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
SERP and NMA

- 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
  – Link to Health and Medical Research Page
  – Streamlining Ethics Review Guide Forms:
    > Human Ethics (applications submitted to the Alfred Hospital Ethics Committee as reviewing site)
    > Research Governance (Alfred Health applications submitted for site assessment as accepting site)
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
Ethics Approval versus Governance 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

- If you are the Co-ordinating PI/Lead Site:
  - Speak to the Alfred Health Office of Ethics & Research Governance before considering streamlined application (some conditions)
  - Book in the application via the Co-ordinating Office, Victorian Department of Health
  - Allocated an HREC number (HREC/15/Alfred/xx)
  - Include HREC number on NEAF, SSA, PICFs
  - Each Site allocates a local Project Number as well
  - Bound by HREC meeting dates and requirements of the Reviewing HREC
  - Submit documents as required (e-copy, hard copies, execution of legal documents)
  - Ethics approval certificate issued
  - At Alfred Health, governance review done concurrently
• **If you are the Co-ordinating PI/Lead Site**
• Forms Required for D&I and H&SS Applications:
  – NEAF (from Online forms)
  – Victorian Specific Module (VSM)
  – Site Specific Assessment (SSA) Form for Alfred Health
  – Alfred Specific Form (ASF)
  – PICF(s)
  – RSO report or Notification to Reviewing HREC: Radiation Form from **each site**
  – Protocol, IB, Questionnaires, Patient Material, Advertising, etc
  – NSW Privacy Form (if NSW sites included)
Lead Site

• If you are the Co-ordinating PI/Lead Site Forms Required:

• Legal Documents:
  – CTN Form for each Site (e-copy, hard copies)
  – Standard indemnity to Alfred Health (e-copy, hard copies)
  – Standard indemnity to other Sites (e-copy only)
  – HREC Review Only indemnity to Alfred Health (lists each Site in paragraph 1; e-copy, hard copies)
  – Insurance certificate (e-copy, reviewed by the VMIA)

• Clinical Trial Research Agreement:
  – Alfred Health and Sponsor (e-copy, hard copies)
  – Alfred Health and other sites if investigator-initiated (e-copy, hard copies)
Lead Site

• If you are the Co-ordinating PI/Lead Site
• Forms Required for Victorian LNR Applications:
  – Victorian Low and Negligible Risk Application Form
  – Victorian Site Specific Assessment (SSA) Form for Alfred Health
  – Low Risk Alfred Specific Form (LR ASF)
  – PICF(s)
  – Biospecimen Addendum
  – Protocol etc
  – Resource Centre Declaration
  – Legal Documents: Agreement (Research Collaboration Agreement) or Material Transfer Agreement
Lead Site

• If you are the Co-ordinating PI/Lead Site
• Forms Required for NMA LNR Applications:
  – NEAF (from Online forms)
  – Victorian Specific Module (VSM)
  – Site Specific Assessment (SSA) Form for Alfred Health
  – Alfred Specific Form (ASF)
  – PICF(s)
  – Protocol etc
  – NSW Privacy Form (if NSW sites included)
  – Resource Centre Declarations
  – Legal Documents: Agreement (Research Collaboration Agreement) or Material Transfer Agreement
Participant Information & Consent Forms (PICFs)

- Please use NHMRC PICF templates

- Require a Master PICF for each type of PICF (Main study, Optional Sub-studies (eg genetic, pharmacogenetic, pharmacogenomic, biobank), pregnant partner, Person Responsible, Carer, Parent/Guardian, Mature Minor etc

- Master PICF should be a template for all Participating Sites to complete.

- Require an “Alfredised” PICF of each PICF for site authorisation

- Same principles apply to a Patient Brochure
Amendments

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

• If submitted by Co-ordinating PI to Reviewing HREC:
  – Use the SERP/NMA amendment application form
  – Submit the usual documents either marked up or accompanied by a summary of changes document
  – Observe requirements of Reviewing HREC (e-copy, hard copies)
  – Site authorisation given with ethics approval (local governance date recorded on amendment approval certificate
  – Amendment review fee charged
Updated Investigator’s Brochures (IBs)/Development Safety Update Reports (DSURs)

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

- Use the SERP/NMA amendment application form or Alfred Health Updated IB form if Alfred Health is the Lead HREC
  - Observe requirements of Reviewing HREC (e-copy, hard copies)
  - IB review fee charged
  - Amendment approval certificate or Acknowledgment of IB letter issued

- 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)
- Responsibility of Co-ordinating Principal Investigator to co-ordinate submission of Progress Report from each Site to the Reviewing HREC
- Each Site also needs to submit to their own Research Governance Office
- If submitting by email, copy in each Site Principal Investigator and each Research Governance Office so all will receive acknowledgment of receipt
Reporting of Serious Adverse Events (SAEs, SUSARs), Protocol Waivers/Violations

- Use the SERP/NMA forms
- Observe requirements of Reviewing HREC (reporting requirements, e-copy, hard copies)
- Responsibility of Co-ordinating Principal Investigator to co-ordinate submission of Progress Report from each Site to the Reviewing HREC
- Each Site also needs to submit to their own Research Governance Office
- If submitting by email, copy in each Site Principal Investigator and each Research Governance Office so all will receive acknowledgment of receipt
Conversions to SERP or NMA

- Application must fit the scope
- Initial application must have been approved after the introduction of SERP or NMA for the category of study:
  > SERP Clinical Trials (December 2009)
  > NMA Clinical Trials (November 2013)
  > SERP H&SS and LNR: (January 2016)
  > NMA H&SS and LNR (14 December 2015)
- Study must involve only Victorian Sites for SERP
- Study must involve only sites in NSW, QLD, SA, VIC for NMA
- Conversion done via an amendment application using the SERP/NMA amendment application form
Conversions to SERP or NMA

– Need to book application through Co-ordinating Office (CCCTR) to obtain HREC Number to be included on all documents
– Current fee is $1,500 + $500 each additional site (+ GST)
– Documents required:
  > NEAF or Victorian LNR listing Co-ordinating PI and other Sites
  > RSO report from each Site
  > Master PICF(s) and Site Master PICF(s)
  > Legal documents:
    – CTN form for each site
    – Standard indemnity to each site (e-copy only)
    – HREC Review Only indemnity to Alfred Health listing all sites in paragraph 1
Thank You!