The Victorian Streamlined Review Process and the National Mutual Acceptance (NMA) Streamlined Review Process for Clinical Trials

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Streamlined Processes: SERP

- Victorian streamlined ethical review process

- Overseen by Victorian Department of Health and Human Services – Consultative Council for Clinical Trial Research (CCCTR)

- Information available at:

- One CCCTR-accredited Victorian Human Research Ethics Committee (HREC) reviews for Victorian sites only
Streamlined Processes: NMA (formerly IMA)

- National Mutual Acceptance (NMA), formerly referred to as Interstate Mutual Acceptance (IMA)

- In Victoria, overseen by Victorian Department of Health and Human Services – Consultative Council for Clinical Trial Research (CCCTR) in Victoria


- One NHMRC-certified Human Research Ethics Committee (HREC) in Victoria, NSW, QLD or SA reviews for Sites in Victoria, NSW, QLD or SA
Streamlined Processes

• The National Approach:
  – Formerly referred to as HoMER
  – Reviewing/Lead HREC is NHMRC-certified
  – Sites across Australia
  – Non-clinical trials eligible
The central system for ethical and scientific review of multi-site clinical trials will apply to **interventional research** involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with **ongoing activities relating to trials** that have been conducted. This may include observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.
The streamlined system for ethical and scientific review of multi-site research projects applies to any form of human research, as defined in the National Statement on Ethical Conduct in Human Research (2007) for which an application must be made to an HREC for the purpose of conducting research at a Public Health Organisation.

Includes: clinical research, registries, social research, low and negligible risk

Now operational within Victoria (SERP) and VIC, NSW, QLD and SA (NMA)
SERP and NMA – Low and Negligible Risk (LNR)

Now operational within Victoria (SERP) and VIC, NSW, QLD and SA (NMA)

For SERP (all sites within Victoria): Use Victorian LNR Form

For NMA (sites in Victoria, NSW, QLD and SA): Have to use NEAF and associated forms
SERP and NMA

Information available:
• Ethics & Research Governance Website:
  http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm

• For Clinical Trials and Interventional Studies:
  http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm
SERP and NMA

Information available:

• For Health and Social Science Studies:

http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm

• For Low and Negligible Risk Studies:

http://www.alfredresearch.org/ethics/applicat/LowRisk.htm
http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm
SERP and NMA

• Principles are the same

• Separates ethics review from governance or site specific assessment:
  – Ethics review by Reviewing HREC – ethics approval
  – Site specific assessment by Institution – site authorisation
• Note some studies that are **ineligible** for single review in certain **States** including:
  – 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.
• Check with the Reviewing HREC and NMA Guidelines

• HRECs are certified/accredited to review certain kinds of studies
SERP and NMA

Information available:
• Ethics & Research Governance Website:
  http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm

  – Link to CCCTR/Clinical Trial Page:
  http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm
SERP and NMA

Information available:

- Link to Health and Medical Research Page
  http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm

- Link to Low & Negligible Risk Application Page:
  http://www.alfredresearch.org/ethics/applicat/LowRisk.htm
Ethics Approval versus Site Authorisation

• **Ethics Approval**
  – Given by an Ethics Committee
  – Medically safe
  – Scientifically sound
  – Ethical
  – Legal

• **Site Authorisation**
  – Given by Institution
  – Accept ethics approval
  – Is the study appropriate?
  – Appropriately qualified staff?
  – Adequate resources
  – Legal
Ethics Approval versus Site Authorisation

Researchers can participate in one of two capacities for each study:

- Co-ordinating (Lead) Principal Investigator

- Site Principal Investigator
Submission to Reviewing HREC

- **Co-ordinating Principal Investigator** appointed for ethics application covering all Sites in application
  > Submits initial ethics application
  > Liaises with Reviewing HREC
  > Submits amendments, updated IBs etc to Reviewing HREC
  > Acts as conduit between participating sites and HREC for the life of the study
    - submission of amendments, updated IBs, progress reports, SAEs/SUSARs, protocol deviations etc to HREC
    - Communicates decisions to Participating Sites
Ethics Approval versus Site Authorisation

Researchers can participate in one of two capacities for each study:

– **Site Principal Investigator** required at each Site takes responsibility for conduct of the trial at the Site
  > Liaises with Institutional Research Governance Office (RGO)
  > Submits amendments, updated IBs for site authorisation following ethics approval from Reviewing HREC
  > Submits progress reports, SAEs/SUSARs, protocol deviations etc to Institutional RGO and Co-ordinating PI to submit to Reviewing HREC
Lead Site versus Accepting Site

- Site Authorisation
  - Given by Institution
  - Accept ethics approval
  - Is the study appropriate?
  - Appropriately qualified staff
  - Training required and provided
  - Adequate resources
  - Legal
  - Complies with Institution’s strategic plan
  - Is there reputational risk?
  - A site authorisation letter issued
  - Cannot start before site authorisation granted.
  - Required if application reviewed and approved by the Alfred Hospital Ethics Committee
Lead Site versus Accepting Site

• If you are the Accepting Site:
  – Speak to the Alfred Health Office of Ethics & Research Governance before considering streamlined application
  – Site allocates a local Project Number as well
  – Not bound by HREC meeting dates but submit only when complete
  – Require entire ethics application approved by the Reviewing HREC (ethics approval certificate and all forms)
  – Use the ethics approval certificate as a guide
  – Label documents appropriately
  – Forms:
    > NEAF
    > Master PICF(s)
    > Protocol, IB, Questionnaires, Advertising, Patient Materials etc
Lead Site versus Accepting Site

• If you are the Accepting Site:
  – Require site assessment submission:
    > Site Specific Assessment (SSA) form
    > Alfred Specific Form (ASF) (one set of signatures SSA/ASF PI should sign both SSA and ASF)
    > “Alfredised PICFs
      – PICFs should be tracked from Master versions
      – Version and date should remain unchanged
      – Local Governance date entered in footer. This is not the date site authorisation will be obtained.
    > Decision-making correspondence from the Lead HREC
    > RSO report
    > Section 4 of the VSM signed by Medical Physicist and Site Principal Investigator
Lead Site versus Accepting Site

• If you are the Accepting Site:
  – Require site assessment submission:
    > Resource Centre Declarations – Please specify if you will not be using certain services (eg central laboratory rather than Alfred Pathology)
    > Budget
    > Legal documents:
      – CTN form (Section 3 signed by Reviewing HREC)
      – Standard indemnity
      – Copy of signed HREC Review Only indemnity to the Institution of the Reviewing HREC.
      – CTRA
      – Insurance certificate
Lead Site versus Accepting Site

• If you are the Accepting Site for a Low Risk Application:
  – Require site assessment submission:
    > Victorian Low and Negligible Risk (LNR) Form
    > LNR Site Specific Assessment (SSA) form
    > Alfred Low Risk Application Form (duplication of information in LNR or SSA not required)
    > “Alfredised PICFs
      – PICFs should be tracked from Master versions
      – Local Governance date entered in footer.
    > Decision-making correspondence from the Lead HREC
    > Resource Centre Declarations
    > Budget
    > Legal documents:
      – Agreement
      – Insurance certificate (if required)
Accepting Site - Essential

• Please notify the Ethics & Research Governance Office (ERGO) once you have agreed to be an Accepting Site.
• It is a requirement for any researcher wishing to use SERP or NMA to have done ERGO training.
• Please seek an Alfred Health Project Number.
• Try and insist that the NHMRC PICF templates are used.
• Please ask for the PICF to review prior to it being submitted to the Reviewing HREC to ensure that it is appropriate for your Site, eg method of reimbursement appropriate?
• If you are not happy with the PICF inform the Sponsor, eg standard wording has not been used for injury and compensation.
• Please review the Protocol before submission to HREC to ensure it is appropriate for your Site, eg is the proposed standard of care, the same as at your Site?
Accepting Site - Essential

- If there are ionising radiation procedures, remind the Sponsor/Co-ordinating Site that the RSO report will be required for HREC review.
- Do not submit for site authorisation until you have ALL of the documents from the initial ethics submission, any subsequent amendment applications and the site authorisation documents, including legal documents.
- Use the approval certificates as a guide.
- Do not submit previous versions of amended documents, only the approved final versions in each submission.
- Please show tracked changes when “Alfredising” the PICFs from the Master versions.
- Read the decision-making correspondence. If a recommendation has been made for all Sites, please ensure that you will comply, eg appointment of a particular consultant.
Amendments

• All amendments apart from changes to research personnel are to be approved by the Reviewing HREC

• Submission for Site Authorisation:
  – Submit amendment approval certificate, amendment application form and associated documents to Research Governance Office
  – PICFs:
    > Submit tracked from Master PICF(s)
    > Keep the version and date unchanged
    > insert Local Governance date in footer
  – Submit other documents showing tracked changes or provide a summary of changes document
  – Amendment authorisation fee charged
  – Amendment authorisation certificate issued
Amendments

• Changes to Research Personnel
  – Unless change to the Site PI, submit only to Site Research Governance Office

  – Change in Site PI needs to be submitted to Reviewing HREC as an amendment application

  – PICFs:
    > Submit tracked from Master PICFs
    > Keep the version and date unchanged
    > insert Local Governance date in footer

  – Amendment authorisation issued
If Alfred Health has been added as a Site later on and there have been a number of amendments since the initial approval:

- Submit initial ethics approval certificate and all amendment approval certificates and other acknowledgments since initial approval

- Use the certificates as a guide as to which documents need to be submitted and as a checklist when submitting documents

- Submit the latest version of each of the documents, namely latest approved Protocol, IB, PICF(s) etc, as well as NEAF, VSM etc.

- Label documents appropriately
Updated Investigator’s Brochures (IBs)/Development Safety Update Reports (DSURs)

• All updated IBs and DSURs are to be approved by the Reviewing HREC

• Require Site authorisation
  – Submit amendment approval certificate or acknowledgment letter to Research Governance
  – Observe requirements of Research Governance Office (e-copy, hard copies)
  – IB review fee charged
  – Amendment authorisation or IB/DSUR acknowledgment issued
Progress Reports

• Based on **ethics approval date** on certificate issued by the Reviewing HREC, not Site Authorisation date

• Use the SERP/NMA Progress Report form

• Observe requirements of Reviewing HREC (e-copy, hard copies)

• Submit the Progress Report to:
  – Co-ordinating Principal Investigator to forward to the Reviewing HREC
  – Your Site Research Governance Office
Reporting of Serious Adverse Events (SAEs, SUSARs), ProtocolWaivers/Violations

• Use the SERP/NMA forms

• Observe requirements of Reviewing HREC (reporting requirements, e-copy, hard copies)

• Submit the Report to:
  – Co-ordinating Principal Investigator to forward to the Reviewing HREC
  – Site Research Governance Office
Thank You!