator-initiated or collaborative group studies – Protocol Amendments	**Fee ($)[1, 2, 3, 4]**
Alfred Health Investigator-initiated	Nil
Alfred Research Alliance Partner Investigator-initiated	Nil
Non-affiliated Investigator-initiated excluding Adaptive Platform/Basket/Umbrella studies	100
Collaborative Group - excluding Adaptive Platform/Basket/Umbrella studies	100
Collaborative Group or Non-affiliated Investigator-initiated Adaptive Platform/Basket/Umbrella studies in which existing Domains are amended and/or new Domains added	300

Investigator-initiated or collaborative group studies – Conversion to NMA, Change to Lead Site or Transfer of ethical oversight to another HREC	**Fee ($)[1, 2, 3, 4]**
Alfred Health Investigator-initiated	Nil
Non-Alfred Health Investigator-initiated	300
Collaborative Group	300
Commercially supported study	650

Commercially sponsored studies (Fees are cumulative)	**Fee ($)[1, 2, 3, 4]**
Amended Protocol Protocol Clarification Letter which in effect amends the Protocol Note to File which in effect amends the Protocol Dear Investigator Letter which in effect amends the Protocol (with or without amended PICFs)	800 each
Protocol Clarification Letter/Note to File/Dear Investigator Letter for an administrative change or correction only	200 each
Minor revisions to the PICFs	200
Addition of new PICFs	200 each
Updated Investigator's Brochure* Addendum to Investigator's Brochure* Instructions for Use* Development Safety Update Report (DSUR)* Product Information* ** not resulting in a revision to the PICFs*	300 each
Updated Investigator's Brochure* Addendum to Investigator's Brochure* Instructions for Use* Development Safety Update Report (DSUR)* Product Information* **resulting in a revision to the PICFs*	650 each
Adaptive Platform/Basket/Umbrella studies in which existing Domains are amended and/or new Domains added Addition of a new domain to an Adaptive Platform trial (includes Protocol, IB and new PICFs Amended Protocol (with or without amended PICFs) Protocol Clarification Letter (with or without PICFs) Investigator's Brochure/Instructions for Use/DSUR/Product Information (with or without amended PICFs) Addition of new PICFs	 50 per cent of the initial application review fee 800 each 300 each 200 each
New or amended OGTR Licence	300 each
Patient-facing material (questionnaires, diary, etc	200 (per bundle of 5 documents)
Advertising/Recruitment material or recruitment strategies (eg telehealth or e-Consent)	200 (per bundle of 5 documents)
Addition of Participating Sites including Satellite Sites	500/Site
Change to Local Sponsor	650
Change to Lead Site	1,600
Change to CPI or Site PI	500

Commercially sponsored studies (Fees are cumulative)	**Fee ($)[1, 2, 3, 4]**
Transfer of HREC oversight from the Alfred Hospital Ethics Committee to another HREC	1,600
Request to re-open a previously closed study	3,000
Amendment to Agreement	100
Additional fee[5] for an expedited review within 3 working days of submission (please note conditions)[6]	2,500
Additional fee[5] for major amendment applications submitted within one month of ethics approval and without impact on participant safety	800
Additional fee[5] for minor amendments submitted within one month of ethics approval	400

Conversion of an existing study to the streamlined process (Fees are cumulative)	**Fee ($)[1, 2, 3]**
Investigator-initiated/Alfred Health	Nil
Investigator-initiated/Non-Alfred Health	300
Collaborative group studies	300
Investigator Initiated, commercially supported studies	650
Commercially sponsored studies	1600
Additional fee per new site added - applies to commercially sponsored studies	500
Additional fee[5] for an expedited review within 3 working days of submission (please note conditions)[6]	2,500
Additional fee[5] for major amendment applications submitted within one month of ethics approval and without impact on participant safety	800

1 For applications undertaken at Alfred Health, only an ethics review fee **or** site-specific assessment (governance review) fee is charged

2 In all circumstances, amendments are to be submitted on the basis of the primary purpose of the amendment.

3 A fee will apply for applications that are withdrawn following submission of an amendment application

4 A discretionary $500 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

5 This fee is additional to the cumulative fee for the documents submitted.

6 Expedited amendment review process: 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.
g. Please note that complex amendments may not be eligible for this expedited review process. Please seek advice.

II. Accepting applications reviewed by an external NMA-certified HREC and submitted for Site Specific Authorisation by Alfred Health]

1. Since Alfred Health cannot influence the amendment applications submitted to external NMA-certified HRECs, for amendments submitted to Alfred Health for site specific authorisation, a cumulative fee schedule has been adopted as per the table below. For documents marked as "each", if there are multiples submitted of each (eg Protocols, Protocol Clarification Letters, IBs, etc), the fee will be multiplied by the number submitted.

2. Each amendment should be accompanied by an Amendment Request Form which includes a clear description of the amendment and the revisions made to each document.

3. As Amendment Request Forms seem to be generally completed by the Sponsor, in addition to the Amendment Request Form, a letter or email from the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI) indicating that they have reviewed the amendment and whether the amendment documents contain any information that might alter the risk:benefit ratio of the study or impact the participants, Protocol or PICF(s) is also to be submitted.

4. If the amendment is more complex, a detailed explanatory statement from the Sponsor and the Co-ordinating Principal Investigator and/or Site Principal Investigator is also required. As above, the letter should identify the reasons for the amendment; any new safety information; any new information that might alter the risk/benefit of the study comment and; if the amendment raised any ethical issues.

5. For amendments which include only an updated IB and/or DSUR Executive Summary, a letter or email from the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI) indicating that they have reviewed the IB and/or DSUR and whether the IB and/or DSUR contains any information that might alter the risk:benefit ratio of the study or impact the participants, Protocol or PICF(s) is also to be submitted.

6. Each amendment will be charged accordingly with some key documents such as the IB; addition of a new domain to an Adaptive Platform trial; and addition of Participating Sites always attracting an additional fee.

7. In addition to the documents approved by the Reviewing HREC, the following governance documents should be submitted as part of the site-specific assessment of the amendment, as required: Alfred Master PICFs; Alfred versions of any other Master documents; standard indemnity to Alfred Health; amended budget; revised Resource Centre Declaration(s); Amendment to the Agreement or Deed of Novation.

8. Please refer to Section D for guidance on documents required for examples of amendments.

Investigator-initiated or collaborative group studies	**Fee ($)[1, 2, 3]**
Collaborative Group - excluding Adaptive Platform/Basket/Umbrella studies	100
Alfred Health Investigator-initiated	Nil
Alfred Research Alliance Partner Investigator-initiated	Nil
Non-affiliated Investigator-initiated	100
Collaborative Group or Non-affiliated Investigator-initiated Adaptive Platform/Basket/Umbrella studies in which existing Domains are amended and/or new Domains added	300

Commercially sponsored studies (Fees are cumulative)	**Fee ($)[1,2,3]**
Amended Protocol Protocol Clarification Letter which in effect amends the Protocol Note to File which in effect amends the Protocol Dear Investigator Letter which in effect amends the Protocol (with or without amended PICFs)	800 each
Protocol Clarification Letter/Note to File/ Dear Investigator Letter for an administrative change or correction only	200 each
Minor revisions to the PICFs	200
Addition of new PICFs	200 each
Updated Investigator's Brochure* Addendum to Investigator's Brochure* Instructions for Use* Development Safety Update Report (DSUR)* Product Information* **not resulting in a revision to the PICFs*	300 each
Updated Investigator's Brochure * Addendum to Investigator's Brochure* Instructions for Use* Development Safety Update Report (DSUR)* Product Information* **resulting in a revision to the PICFs*	650 each
Adaptive Platform/Basket/Umbrella studies in which existing Domains are amended and/or new Domains added Addition of a new domain to an Adaptive Platform trial (includes Protocol, IB and new PICFs) Amended Protocol (with or without amended PICFs) Protocol Clarification Letter (with or without PICFs) Investigator's Brochure /Instructions for Use/DSUR/Product Information (with or without amended PICFs) Addition of new PICFs	 50 per cent of the initial application review fee 800 each 300 each 200 each

Commercially sponsored studies (Fees are cumulative)	Fee ($)1,2,3
New or amended OGTR Licence	300 each
Change to Local Sponsor	650
Change to CPI or Site PI	500
New or amended Patient-facing material (questionnaires, diary, participant card, patient brochure, etc)	200 (per bundle of up to 5 documents)
Advertising/Recruitment Material or new/revised recruitment strategies	200 (per bundle of up to 5 documents)
Addition of Satellite Sites	500/Site
Amendment to Agreement	100
Additional fee[4] for major amendment applications submitted within one month of ethics approval and without impact on participant safety	800
Additional fee[4] for minor amendments submitted within one month of ethics approval	400

1 A fee will apply for applications that are withdrawn following full submission of an amendment application

2 A discretionary $500 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 All fees that apply are cumulative.

4 This fee is additional to the cumulative fee for the documents submitted.

C. Archiving fees

Archiving	**Fee ($)**
Studies to be archived indefinitely	600 per box
Studies to be archived for 7 years	250 per box

D. Appendix: Helpful tips for Amendment Applications for Reviewing and Accepting Applications[1]

Theme of Amendment	Documents to be included in the Ethics Application	Documents to be included in the Governance Application to Alfred Health as Required[2]
An amended Protocol and associated PICFs which results in a change to the study title	• Amended Protocol (Tracked and clean) • A summary of changes – either in the Protocol or as a separate document) • Revised Master PICF(s) • Insurance certificate • Draft CTN • HREC Review Only Indemnity	• Alfred Master PICFs • Standard indemnity Amendment to the CTRA • Budget (if revised)
An amended Protocol which involves the addition of new study arm(s) or Extension Protocol and associated PICFs	• Amended Protocol and Summary of Changes • New IBs and/or Product Information • New Master PICFs for new arms (if required) • Revised Master PICF(s) (if required) • New or related diaries (if relevant) • New questionnaires (if relevant) • Draft CTN • If there is also a change to study title, please include the documents as per above.	• Alfred Master PICFs • Amendment to the CTRA • Revised budget • If there is also a change to the study title, as per above.
A new domain for an Adaptive Platform study	• Domain Protocol • IB/Product Information Medical Physicist's Report (if required) • New Domain-specific PICFs (if required) • Revised Master PICFs (if required) • New or related diaries (if relevant) • New questionnaires (if relevant) • Draft CTN • If there is also a change to study title, please include the documents as per above	• Alfred Master PICFs • Amendment to the CTRA • Revised budget • If there is also a change to the study title, as per above.

Theme of Amendment	Documents to be included in the Ethics Application	Documents to be included in the Governance Application to Alfred Health as Required[2]
An updated IB or DSUR Executive Summary with no impact on the Protocol or PICF(s)	• Updated IB (Tracked and clean) • A summary of changes – either in the IB or as a separate document • An impact Statement from the CPI and/or Site PI	• An impact Statement from the Site PI
A change to the Local Australian Sponsor	• Letter from Sponsor detailing impact of change to Local Sponsor and justification for documents to be revised at the time and which will be amended in the future covering • Notification Letter to participants • Revised Master PICFs • Insurance certificate • Draft CTN • HREC Review Only indemnity • Any other documents which list the Local Sponsor	• Revised Alfred Master PICFs • Standard indemnity to Alfred Health • Deed of Novation between initial Local Sponsor, New Local Sponsor, Alfred Health (and Monash University, if relevant)
Adding a Teletrial Site	• HREC Supervision Plan • Teletrial Master PICF or Amended Master PICF • RSO Report from Satellite Site • Three Way Agreement between Sponsor, Primary and Satellite Site re use of Teletrial model • Draft CTN • HREC Review Only indemnity	• Revised Alfred Master PICFs or Alfred Teletrial Master • Standard indemnity to Alfred Health, if required • Amendment to the CTRA • Teletrial Sub-contract
Addition of new Participating Sites	• CVs of Site PI • Draft CTN • HREC Review Only Indemnity • Medical Physicist's Report (if required)	
A change to the Co-ordinating Principal Investigator (CPI) or Site Principal Investigator (PI):	• New CPI CV • Revised Master PICFs • HREC Review Only indemnity • Standard indemnity • Draft CTN	• New Site PI CV • Revised Alfred Master PICFs • HREC Review Only indemnity • Amendment to the CTRA • Standard indemnity

Theme of Amendment	Documents to be included in the Ethics Application	Documents to be included in the Governance Application to Alfred Health as Required[2]
		• Draft CTN

1 For Accepting applications reviewed by an external NMA-accredited HREC, it is expected that:
   a. the Ethics Committee requirements are fulfilled by the Reviewing HREC, including obtaining an independent expert review for a true First Time in Human (FTIH) clinical trial
   b. the documents approved by the Reviewing HREC are provided for site-specific assessment by Alfred Health

2. In addition, for ALL amendments submitted to Alfred Health for site-specific assessments (Reviewing and Accepting) please consider whether the following documents/processes are also required:

- An amended budget
- An Amendment to the Agreement
- Revised or new Alfred Resource Centre Declarations (RCD) if there are additional services required or new research personnel added (HIS RCDs)
- A revised Pharmacy Resource Centre Declaration if there are new drugs added or a change to arrangements previously agreed upon.
- A review from the New Research Product Introduction Committee if there are new devices or consumables added. If there is a digital (software/hardware) component, a Digital Health review is also required.
- A data governance and cybersecurity review may be necessary if there is a change to the Data Management Plan affecting Alfred Health data.
- A revised Medical Physicist's Report may be necessary if there is additional or less ionizing radiation imaging or a Satellite Site has been added to an Alfred Health Primary Site, particularly if the radiation is additional to standard of care.
- A review by the GMO Advisory Committee is required if there is a new or revised OGTR Licence or an Exempt Dealing has been modified or amended. This also applies to studies which involve a gene therapy.