

NEAF National

These forms are suitable for research to be conducted either at Alfred Health alone or at more than one institution. If the research is to be conducted at more than one institution, researchers are advised to consult those institutions' HRECs about their application and submission requirements.

NEAF National is suitable for projects using the National Ethics Application Form (NEAF) but **not** using the Victoria Government Streamlining Ethics Review of Multi-Site Clinical Trials "[NEAF Streamlined](#)" system.

NEAF National is an alternative to the [CAF](#). The research may be a [clinical trial](#), but typically will not be commercially sponsored and is more likely to be student, epidemiological or allied health research or surveys, focus groups or program evaluations.

When completing the NEAF online, researchers will also be prompted to complete an online Site Specific Assessment (SSA) form. This form is not required for NEAF National. Instead, please submit the [Alfred Specific Form](#) (ASF).

NEAF - must be completed

[Form](#)

Information and Consent Forms - if required, choose from the following templates

[Participant Information and Consent Form - Health and/or social science - Version October 2010 \(72KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical drug/device - Alfred Version October 2010 \(145KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical non drug/device - Alfred Version October 2010 \(126KB, MS Word\)](#)

[Participant Information and Consent Form Recommended Wording for Specific Procedure and Situations](#)

Victorian-Specific Module (VSM) - must be completed

[Form](#)

[Research involving ionising radiation](#) - if required

Alfred Specific Form (ASF) - must be completed

[Form](#)

[\[^Top \]](#)

Use of Alfred services

Please note that where Alfred services are being used in the course of the study, a declaration will need to be signed by the relevant Resource Centre Manager. This applies to routine tests as well as additional tests.

1.5.4 Instructions for submitting research applications

Resource Centre Declaration forms and information are provided below. These are to be completed where applicable.

- [Alfred Heart Centre Declaration form \(18 KB, MS Word\)](#)
- [Alfred Lung Function Laboratory Services Declaration form \(42 KB, MS Word\)](#)
- [Alfred Pathology Services Declaration form \(26 KB, MS Word\)](#)
- [The Baker IDI Biobank](#)
- [Patient records](#)
- [Pharmacy](#)
- [Pharmacy - Request for Clinical Trials Pharmacy Costing \(33 KB, MS Word\)](#)
- [Radiation Services](#)

Legal and regulatory requirements

See [Legal and regulatory requirements](#).

Nursing Research

All nursing research applications need to be submitted to the Nursing Research and Access Committee prior to submission to the Ethics Committee. Please click [here](#) for further information

External applicants

If you are an applicant who is not a staff member of The Alfred you must include at least one senior member of staff on the research team.

Ethics Committee fees (Ethics infrastructure fees)

Fees apply for certain categories of applications. For full details, see [Fees](#).

Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) has adopted a policy that the member journals will only consider publication of clinical trials if the trial has been registered in a World Health Organisation (WHO)-accredited clinical trial registry. Trials can be registered with:

- The ClinicalTrials.gov registry of the US National Institutes of Health and developed by the National Library of Medicine: <http://www.clinicaltrials.gov>
- The NHMRC-developed Australian Clinical Trials Registry (ACTR): <http://www.actr.org.au>

Common Application Form

The modular forms are suitable as an alternative to "[NEAF National](#)". If researchers propose to conduct their research at other institutions, they should check those institutions' HRECs to see if they will accept the form and to obtain submission instructions.

The application form consists of a number of modules with accompanying guidelines. The guidelines should be read before completing the corresponding module.

All applicants must complete and submit:

- Module 1 – Core Application Form
- Any other modules relevant to your project
- Module 6 – Alfred-specific financial details

Modules

Module 1 - Core application - must be completed

[Guidelines - Version May 2008 \(259 KB, PDF\)](#)

[Form - Version May 2008 \(400 KB, MS Word\)](#)

Information and Consent Forms - if required, choose from the following templates

[Participant Information and Consent Form - Health and/or social science - Version October 2010 \(72KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical drug/device - Alfred Version October 2010 \(145KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical non drug/device - Alfred Version October 2010 \(126KB, MS Word\)](#)

[Participant Information and Consent Form Recommended Wording for Specific Procedures and Situations](#)

Module 2 - Projects involving drugs and other therapeutic devices - if required

[Guidelines - Version January 2008 \(128 KB, PDF\)](#)

[Form - Version January 2008 \(165 KB, MS Word\)](#)

Module 3 - Human tissues - if required

[Guidelines - Version January 2008 \(42 KB, PDF\)](#)

[Form - Version January 2008 \(152 KB, MS Word\)](#)

Module 4 - Ionising Radiation - if required

1.5.4 Instructions for submitting research applications

[Research involving ionising radiation](#)

[Guidelines - Version March 2008 \(504 KB, PDF\)](#)

[Form - Version March 2008 \(157 KB, MS Word\)](#)

Module 6 - Alfred-specific financial details - must be completed

[Form - Version March 2010 \(103 KB, MS Word\)](#)

[\[^Top\]](#)

Use of Alfred services

Please note that where Alfred services are being used in the course of the study, a declaration will need to be signed by the relevant Resource Centre Manager. This applies to routine tests as well as additional tests.

Resource Centre Declaration forms and information are provided below. These are to be completed where applicable.

- [Alfred Heart Centre Declaration form \(18 KB, MS Word\)](#)
- [Alfred Lung Function Laboratory Services Declaration form \(42 KB, MS Word\)](#)
- [Alfred Pathology Services Declaration form \(26 KB, MS Word\)](#)
- [The Baker IDI Biobank](#)
- [Patient records](#)
- [Pharmacy](#)
- [Pharmacy - Request for Clinical Trials Pharmacy Costing \(33 KB, MS Word\)](#)
- [Radiation Services](#)

Legal and regulatory requirements

See [Legal and regulatory requirements](#).

Nursing Research

All nursing research applications need to be submitted to the Nursing Research and Access Committee prior to submission to the Ethics Committee. Please click [here](#) for further information

External applicants

If you are an applicant who is not a staff member of The Alfred you must include at least one senior member of staff on the research team.

Ethics Committee fees (Ethics infrastructure fees)

Fees apply for certain categories of applications. For full details, see [Fees](#).

Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) has adopted a policy that the member journals will only consider publication of clinical trials if the trial has been registered in a World Health Organisation (WHO)-accredited clinical trial registry. Trials can be registered with:

- The ClinicalTrials.gov registry of the US National Institutes of Health and developed by the National Library of Medicine: <http://www.clinicaltrials.gov>
- The NHMRC-developed Australian Clinical Trials Registry (ACTR): <http://www.actr.org.au>

NEAF Streamlined

The Victorian Government Streamlining Ethical Review of Multi-Site Clinical Trials ("NEAF Streamlined") system is suitable for multicentre [clinical trials](#) that are eligible to undergo a single review by a CCHRE accredited HREC (<http://www.health.vic.gov.au/cchre/>).

These trials are typically commercially sponsored or sponsored by a collaborative group. Researchers will normally be approached to submit under this system by a commercial sponsor or a collaborative group, who will provide instructions about the application process.

Before embarking upon their applications, researchers will need to consult [s 47F](#), Ethics Officer, Alfred Hospital on [s 47F](#) or [s 47F](#) about their eligibility to use this system at Alfred Health and, if eligible, to obtain submission instructions.

Please refer to the application instructions:

http://www.health.vic.gov.au/cchre/applications/applications_how_to.htm

NEAF and Site Specific Assessment (SSA) - must be completed

[Form](#)

Information and Consent Forms - if required, choose from the following templates

[Participant Information and Consent Form - Health and/or social science - Version October 2010 \(72KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical drug/device - Alfred Version October 2010 \(145KB, MS Word\)](#)

[Participant Information and Consent Form - Clinical non drug/device - Alfred Version October 2010 \(126KB, MS Word\)](#)

[Participant Information and Consent Form Recommended Wording for Specific Procedures and Situations](#)

Victorian-Specific Module (VSM) - must be completed

[Form](#)

[Research involving ionising radiation](#) - if required

Alfred Specific Form (ASF) - must be completed

[Form](#)

[\[^Top \]](#)

Use of Alfred services

Please note that where Alfred services are being used in the course of the study, a declaration will need to be signed by the relevant Resource Centre Manager. This applies to routine tests as well as additional tests.

Resource Centre Declaration forms and information are provided below. These are to be completed where applicable.

1.5.4 Instructions for submitting research applications

- [Alfred Heart Centre Declaration form \(18 KB, MS Word\)](#)
- [Alfred Lung Function Laboratory Services Declaration form \(42 KB, MS Word\)](#)
- [Alfred Pathology Services Declaration form \(26 KB, MS Word\)](#)
- [The Baker IDI Biobank](#)
- [Patient records](#)
- [Pharmacy](#)
- [Pharmacy - Request for Clinical Trials Pharmacy Costing \(33 KB, MS Word\)](#)
- [Radiation Services](#)

Legal and regulatory requirements

See [Legal and regulatory requirements](#).

Nursing Research

All nursing research applications need to be submitted to the Nursing Research and Access Committee prior to submission to the Ethics Committee. Please click [here](#) for further information

External applicants

If you are an applicant who is not a staff member of The Alfred you must include at least one senior member of staff on the research team.

Ethics Committee fees (Ethics infrastructure fees)

Fees apply for certain categories of applications. For full details, see [Fees](#).

Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) has adopted a policy that the member journals will only consider publication of clinical trials if the trial has been registered in a World Health Organisation (WHO)-accredited clinical trial registry. Trials can be registered with:

- The ClinicalTrials.gov registry of the US National Institutes of Health and developed by the National Library of Medicine: <http://www.clinicaltrials.gov>
- The NHMRC-developed Australian Clinical Trials Registry (ACTR): <http://www.actr.org.au>