

The Alfred Streamlining Ethical Review Guide

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OVERVIEW

Streamlined ethical review means that an eligible multi-site research project is only required to have one ethical review conducted by a human research ethics committee (HREC). Each site involved in the research project must also obtain separate site authorisation by submitting a site specific assessment (SSA) application.

A research project requires both ethics approval and site authorisation before it can commence at a site.

At Alfred Health

- Ethics approval is granted by the Reviewing HREC when the Ethics Application is satisfactory. Alfred Health must be listed on the approval.
- Site authorisation is granted by Alfred Health following satisfactory Site Specific Assessment.

THE REVIEW SCHEMES

The current streamlined ethical review schemes are:

- **National Mutual Acceptance (NMA)** is a national system for multi-centre trials to be conducted in **publicly funded health services** in one or more of the following: Victoria, QLD, NSW, SA, WA or the ACT.

NMA applies to any form of human research, as defined in the National Statement on Ethical Conduct in Human Research (2007), including low risk research, which is to be conducted at a public health organisation.

NMA is not retrospective.

Ethics reviews of interventional research involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that occurred before 1st November 2013 remain under the arrangements in place at the time of their review.

Ethics reviews of medical research and low risk research that occurred before 14th December 2015 remain under the arrangements in place at the time of their review.

In certain states some trials are exempt from single review. Exemptions include:

- Clinical trials involving persons in custody or staff of the jurisdictional Justice Health departments
- Clinical trials specifically affecting the health and wellbeing of Aboriginal people and communities
- Clinical trials requiring access to state-wide data collections
- Clinical trials involving access to coronial material.
- Clinical trials of supportive care and psycho-oncology.

The reviewing HREC must be certified by the National Health and Medical Research Council (NHMRC) and be certified for the type of research to be reviewed, and if Victorian also be accredited by the Consultative Council for Clinical Trial Research.

- **Victorian State Single Ethical Review (SERP)** for multi-site research within Victoria

Victorian SERP applies to any form of human research, as defined in the National Statement on Ethical Conduct in Human Research (2007), including low risk research, which is to be conducted at a public health organisation.

Low risk research can be submitted using a Victorian low and negligible risk application form, however all applications to the Alfred Hospital Ethics Committee are to be on the Human Research Ethics Application (HREA) form

The reviewing HREC must be accredited by the Consultative Council.

What is meant by REVIEWING or ACCEPTING?

Reviewing refers to Alfred Health coordinating and undertaking the ethics review as well as undertaking the site specific assessment. This is done in parallel. Whilst not mandatory, it would be anticipated the HREC undertaking the review is the Alfred Hospital Ethics Committee.

Accepting refers to Alfred Health accepting the ethics review conducted by an external HREC and undertaking the site specific assessment only.

Fees apply for either an ethics review or a site-specific assessment review.

WHERE TO FIND INFORMATION

On the Department of Health and Human Services Website

<https://www2.health.vic.gov.au/about/clinical-trials-and-research>

Instructions, SOPs, links to the ERM (Ethics Review Manager) website, and templates can be found by selecting Clinical Trials or Health and Medical Research. The templates include the VSM, PICFs, amendment application forms, safety reporting, progress and final reports, and protocol breaches, which are particularly important for non-ERM users.

The website has a table outlining the arrangements for interstate sites not using ERM:

<https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/national-mutual-acceptance>

Clinical trials

How to make an HREC application (ethics) <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>

How to make a site specific assessment: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/site-specific-assessment-and-research-governance-in-clinical-trials>

Health and medical research and low risk research

How to make an HREC application: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research/how-to-make-an-hrec-application-and-reporting>

How to make a site specific assessment application: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research/site-specific-assessment-and-research-governance>

ERM – Frequently Asked Questions

Answers to frequently asked questions in the Help section of the ERM website:

<https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/10>

On the Alfred Health Ethics and Research Governance Website

Ethics Applications (for ethics applications to the Alfred Hospital Ethics Committee as **reviewing** site)

<https://www.alfredhealth.org.au/research/ethics-research-governance/ethics-applications>

Site Specific Assessment (for Alfred Health **accepting** site projects)

<https://www.alfredhealth.org.au/research/ethics-research-governance/site-specific-assessment>

SUBMITTING AN ETHICS APPLICATION AS THE REVIEWING SITE (A guide for Alfred Health researchers)

A. Ethics Review

Contact the Alfred Health Office of Ethics & Research Governance to discuss the application.

A training session (in person or via phone) is advisable for researchers without prior experience in submitting a streamlined ethical review application.

Check submission dates on the Alfred Health website.

If Alfred Health is the lead site but an external HREC is selected to review, you will need to be aware of the submission instructions and dates of the Reviewing HREC and are bound by those.

For submission to the Alfred Hospital Ethics Committee the following documents will be required:

- **Human Research Ethics Application (HREA)** created in ERM (not submitted)
- **Protocol/Project Proposal** (see Help section on ERM website for Project Description outline): <https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/9>
- **Victorian Specific Module (VSM)** created in ERM (not submitted)
- **Western Australian Specific Module** (where a WA site is included in the application)
- If there are procedures involving **ionizing radiation**:
 - For Victorian sites - check with each site whether a **medical physicist report** is mandatory or not. A **medical physicist report** is required for each site where the radiation exposure is additional to routine care. Some sites may provide a **HREC Radiation Notification Letter** where the radiation is considered equivalent to standard care.
 - For interstate sites - a **medical physicist report** for each site where the radiation is additional to standard care **OR** the **HREC Radiation Notification Letter** for each site where the radiation is considered equivalent to standard care.
- **Participant Information and Consent Forms/Sheets/Opt-out information:**
 - Master:
 - Create like a template to guide the other Sites as to what changes they can make (e.g. [Insert Site Name] or highlight sections requiring site changes)
 - Alternative wording can be included with instructions to sites to delete alternatives not applicable to them.
 - Define as Master in the footer with a version number and version date.
 - Include in the footer as a second line: [Insert Site Name] - Local Governance Version [Insert Date Only]
 - Site Master: Only create a Site Master if there are site specific requirements that cannot be included as alternative wording in the Master.
 - In the footer, indicate both the Site Master PICF version number and version date and the Master PICF version number and version date.
 - Include in the footer a blank Site governance date (date to be added post HREC approval)
 - If the participant information is not to be made site specific (will not have logos, site investigator or local contact details), for example, an online statement as part of a national online survey, a generic document may be created.
- **Investigators' Brochure, Participant Materials, Advertisements, Questionnaires, Data Collection Forms, Surveys etc**

- **Legal Documents – electronically and in hard copy as relevant:**
 - CTN details form (for notifying the Therapeutic Goods Administration [TGA] of use of 'unapproved' goods in research)
 - Insurance certificate
 - Standard indemnity for each Site (hard copies only for Alfred Health indemnity)
 - Indemnity for HREC Review Only to Alfred Health with each Site and Site PI listed in paragraph 1 (combined or single indemnities)
 - Note: Always use legal names of Institutions (eg Alfred Health, Melbourne Health, etc)

Researchers should follow the instructions on the ethics submission and review webpages of the Alfred Health website.

The submission must be emailed to research@alfred.org.au. If the application is for low risk review, “low risk” must be flagged in the email subject line.

Researchers should retain a copy of all HREC correspondence throughout the ethics review process as this may be required by accepting sites.

Researchers must pay attention to the instructions provided by the Alfred Health Office of Ethics & Research Governance about using ERM (DHHS system) and ERA (Alfred Health system).

B. Site Specific Assessment (for site authorisation)

The site specific assessment is done concurrently with ethics review (if reviewed by the Alfred Hospital Ethics Committee) but needs separate site authorisation.

The following documents will be required:

- **SSA Form (for Alfred Health Only)** created in ERA.
 - For studies involving any form of intervention, select one of the ‘Clinical trial’ options in Q1.2 (Study type) to unlock further relevant questions in the SSA Form.
- **“Alfredised” Participant Information and Consent Forms/Sheets/Opt-out information**
 - Keep the version and date the same as in the Master document
 - Insert an Alfred site governance date in the footer.
 - Do not change any of the set text. Insert site details and select appropriate alternative wording where required.
- **Use of Alfred Health services form**
- **Resource Centre Declarations**
- **Budget**
- **Ethics & Governance Fee payment form**
- **Legal documents – electronically and in hard copy as relevant**
 - CTRA/CIRA/Research Agreement
 - Agreement Checklist
 - Evidence of review of schedule 4 or 7 wording by the Victorian Department of Health

If the research is an investigator-initiated trial, there will need to be research agreements between Alfred Health and each participating Site.

SUBMITTING A SITE SPECIFIC ASSESSMENT APPLICATION AS AN ACCEPTING SITE (Reviewing HREC is not the Alfred Hospital Ethics Committee)

The Alfred Health site PI or Alfred Health site coordinator should contact the Alfred Office of Ethics and Research Governance

- prior to agreeing to be an accepting site to determine appropriateness and any specific requirements for ethics review and site assessment such as:
 - who can be site PI;
 - radiation requirements;
 - use of template text in clinical trial PICFs;
 - research involving first in human drugs or device;
 - the impact of differences in standard care; and
 - documentation when only part of the protocol will be conducted.
- prior to submission for site assessment to nominate a submission date.

The submission must be made by Alfred Health staff with an Alfred Health PI.

Ethics approval is not required to commence preparing site documents.

The Victorian LNR ethics application form may be accepted for a SERP low risk project if the HREA has not been used.

For submission to Alfred Health the following documents will be required:

A. From the Ethics Review

- **A copy of the entire application submitted to the reviewing HREC: HREA (or Victorian LNR), VSM, Master and Site Master Participant Information and Consent Forms/Sheets/Opt-out information, Protocol, IB, Participant Materials, Advertisements, Questionnaires etc**
- **Ethics Approval certificate (listing Alfred Health as a participating site)**
- **Any decision-making correspondence**
- **HREC review only indemnity (if a commercially sponsored trial)**

B. Site Specific Assessment (site authorisation):

- **SSA Form** created in ERM
 - Ensure the SSA is transferred/shared with the site.
 - For studies involving any form of intervention, select one of the 'Clinical trial' options in Q1.2 (Study type) to unlock further relevant questions in the SSA Form.
 - For interventional research, the Alfred Health guideline is that all data needs to be retained indefinitely for clinical trials. The question on data storage should reflect this requirement.
 - Particular attention should be given to providing detailed responses to questions on recruitment.
 - Signatures will be accepted if electronic in ERM or printed, signed and sent as a PDF.
- **"Alfredised" Participant Information and Consent Forms/Sheets/Opt-out information**
 - Keep the version and date the same as in the Master PICF approved by the Reviewing HREC
 - Insert an Alfred site governance date in the footer.
 - Do not change any of the set text. Insert site details and select appropriate alternative wording where required.
- **Use of Alfred Health services form**
- **Resource Centre Declarations**
- **Budget**

- **Legal Documents– electronically and in hard copy as relevant:**
 - e-CTN draft
 - Insurance certificate
 - Standard indemnity to Alfred Health
 - CTRA/CIRA/Research Agreement
 - Agreement Checklist
 - Evidence of review of schedule 4 or 7 wording by the Victorian Department of Health.

- **Ethics & Governance Fee payment form**

Researchers should follow the instructions on the site specific applications webpage of the Alfred Health website.

The submission must be emailed to research@alfred.org.au. If the application is for a low risk project, “low risk” must be flagged in the email subject line. The SSA form should be submitted in ERM at the same time the application is emailed.

Researchers must pay attention to the instructions provided by the Alfred Health Office of Ethics & Research Governance about using ERM (DHHS system) and ERA (Alfred Health system)

AMENDMENTS

Amendments require both ethics approval and site authorisation before implementation.

SUBMITTING AN AMENDMENT AS THE COORDINATING/ REVIEWING SITE

A. The following documents are required for Ethics Review
(Submit to the Reviewing HREC and follow instructions of Reviewing HREC)

- Use the Streamlined Amendment Application Template
- Submit the amended and/or additional documents
- Submit Master and Site Master PICFs/information sheets/opt-out information
- Submit any relevant legal and regulatory documents
- Upload documents (apart from financial documents: budget, Agreement) into ERM

B. Site Specific Assessment Review

Is done concurrently with ethics review so “Alfredised” PICFs, revised resource centre declarations, site legal documents and the Amendment Payment Form should be submitted at the same time as the ethics documents.

SUBMITTING AN AMENDMENT AS AN ACCEPTING SITE

This can be submitted at any time once the amendment has been approved by the Reviewing HREC

A. The following documents are required from the Ethics Review:

- The application submitted to the reviewing HREC: Amendment Application Form, Revised Master and Site Master PICFs, Protocol, IB, participant materials etc
- Ethics Amendment Approval certificate
- Any decision-making correspondence

B. Site Specific Assessment Review

- “Alfredised” PICFs
- Revised Resource Centre Declarations
- Any new legal documents (Amendment/Addendum to an Agreement)
- Amendment Payment Form
- A site Amendment Application Form is only required when the amendment is not applicable to all sites

SUBMITTING AN ALFRED SPECIFIC MINOR AMENDMENT

The most common example involves changes to research personnel.

Complete the change to research personnel form.

Submit revised “Alfredised” PICFs **keeping the version and date the same** as in the approved Master document but update the Alfred site governance date in footer.

SUBMISSION OF PROGRESS REPORTS

Use the streamlined templates (project form, site form, final report).

Each Site should submit their Site report to the Coordinating Principal Investigator for compilation into a project report to go to the Reviewing HREC.

Follow the submission instructions of the Reviewing HREC.

Each Site PI should to submit their Site report to their own Research Governance Office as well.

Acknowledgements from external reviewing HRECs do not need to be submitted to the Alfred Office of Ethics and Research Governance. Researchers should retain a copy in their research records.

SUBMISSION OF SAFETY INFORMATION

Use the streamlined templates, except for local SAE reporting.

Follow the submission instructions of the Reviewing HREC.

Alfred Health requires all local and related SAEs to be reported.

SUBMISSION OF BREACHES

Use the streamlined template.

To be submitted by each Site via the Coordinating Principal Investigator to the Reviewing HREC

Follow the submission instructions of the Reviewing HREC

Each Site PI to submit the report to their own Research Governance Office as well

SUBMISSION OF COMPLAINTS

Use the streamlined template

To be submitted by each Site via the Coordinating Principal Investigator to the Reviewing HREC

Follow the submission instructions of the Reviewing HREC

Each Site PI to submit the report to their own Research Governance Office as well

APPROVALS AND ACKNOWLEDGEMENTS

Ethics Approval Letter – Lists all approved documents; lists sites which the Alfred Hospital Ethics Committee has ethical oversight for; states SSA authorisation is required at all participating sites, states conditions of approval and any special consent processes.

Site Authorisation Letter – DHHS template and lists the protocol and site specific documents only. The letter also states any special conditions of authorisation.

Amendments:

Ethics approval is documented with an amendment approval letter generated on an Alfred Health template. Site authorisation is documented with amendment authorisation letter generated on an Alfred Health template.

Acknowledgements:

Progress reports and breaches are acknowledged on an Alfred Health acknowledgement template. All other correspondence will be acknowledged by email.