

ALFRED HOSPITAL ETHICS COMMITTEE

The SERP Guide

At The Alfred we commonly refer to the Streamlined Ethical Review Process in Victoria as SERP. This guide was developed by the Alfred Ethics Office to assist at information sessions held for Alfred Health researchers involved in SERP.

OVERVIEW

SERP is open to multi-centre trials in Victoria.

Scope:

- Research involving an interventional drug or device trial, radiation therapy, surgery, treatment and diagnostic procedure
- Commercially sponsored, collaborative group, investigator-initiated studies

At this stage SERP excludes research that involves supportive care and psycho-oncology only, epidemiological studies

A key feature of SERP is that it separates ethics review from governance:

- Ethics review is conducted by the reviewing HREC = **ethics approval**
- Governance review is conducted by the institution = **governance authorisation**

Either an ethics review or governance review fee is payable to each Victorian Site for each category of study, both for initial submissions and amendments

FORMS AND INSTRUCTIONS

Instructions can be found on the Alfred Hospital Ethics Committee Website

- Human Ethics/Applications/[NEAF Streamlined](http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm):
http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm
- You have to use the NEAF from the [Online Forms](#) website

You should also familiarise yourself with the Consultative Council for Human Research Ethics (CCHRE):

<http://www.health.vic.gov.au/cchre/>

Please use SERP forms for amendments, SAEs, progress reports, protocol deviations/violations accessible at: http://www.health.vic.gov.au/cchre/applications/applications_how_to.htm

SUBMITTING AN ETHICS APPLICATION UNDER SERP AS THE CO-ORDINATING PRINCIPAL INVESTIGATOR

A. Ethics Review

The application needs to be booked via the SERP Central Allocation System (CAS) by the Sponsor or the Co-ordinating Principal Investigator.

You will need to be aware of the submission instructions of the Reviewing HREC and are bound by those submission dates

The following documents will be required:

- **NEAF**
- **Victorian Specific Module (VSM)**
 - If there are procedures involving ionizing radiation, also submit the RSO report or letter from the RSO from each Victorian Site.
 - If the RSO report differs, also submit the VSM and Site Master PICF for each site
- **PICFs:**
 - Updated CCHRE PICF template.
 - Master:
 - Define as Master on page 1 and in footer
 - Create like a template to guide the other Sites as to what changes they can make (eg <Insert Name of Institution>)
 - An “Alfredised” PICF will be required for governance review
 - The Site Master: If there are site specific requirements (eg contraception wording for Catholic institutions, RSO radiation risk wording, data retention period)
 - On page 1, please include a statement such as “Based on the [HREC Reference Number] Master Consent Document Version [number] and date.
 - In the footer, indicate both the Site Master PICF version and date and the Master PICF version and date.
 - Data Retention Period
 - For SERP studies only, “at least 15 years upon completion of the trial”.
 - However, AMREP policy is still that all data need to be retained indefinitely so ethics application (NEAF, VSM, SSA, ASF) should reflect the policy.
 - Complaints and complaints
 - List Rowan Frew as the Ethics Committee contact (Ethics Manager, Alfred Health)
 - Include a section for the Site contact (eg “If you would also like to speak to someone at (insert name of Institution>, please contact: Name, Position, Number”)
- **Protocol, Investigators’ Brochure, Participant Materials, Advertisements, etc**
- **Legal Documents – electronically and in hard copy:**
 - CTN form for each Victorian Site
 - Insurance certificate
 - Standard indemnity for each Victorian 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)
 - DLA Piper or VMIA review
 - Always use legal names of Institutions (eg Alfred Health, Melbourne Health, Austin Health, Southern Health, Eastern Health, Barwon Health etc)

Upload documents (apart from financial documents: budget, ASF, CTRA) into Online Forms

B. Governance Review

The following documents will be required:

- **SSA Form (Alfred Health Only)** One set of signatures
- **Alfred Specific Form**
- **Resource Centre Declarations**
- **CTRA, indemnity and Checklist**

If an investigator-initiated trial, CTRA between Alfred Health and each participating Site (VMIA Investigator Initiated CTRA template)

The governance review is usually done simultaneously with ethics review (if reviewed by the Alfred Hospital Ethics Committee) but needs separate governance authorisation

Upload documents (apart from financial documents: budget, ASF, CTRA) into Online Forms.

SUBMITTING AN ETHICS APPLICATION UNDER SERP AS A PARTICIPATING SITE

A. Ethics Review

The following documents are required electronically and in hard copy:

- **A hard copy of the entire application submitted to the reviewing HREC: NEAF, VSM, Master and Site Master PICFs, Protocol, IB, Patient Materials etc**
- **Ethics Approval certificate**
- **Any decision-making correspondence, including DLA Piper review**

B. Governance Review

This can be submitted at any time once the application is complete.

The following documents are required electronically and in hard copy:

- **SSA (One set of signatures)**
- **Alfred Specific Form**
- **“Alfredised” PICFs**
 - Keep the version and date the same as in the PICF approved by the Reviewing HREC
 - If the data retention period was “at least 15 years upon completion of the trial”, do not change to “indefinitely”
 - Complaints: Keep the contact from the reviewing HREC
 - Complaints: Include a section for the Alfred Health contact (eg “If you would also like to speak to someone at (insert name of Institution>, please contact: Name: Rowan Frew, Position, Number”)
- **Resource Centre Declarations**
- **Legal Documents:**
 - CTN form signed by the Reviewing HREC
 - Insurance certificate
 - Standard indemnity to Alfred Health
 - CTRA, indemnity and CTRA and Indemnity Checklist

Upload documents (apart from financial documents: budget, ASF, CTRA) into Online Forms

SUBMITTING AN AMENDMENT UNDER SERP AS CO-ORDINATING PRINCIPAL INVESTIGATOR

A. Ethics Review

Needs to be submitted to the Reviewing HREC

Use the SERP Amendment Application Form

Following the submission instructions of Reviewing HREC (at Alfred Health submit two copies of each document to be provided in tracked and clean versions, summary of changes etc)

Submit Master and Site Master PICFs

- An “Alfredised” PICF will be required for governance review

Submit any relevant legal documents:

- CTN forms, indemnities

Upload documents (apart from financial documents: budget, ASF, CTRA) into Online Forms

B. Governance Review

Usually done simultaneously with ethics review

Require governance authorisation

SUBMITTING AN AMENDMENT UNDER SERP AS ACCEPTING SITE FOR GOVERNANCE REVIEW

This can be submitted at any time once application is complete

The following documents are required electronically and in hard copy:

- **Ethics Review**

- A hard copy of the entire application submitted to the reviewing HREC: SERP Amendment Application Form, Revised Master and Site Master PICFs, Protocol, IB etc
- Ethics Amendment Approval certificate
- Any decision-making correspondence

- **Governance Review**

- SERP Amendment Application Form signed by Site PI
- “Alfredised” PICFs (tracked and clean) with the same version and date as those approved by the reviewing HREC
- Any revised Resource Centre Declarations
- Any new legal documents (CTN form, Amendment/Addendum to CTRA)

Upload documents (apart from financial documents: budget, ASF, CTRA) into Online Forms

SUBMITTING A MINOR AMENDMENT UNDER SERP

The most common example involves changes to research personnel

Only requires governance authorization

Submit revised “Alfredised” PICFs **keeping the version and date the same** as in the approved document but add “Authorised: <insert date>” on page 1 under Master/Site Master version and date and in footer

SUBMISSION OF PROGRESS REPORTS UNDER SERP

Use the SERP form

To be submitted by each Victorian Site via the Co-ordinating Principal Investigator to the Reviewing HREC

Follow the submission instructions of the Reviewing HREC

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

SUBMISSION OF SERIOUS ADVERSE EVENTS UNDER SERP

Use the SERP form

To be submitted by each Victorian Site via the Co-ordinating Principal Investigator to the Reviewing HREC

Follow the submission instructions of the Reviewing HREC

Each Site PI to submit to their own SAE report to their own Ethics Committee/Research Governance Office as well

SUBMISSION OF PROTOCOL WAIVERS/DEVIATIONS UNDER SERP

Use the SERP form

To be submitted by each Victorian Site via the Co-ordinating Principal Investigator to the Reviewing HREC

Follow the submission instructions of the Reviewing HREC

Each Site PI to submit report to their own Ethics Committee/Research Governance Office as well

Tips for Participant Information & Consent Forms

Templates

- Please use our [templates](#) (new drug/device SERP template)
- We can accept non-standard PICFs but they need to include the essential elements of the template

Sponsors

- Identify the international Sponsor and the local Sponsor (please use full legal names, eg Pty Ltd).

Participants

- Please specify the anticipated number of participants to be recruited from this site
- Please refer to “participants” or “patients” rather than “subjects”

TGA

- Define the Therapeutic Goods Administration (TGA) as Australia’s regulatory authority and detail the TGA-status of each of the drugs/devices to be used.
 - Helpful to define the drug/device as experimental.

Tissue Samples

- Express volumes in mLs and include teaspoon/tablespoon equivalents.
- If there is testing for any Department of Health-reportable conditions, eg Hepatitis, HIV, include wording from PICF template.
- Always include a “What will happen to my test samples?” section as found in the PICF template.
- Discuss the categories of samples separately: routine diagnostic, pharmacokinetic, pharmacogenetic etc.
- Outline the purpose of each category of sample and whether the samples will be destroyed after analysis or stored. If stored, detail the purpose, location and duration of storage.
- Optional samples:
 - Yes/No check box in Consent section.
 - Separate PICF for optional pharmacogenetic testing or tissue which should be mentioned in the main PICF
- For pharmacogenetics, always explain whether or not:
 - a. the information generated will have the capacity to provide information about an identifiable participant’s future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the study. If relatives are also to be approached, the researcher will need the consent of the research participant to do this, and should provide information concerning the method of approach to relatives.
 - b. participants will be advised of project results and, if so, whether this will be grouped data or relate to individual participants and whether counselling will be provided;
 - c. the research has the potential to detect/generate information of social significance, e.g. non-paternity or non-maternity information that may influence access to insurance/employment

Risks

- Always include a statement that there may be unknown or unforeseen risks

Contraception:

- If the PICF mentions collection of data from a pregnant partner of a participant, please provide a separate PICF.
 - Include the specific data to be collected
 - How long the data will be collected for the mother and child

Confidentiality

- Always include the reference to the Freedom of Information Act from the PICF template
- Please mention in what form the Sponsors will receive the data/samples, eg de-identifiable, coded etc.

Injury and Compensation

- Please use the latest injury and compensation wording as found in the PICF template
 - The local Sponsor listed on the CTN form and indemnity should be listed as the Sponsor providing indemnity
 - Please list the full legal name of the local Sponsor (ACME Pty Limited)

Ethics Committee

- The Alfred Hospital Ethics Committee (official name) or
- The Human Research Ethics Committee of Alfred Health

Devices

- There is now a separate indemnity and CTRA for devices.
 - Slightly different wording in PICF (MTAA rather than Medicines Australia)
- For all devices provided by Sponsor (interventional, diagnostic (ECG machines, Point of care devices) confirm that:
 - It is TGA-approved
 - Will be sourced from the Sponsor (distributor) listed on ARTG
 - If not, please list device on CTN form and include wording in PICF.

Tips for Legal Documents

- Please use the templates
- Please use the CTRA and indemnity checklist
- Name of Institution is "Alfred Health".
- Schedule 1 Details:
 - Numbers of participants at this Site
 - Recruitment Period dates
 - Name of Ethics Committee
 - Any equipment to be provided by Sponsor
- Schedule 3: Unsigned indemnity attached?
- Schedule 4: Insurance certificate attached?
- Schedule 7: Check with Sponsor if wording approved by VMIA or Medicines Australia
- Full legal name of the local Sponsor should be listed on the:
 - CTN form
 - indemnity
 - insurance certificate (at least as an additional insured)
 - possibly the CTRA (not necessarily)
- CTN Forms:
 - For investigator-Initiated trials, name of Sponsor is Alfred Health
 - Sponsor should be an Australian entity
 - Site start date should be after Ethics Committee approval date and Authorisation date.
 - Name of Ethics Committee is "The Alfred Hospital Ethics Committee"