

Ethics applications

Most research involving humans will require ethical review, and the level of review will be commensurate with the level of risk to which participants are exposed.

Research that can be exempted from review

If the research has [negligible risk](#) and involves the use of totally [non-identifiable data](#) about humans, ethical review may not be necessary.

If the research is exempt from ethical review, researchers can submit an 'application-by-letter' addressed to the Ethics Manager, The Alfred, and email it to research@alfred.org.au. The letter should provide all details to justify a waiver of the requirement for ethical review.

Research that has negligible risk but **does** use data that could possibly identify individuals is **not** exempt from ethical review.

Low risk research

If the research cannot be exempt from review, is [negligible](#) or [low risk](#), full ethical review may not be required. If the research fits into this category, researchers should read the [Low Risk Guide](#) and if appropriate complete the [application for ethical review of low risk projects](#) (MS Word) and submit it to research@alfred.org.au for opinion.

When researchers have completed their low risk project, they should submit the [Low Risk Final Report](#).

More than low risk research

For all research more than low risk, full ethical review is required and research personnel are required to complete and submit a full application to the Ethics Committee for review and approval.

There are three methods of applying for ethics approval. Researchers are to be advised to read each option carefully and make a choice depending on the type and scope of the study.

Researchers choose **one** of the following:

[National Ethics Application Form \(NEAF\) National](#)

[Victorian 'Common Application Form' \(CAF\)](#) - DHS modules

[National Ethics Application Form \(NEAF\) Streamlined](#)

They should also familiarise themselves with the [Alfred Ethics Committee guidelines](#) page, covering a range of research activities.

Submitting applications to the Ethics Committee

This applies to **all** types of applications requiring full ethical review.

Step 1 - Project registration

To register an application, researchers should download the appropriate application forms and complete them. They will then need to submit the application by email to research@alfred.org.au by the [project registration date](#). Electronic signatures are not necessary at this stage, but original hard copy signatures must be submitted with the project submission.

NEAF applications done on-line need to be saved as a PDF and emailed to us as a document attached to the email, rather than using the on-line email notification process.

Resource centre declarations and radiation safety documentation may be incomplete at the time of project registration. These and any additional documentation that **cannot** be emailed are to be included in the full, hard copy submission.

Researchers will need to indicate in the project registration email which documentation is missing.

Step 2 - Project submission

At registration time, the application will be checked for completeness by the Ethics Office and any omissions or changes requested will be conveyed to the Principal Research and contact person/research coordinator by email. They will receive detailed submission instructions from us, such as a unique project number, the number of paper copies required and the date for full project submission.

Researchers will also be asked to submit an electronic version of the complete application at full project submission time, incorporating any requested changes.

All hard copy documentation is to be collated as instructed before project submission so that each item of supporting documentation is attached to each copy of the application. Individual items such as indemnity statements, CVs, CTN forms and clinical trial research agreements (CTRAs) are to be placed with the original, paper application.

First review

Projects are saved in the 'CD' folder by meeting year/month/project number/sub-group (either Drugs and Interventions or Health and Social Sciences)

A CD is prepared and sent to all Ethics Committee members. The CD contains the agenda, instructions for reviewers and all project applications. Members email their reviews back to the Ethics Office two weeks prior to the main meeting.

Projects in the D&I group are first reviewed the day following the submission of reviews at the Research Review Sub-Committee Meeting.

The reviewers' questions are sent to the researchers and a response requested in one week's time to enable inclusion in the main meeting agenda.

The process of registration/screening and first review prior to the meeting enable the Committee to clarify and resolve the majority of issues (eg. questions, concerns and requests for information) prior to the meeting. This enables decisions to be reached at the meeting and avoids delays in the review and approval process.

1.5.1 Standard Operating Procedure: ethical review and administration

Second review and approval

The Ethics Committee members receive a CD with all projects, reviews and responses one week prior to the meeting. The members check the researchers' responses to their queries prior to the meeting. The second review and discussion takes place at the Ethics Committee meeting. The project is either approved outright, not approved or approved subject to changes. If changes are requested, a letter is sent to the researchers and the project is approved once the Ethics Committee members deem the researchers' response satisfactory. This may involve some email correspondence back and forth. The project is generally approved out of session, though if a number of significant concerns remain, the project may be included on the agenda for the following meeting, to enable further discussion.

Once approved, an approval certificate is issued in hard copy and posted to the Principal Investigator. The project is filed.

Sample of letter with detailed submission instructions

Dear

Thank you for submitting your application to the Alfred Hospital Ethics Committee.

Your project number is **Project /11**.

Please note: The Ethics Committee has requested that incomplete applications be deferred until the next month's meeting. This means that all relevant documentation must be included with your full submission, signed by all signatories (and original signatures provided).

The following items need attention before you submit your full application:

NEAF

•

Victorian-Specific Module

•

Alfred Specific Form

•

Please include all questionnaires and scales with your full submission.

Please include current CVs for

Documents	Total number required
NEAF - Core module	4
Victorian-Specific Module	4
Alfred Specific Form	4
Attachments (eg protocol, Participant Information & Consent Form, Resource Centre Declarations, CVs, questionnaires, advertisements, brochures, etc)	4

Submission instructions:

1. **Print** the project number given above on the top right hand corner of the front page of each document.
2. **Label** all attachments referred to in your application.
3. **Collate** the project documents into 4 complete, separate, ordered sets (1 original, 3 copies). If possible, documents should be photocopied double sided. The original set should have the original signatures (ideally in blue pen).
4. **Deliver/send** the hard copies to the Ethics Office, Ground Floor, Linay Pavilion, The Alfred, 55 Commercial Road, PRAHRAN, 3181.
5. **Email** your *entire revised application* to research@alfred.org.au with the project number in the subject field. It is helpful if each electronic document is clearly labeled (eg. 'NEAF', 'Victorian-Specific Module', etc.).
6. **DEADLINE** for submissions (electronic and hard copies) is **1pm, Wednesday 2nd February 2011**. If the submission does not conform to the above requirements it will be difficult for the Office to process and it may be held over until the following month.

You will hear from us further after the 10th February 2011.

Best wishes

s 47F s 47F

25 January 2011

Sample of letter requesting changes following first review

11 February 2011

«Title» «Given_name» «Surname»
«Department_Name»
«Daddress_1»
«Daddress_2»
«Daddress_3» «Dpost»

Dear «Given_name»

RE: Project No «Project_number» «Project_name»

Following consideration of your ethics project application, I wish to advise that your proposal will be referred to the main Committee for final consideration on 24th February 2011.

Consideration at the meeting will be subject to the following amendments being made to your application.

[insert numbered items]

Please submit your responses to the points above by no later than **1pm on Wednesday, 16th February 2011** to enable inclusion on the agenda for the main meeting. Please note that in order for the Ethics Office to meet committee mailing timelines, **this submission deadline cannot be extended.**

Please do not resubmit a full application, only your responses to the points made. Responses should be made in the following way:

- **Response cover letter:** In your written response, please repeat my questions above and follow each one with your answer (in another style, such as *italics*). The letter should be signed by the Principal Researcher.
- For changes to modules, protocols or project proposals please provide **only those pages** where further changes have been made, with the **changes marked up** (ie. using 'track changes').
- For changes to the PICF, advertisements or other recruitment materials, please provide the full document in both **clean** and **marked up** form.
- Please **update version numbers and dates** of revised documents (where applicable) so that the correct version can be identified on the Certificate of Approval.
- Please provide **one hard copy** and **email** all revisions to research@alfred.org.au with the project number in the subject line.

I will advise you of the outcome of your project application following the meeting.

Should you have any queries, you may contact me on tel: **s 47F** or via email.

Yours sincerely

s 47F
s 47F, Alfred Research & Ethics Unit
on behalf of
The Alfred Hospital Ethics Committee

Sample of letter requesting changes following the Ethics Committee meeting

17 December 2010

«Title» «Given_name» «Surname»
«Department_Name»
«Daddress_1»
«Daddress_2»
«Daddress_3» «Dpost»

Dear «Given_name»

Re: Project No «Project_number» «Project_name»

Your project was discussed at the recent Ethics Committee meeting and the points below need to be addressed to the Committee's satisfaction before your project can be approved. Please do not begin your project until you receive the Certificate of Approval.

Submission instructions:

Please do not resubmit a full application, only your responses to the points made. Responses should be made in the following way:

- **Response cover letter:** In your written response, please repeat my questions above and follow each one with your answer (in another style, such as *italics*). The letter should be signed by the Principal Researcher.
- For changes to modules, protocols or project proposals please provide **only those pages** where further changes have been made, with the **changes marked up** (ie. using 'track changes').
- For changes to the PICF, advertisements or other recruitment materials, please provide the full document in both **clean** and **marked up** form.
- Please **update version numbers and dates** of revised documents (where applicable) so that the correct version can be identified on the Certificate of Approval.
- Please provide **one hard copy** and **email** all revisions to research@alfred.org.au with the project number in the subject line.

A response to the above queries **MUST** be received by the Ethics Office within 3 months from the date of this letter. Failure to respond within this time frame will result in the project being withdrawn from the HREC agenda and any further consideration. If you require the project to be reviewed after this time, a full new HREC application will need to be submitted.

Thank you for submitting your research proposal to the Ethics Committee.

Should you have any queries, you may contact me on tel: **s 47F** or via email.

Yours sincerely

s 47F
s 47F
for

The Alfred Hospital Ethics Committee